DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 438, 442, 460, 482, 483, 485, and 494

[CMS–3484–P]

RIN 0938–AW04

Medicare and Medicaid Programs; Cutting Administrative Requirements for Excellence in Patient Care

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would reform Medicare and Medicaid regulations deemed obsolete or excessively burdensome on healthcare providers and suppliers, with the objective of reducing costs, enhancing flexibility in delivering innovative care, and streamlining existing regulations. This reform seeks to enable healthcare professionals to devote more resources to improving patient care by eliminating or minimizing requirements that impede quality patient care or that divert resources away from furnishing high quality patient care.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by January 11, 2027.

ADDRESSES: In commenting, please refer to file code CMS–3484–P. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov/docket/CMS-2026-3631.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3484–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3484–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the ''**SUPPLEMENTARY INFORMATION**'' section.

FOR FURTHER INFORMATION CONTACT: CMS Health and Safety Inquiries, 410–786–6633, *HealthandSafetyInquiries@cms.hhs.gov,* for further information related to the following: Ongoing and public health emergency (PHE) respiratory illness data reporting for hospitals, critical access hospitals, long-term care facilities and rural emergency hospitals; obstetrical services quality assessment and performance improvement, all staff trainings, and critical access hospital co-location; long-term care facility staff COVID–19 vaccination education and Ombudsman notice; intermediate care facility for individuals with intellectual disabilities staff vaccination education; and Life Safety Code, Health Care Facilities Code, and Emergency and Standby Powers Systems Code. *DCWReporting@cms.hhs.gov,* for further information related to Medicaid institutional payment transparency reporting.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at *https://www.regulations.gov/.*

I. Background

A. Executive Summary

The Centers for Medicare & Medicaid Services (CMS) is committed to incorporating and integrating ongoing retrospective review of regulations to achieve a more streamlined and effective regulatory framework. CMS routinely reviews its regulations to identify opportunities to strengthen the patient health and safety requirements by revising the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), Conditions for Certification, and Requirements for Participation, (collectively referred to as CoPs).

We conducted a comprehensive review of the CoPs for all 21 provider and supplier types with the objectives of improving the quality of existing regulations consistent with statutory requirements; streamlining procedural solutions; maximizing net benefits (including benefits that are difficult to quantify); and reducing costs and other burdens on facilities to comply with regulations. We identified obsolete and burdensome regulations that could be eliminated or reformed to enhance the effectiveness of facility operations and reduce unnecessary burden or other costs, with a particular focus on freeing up resources that health care providers could otherwise use to improve patient health and safety. We have also identified unnecessary and burdensome reporting requirements that can be eliminated to improve the efficiency of the Medicaid program.

Relationship of This Rulemaking to Future Reforms: We are committed to working with, and welcome suggestions for future rulemaking from, interested parties to identify other reforms to the CoPs that would improve patient health and safety while reducing unnecessary burden on health care facilities and entities or improve flexibility in meeting the Federal requirements.

B. Summary of Major Provisions

We propose to reduce regulatory burden on providers and suppliers by modifying, removing, or streamlining current regulations that we now believe are excessively burdensome. We note that the appropriate term for the individual receiving care and/or services differs depending upon the facility type, such as hospital ''patients'' and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID) ''clients.'' When discussing each individual provider or supplier type, we use the appropriate term; however, when discussing all or multiple provider or supplier types we will use the general term ''patient.'' Similarly, despite the different terms used for specific entities (such as campus, center, clinic, facility, organization, or program), when we are discussing all or multiple entities, we will use the general term ''facility.''

1. Hospitals

For hospitals, we propose to remove the recently finalized staff training requirements for transfer protocols, emergency services readiness, and obstetrics (OB) care, as well as OB-specific quality assessment and performance improvement (QAPI) requirements. We are also proposing policies that address informed consent requirements and policies and procedures that aim to support families' ability to request collection of birth tissues, including for cultural, religious, or personal reasons in hospitals.

2. Long Term Care (LTC) Facilities

For LTC facilities, we propose to revise the facility assessment requirement by removing the requirement for the active involvement of representatives of direct care staff in conducting the LTC facility assessment. We also propose to revise the infection control requirement to remove the ongoing (weekly) acute respiratory illness data reporting requirements and amend the reporting requirements during a Public Health Emergency (PHE) to include the data elements originally specified in the ongoing data reporting section. We are also proposing to remove requirements related to educating staff about COVID–19 vaccine and its benefits and risks, offering it to them, and documenting these actions.

Additionally, we propose to revise the physical environment requirements to exempt existing facilities from the room occupancy and bathroom facility standards when there is a change of ownership (CHOW) for the facility or a lapse in and restoration of a facility's certification. We also propose to remove the requirement for LTC facilities to provide Ombudsman notice of resident transfers related to emergent care and solicit public comment regarding additional changes to the Ombudsman notice. Finally, we solicit public comment on the role of physician assistants and nurse practitioners in delivering resident care.

3. Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs/IID)

For ICFs/IID, we propose to remove requirements related to educating staff about the COVID–19 vaccine and its benefits and risks and offering it to them.

4. Rural Emergency Hospitals (REHs)

For REHs, we propose to remove expired COVID–19 requirements related to ongoing data reporting and staff vaccination regulations. We propose to remove the data reporting requirement during a PHE to reduce burden. We also propose to update the emergency preparedness requirement to revise the point of contact that REHs may use to obtain copies of standards that are incorporated by reference and to correct an inaccurate cross-reference.

5. Critical Access Hospitals (CAHs)

For CAHs, we propose revising the regulation to clarify current CMS policy that CAH distance eligibility determinations are based on proximity to hospitals that provide acute inpatient care services, including other CAHs, rather than hospitals that provide only specialty services, such as psychiatric hospitals, long-term care hospitals (LTCHs), or rehabilitation hospitals. We also propose adding a requirement that implements section 241 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75), that revised the application of the statutory distance requirement in specified circumstances as set forth in the law. In addition, we propose to remove recently finalized staff training requirements for emergency services readiness, and obstetrical (OB) care, as well as OB-specific quality assessment and improvement (QAPI) requirements. We are also proposing policies that address informed consent requirements and policies and procedures that aim to support families' ability to request collection of birth tissues, including for cultural, religious, or personal reasons in CAHs.

6. Life Safety Code (LSC) and Health Care Facilities Code (HCFC) Updates for All Applicable Providers and Suppliers

We propose to update the National Fire Protection Association (NFPA) LSC and HCFC editions that are incorporated into the regulations for religious nonmedical health care institutions (RNHCIs), ambulatory surgical centers (ASCs), inpatient hospices, programs of all-inclusive care for the elderly (PACE), hospitals, LTC facilities, ICFs/IID, REHs, CAHs, and dialysis facilities. The LSC and HCFC are nationally recognized fire and building safety standards published by the NFPA. We propose to adopt the most recent (2024) editions of the LSC and HCFC, with limited exceptions.

7. Emergency and Standby Power Sources

For hospitals, CAHs, REHs, and LTC facilities that are required to have emergency and standby power systems, we propose to update the current requirements to allow the use of additional sources of emergency power. We also propose to adopt the 2022 edition of the Standard for Emergency and Standby Power Systems (ESPS), which establishes safety and performance requirements for emergencies and standby power systems.

8. Outside Window or Door Requirement Updates

For RNHCIs, inpatient hospices, hospitals, CAHs, and LTC facilities, we propose to remove the requirement for windows and doors in every patient sleeping area and a 36-inch windowsill requirement for buildings constructed after July 5, 2016, and defer to the egress requirements within the health care occupancy chapters of the LSC. Additionally, for hospitals and CAHs, we also propose to remove the 60-inch windowsill requirement for special nursing care areas in new occupancies. We propose to remove a similar requirement for ICFs/IID related to windows in client bedrooms that are below the level of the ground outside and defer to the window requirements for resident board and care occupancies within the LSC.

9. Life Safety Code and Health Care Facility Code Waiver Authority

We propose to codify our authority to waive certain LSC and HCFC provisions in the regulatory text applicable to each affected provider type. We would permit facilities to comply with specific provisions of a newer edition of the LSC or HCFC, subsequent to CMS review. We would permit this exception after we have determined that the provision provides an equal or superior means of ensuring patient safety as compared to the provisions of the code edition currently adopted in regulation at that time.

10. Transplant Programs Request for Information (RFI)

CMS' policy on organ transplantation is to increase the number of transplants available to patients on the organ transplant waiting lists. Achieving this goal requires a sufficient number of transplant programs to provide lifesaving surgeries. There are currently over 250 Medicare-approved programs providing organ transplantation services. However, programs seeking initial Medicare approval report challenges in meeting the initial requirements for Medicare certification. We are soliciting public comments on how to reduce potential barriers for new transplant programs seeking Medicare certified transplant programs.

11. Supervision of Anesthesia Services RFI

We are soliciting public comments related to Medicare's physician supervision requirement for certified registered nurse anesthetists (CRNAs) administering anesthesia services in hospitals, CAHs, REHs, and ASCs. Under current policy, anesthesia must be administered only by qualified practitioners. When a CRNA administers anesthesia, a physician, such as the operating practitioner or an anesthesiologist, must be immediately available to provide supervision. Since 2001, CMS has allowed a State's Governor to request an exemption from this requirement, permitting CRNAs to practice independently where consistent with State law. CMS is now requesting public input on this policy, including whether it should be retained, revised, or otherwise modified.

12. Reducing Reporting Burden for Hospital and CAH Respiratory Illness and Infectious Disease Data RFI

We are soliciting public comments on ways to reduce the reporting burden associated with respiratory illness and infectious disease data reporting requirements for hospitals, including CAHs (collectively referred to as ''hospitals'' for purposes of this RFI). Following the COVID–19 response, the health care community identified a need for standardized data elements and digital data collection approaches to ease this burden, particularly given the risk of overlapping or duplicative requirements across agencies for smaller or resource-constrained facilities. CMS, in partnership with CDC, has worked to reduce this burden through the development of data standards, adoption of interoperability modernization activities, and use of a single reporting system, the National Healthcare Safety Network (NHSN), which currently offers flexible reporting options such as Comma-Separated Values (CSV) import, Application Programming Interface (APIs), and Fast Healthcare Interoperability Resources (FHIR)-based approaches. Building on these efforts, CMS is requesting public comment on how to further support hospitals' adoption of data and interoperability capabilities to reduce burden through greater automation and digital data collection.

13. Medicaid Institutional Payment Transparency

We propose to rescind requirements for States to report annually, at the facility level, on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff, and the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff. We also solicit public comment on approaches to address direct care worker shortages and strengthen the direct care workforce in nursing facilities and ICFs/IID.

C. Statutory and Regulatory Background

The Social Security Act (the Act) sets forth definitions for the types of providers and suppliers that may participate in Medicare and Medicaid, the requirements that each must meet to be eligible for Medicare and Medicaid participation, and the Secretary's authority to establish other requirements as necessary to protect the health and safety of patients. The following list identifies the statutory and regulatory citations for the providers and suppliers for which we are proposing to revise or remove regulations in this rule:

- Religious Nonmedical Health Care Institutions (RNHCIs)—section 1821 of the Act and 42 CFR 403.700 through 403.770.
- Ambulatory Surgical Centers (ASCs)—section 1832(a)(2)(F)(i) of the Act and 42 CFR 416.
- Hospices—section 1861(dd)(1) of the Act and 42 CFR 418.
- Programs of All-Inclusive Care for the Elderly (PACE)—sections 1894, 1905(a), and 1934 of the Act and 42 CFR 460.
- Hospitals—section 1861(e)(9) of the Act and 42 CFR 482.
- Long Term Care (LTC) Facilities—Skilled Nursing Facilities (SNFs)—under section 1819 of the Act, Nursing Facilities (NFs)—under section 1919 of the Act, 42 CFR 483.1 through 483.315, 42 CFR 438.72, and 42 CFR 442.43.
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)—section 1905(d) of the Act, 42 CFR 483.400 through 483.480, and 42 CFR 442.43.
- Rural Emergency Hospitals (REHs)—sections 1861(kkk) of the Act and 42 CFR 485.500 through 485.546.
- Critical Access Hospitals (CAHs)—sections 1820 and 1861(mm) of the Act and 42 CFR 485.601 through 485.649.
- Dialysis Facilities—sections 1881(b), 1881(c), 1881(f)(7) of the Act and 42 CFR 494.

In addition, Title XIX of the Act established the Medicaid program as a joint Federal and State program to provide medical assistance to eligible individuals. Section 1902(a)(30)(A) of the Act requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. Section 1902(a)(6) of the Act requires State Medicaid agencies to make reports, in such form and containing such information, as the Secretary may from time to time require. To comply with provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports, section 1932(c) of the Act lays out quality assurance standards with which States must comply when delivering Medicaid services through managed care organizations (MCOs). Section 1902(a)(4) of the Act provides authority to specify ''methods of administration'' that are ''necessary for proper and efficient'' administration of the State plan.

CMS previously published four final rules [1] [2] [3] [4] that removed or revised unnecessary, obsolete, or excessively burdensome regulations for these health care providers and suppliers, resulting in significant annual Medicare and Medicaid savings. These rules also enhanced health care professionals' ability to focus on improving patient care by eliminating or reducing requirements that hindered quality or diverted resources away from delivering high-quality care. The 2019 final rule produced an estimated savings of $800 million annually.[5] Among other things, in the 2019 final rule, we scaled back the emergency preparedness requirements across providers; revised

[1] ''Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,'' published May 16, 2012. 77 FR 29002.

[2] ''Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation,'' published May 16, 2012. 77 FR 29034.

[3] ''Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II,'' published May 12, 2014. 79 FR 27106.

[4] ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care,'' published September 30, 2019. 84 FR 51732.

[5] ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care,'' published September 30, 2019. 84 FR 51732.

the hospital and CAH CoPs for infection control, swing beds, and documentation; simplified hospice requirements for medications; and added flexibility to the home health CoPs for home health aide competency evaluations.

This proposed rule is a continuation of our efforts to reduce regulatory burden and is in accordance with recent Executive Order (E.O.) 14192 ''Unleashing Prosperity Through Deregulation'' [6] and E.O. 14219: ''Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative.'' [7]

This proposed rule is also related to the RFI ''Unleashing Prosperity Through Deregulation of the Medicare Program Request for Information,'' that CMS released in April 2025 (henceforth referred to as the 2025 deregulatory RFI).[8] The RFI sought public feedback on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers and beneficiaries. CMS reviewed the 937 timely submissions and considered the comments and suggestions. Additionally, we have conducted our own review and evaluation of current practices. This included an analysis of regulations released by the prior Administration and long-standing requirements, meetings with external interested parties, and collaboration with other CMS interested parties to identify opportunities to improve patient care by reducing unnecessary provider compliance burden through deregulation.

In 2024, we finalized Medicaid institutional payment transparency reporting requirements in the ''Minimum Staffing Standards for Long-Term Care (LTC) Facilities and Medicaid Institutional Payment Transparency Reporting'' final rule (2024 Minimum Staffing final rule; CMS 3442–F) [9] to promote public transparency around States' statutory obligation under section 1902(a)(30)(A) of the Act and around the quality requirements in section 1932(c) of the Act for services furnished through MCOs and prepaid inpatient health plans (PIHPs) [10] under our authority under section 1902(a)(4) of the Act.

To support the implementation of the Medicaid institutional payment transparency reporting requirements, we engaged with States, providers, and other interested parties to provide training and technical assistance and address questions. Based on the public input received through this engagement and our internal deliberations as we developed guidance and technical specifications, we have a better understanding of the complexity and challenges of implementing certain components of the requirements we finalized. This understanding has led us to propose to deregulate some of the provisions from that 2024 final rule.

D. Summary of Costs and Benefits

1. Overall Impact

This proposed rule would create savings and reduce burden in many areas. Several of the proposed changes would create measurable monetary savings for providers and suppliers, while others would create less quantifiable savings of time and administrative burden. We estimate an average annual savings of approximately $320 million.

2. Section-By-Section Economic Impact Estimates

Hospitals: We expect average annual savings of $123.2 million and $1.23 billion over 10 years for hospitals.

Long Term Care Facilities (LTC): We expect average annual savings of $142.6 million and $1.426 billion over 10 years for LTC facilities.

Critical Access Hospitals (CAHs): We expect an average annual savings of $16.6 million and $166 million over 10 years for CAHs.

Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID): We expect an average annual savings of $6.6 million and $66 million over 10 years for ICFs/IID.

Rural Emergency Hospitals (REHs): This proposed rule would not result in any costs or savings for REHs.

Life Safety Code (LSC) and Health Care Facilities Code (HCFC) Updates: We expect an average annual cost of approximately $112,000, and $1,120,000—over 10 years that would be offset by unquantified flexibility savings.

Emergency and Standby Power Sources: These proposals would not result in costs but would provide providers with increased flexibility.

Outside Window or Door Requirement Updates: These proposals would not result in any costs but would provide providers with increased flexibility for building construction.

Medicaid Institutional Payment Transparency Reporting: We expect an average annual savings of approximately $68,760, and $687,600 over 10 years for the Federal Government. We expect an average annual savings of approximately $68,760 and $687,600 over 10 years for States. We expect an average annual savings of $30.4 million and $304.1 million over 10 years for providers.

E. Severability

We are clarifying and emphasizing our intent that if any provision of this proposed rule, if finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from the remainder of the final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. If any provision is held to be invalid or unenforceable, the remaining provisions which could function independently should take effect and be given the maximum effect permitted by law. In this rule, we propose several provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear.

II. Provisions of the Proposed Regulations

A. Hospitals

Hospitals provide a range of services to treat patients with acute care needs, which may include emergency medicine, surgery, labor and delivery, cardiac care, oncology, among a wide variety of other services. Hospitals also administer general and specialty care that cannot safely be provided in other settings, under the supervision of physicians and licensed practitioners. They may operate as independent institutions or as part of a larger health care system or learning institution. As of January 2026, there are around 4,700 Medicare-certified hospitals.[11]

Under sections 1866 and 1902 of the Act, hospitals seeking to participate in

[6] 90 FR 9065.

[7] 90 FR 10583.

[8] ''Medicare Regulatory Relief | CMS.'' *Cms.gov,* 2025, *https://www.cms.gov/files/document/unleashing-prosperity-through-deregulation-medicare-program-request-information.pdf.* Accessed September 2025.

[9] *https://www.federalregister.gov/documents/2024/05/10/2024-08273/medicare-and-medicaid-programs-minimum-staffing-standards-for-long-term-care-facilities-and-medicaid#h-32.*

[10] Throughout this section, the use of the term ''managed care plan'' means MCOs and PIHPs.

[11] Centers for Medicare & Medicaid Services. Quality, Certification and Oversight Reports (QCOR), Hospital provider reports, Active Provider and Supplier Counts Report, FY 2025. Accessed January 30, 2026. *https://qcor.cms.gov/main.jsp.*

the Medicare or Medicaid program, respectively, or both, must enter into an agreement with the Secretary or the State Medicaid agency, as appropriate. Hospitals (all hospitals to which the requirements of 42 CFR part 482 apply, including short-term acute care hospitals, long term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals), seeking to be Medicare and Medicaid providers of services must be certified as meeting Federal participation requirements. Our CoPs set out at 42 CFR part 482 establish the patient health and safety protections established by the Secretary for hospitals (except for critical access hospitals (CAHs)). The specific statutory authority for hospitals is set forth in section 1861(e) of the Act. In addition to specific terms of that subsection, the hospital provision at section 1861(e)(9) of the Act authorizes the Secretary to issue any additional regulations deemed necessary to protect the health and safety of those receiving services in the hospital.

In accordance with section 1864 of the Act, State surveyors assess hospital compliance with the conditions as part of the process of determining whether a hospital qualifies for a provider agreement under Medicare. However, under section 1865 of the Act, hospitals can elect to be reviewed instead by private accrediting organizations approved by CMS as having standards that meet or exceed the applicable Medicare standards and survey procedures comparable to those CMS requires for State survey agencies.

1. Proposal To Remove OB QAPI Requirements (§ 482.21(b) and (e))

In November 2024, as part of the final rule, ''Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities'' (henceforth referred as CY 2025 OPPS/ASC final rule) [12] CMS finalized new CoPs for hospitals that offer obstetrical (OB) services. Prior to the CY 2025 OPPS/ASC final rule, CMS had not established CoPs specifically for OB services. Rather those services fell within the scope of broader CoPs applicable to hospitals, including the QAPI requirements. Separate from the CoPs, CMS also addressed maternal health through sub-regulatory guidance,[13] [14] hospital quality measures, and initiatives such as the Birthing-Friendly Hospital designation.

In the CY 2025 OPPS/ASC final rule,[15] we finalized additional QAPI requirements for hospitals that offer OB services (§ 482.21(b)(4) and (e)), revisions to the discharge planning CoP for all hospitals related to transfer protocols (§ 482.43(c)), revisions to the CoP related to emergency services readiness for hospitals that provide emergency services (§ 482.55(c)(3)), as well as baseline standards for the organization, staffing, and delivery of OB care, including staff training on evidence-based maternal health practices (§ 482.59). In this section we discuss the proposed changes to the hospital QAPI requirements. Revisions to the discharge planning CoP, emergency services CoP, and obstetrical services CoP, are discussed in sections II.A.2., II.A.3., and II.A.4. of this proposed rule, respectively.

On January 25, 2003, we published the Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement final rule,[16] which codified provisions in the hospital CoPs, requiring hospitals to develop, implement, and maintain a QAPI program (§ 482.21). The hospital QAPI program CoP requires hospitals to implement an ongoing hospital-wide, data-driven system to improve quality of care, patient safety, and improved health outcomes. Hospitals must use data to identify and prioritize improvement areas (§ 482.21(b)), sustain measurable improvements (§ 482.21(c)), conduct performance improvement projects (§ 482.21(d)), and demonstrate leadership oversight over the program and that the program reflects the complexity of the facility's organization and services (§ 482.21(e)). On September 30, 2019, CMS published the ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' final rule,[17] which finalized a new standard at § 482.21(f), to allow a hospital that is part of a hospital system to elect to have a unified and integrated QAPI program for all of its member hospitals. This rule also expanded the program data requirements at § 482.21(b), to require that the hospital QAPI program incorporate quality indicator data submitted to or received from quality reporting and quality performance programs. In the CY 2025 OPPS/ASC final rule,[18] we finalized additional QAPI requirements for hospitals that offer OB services (89 FR 94593). Specifically, effective January 1, 2027, the facility at a minimum, will be required to: (1) analyze data and quality indicators by diverse subpopulation as determined by the facility; (2) measure, analyze, and track outcomes and disparities in processes of care, services, and outcomes among OB patients; (3) analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained when disparities exist among OB patients; and (4) conduct at least one measurable performance improvement project that focuses on improving health outcomes and maternal health disparities, annually. Additionally, hospitals that offer OB services are required to have their OB leadership participate in the facility's QAPI program (§ 482.21(e)(1)) and, where a state, local, or tribal maternal mortality review committee (MMRC) exists, the facility must have a process for incorporating publicly available MMRC data and recommendations into its QAPI program (§ 482.21(e)(2)).

This proposal to remove OB QAPI requirements at § 482.21(b)(4) and (e) would promote efficiency and reduce waste, consistent with the E.O. 14219 and E.O. 14192. As part of regulatory reviews conducted in response to these E.O.s, CMS received input through the

[12] 89 FR 93912.

[13] Centers for Medicare and Medicaid Services. *State Operations Manual Appendix A -Survey Protocol, Regulations and Interpretive Guidelines for Hospitals Transmittals for Appendix A.* 2024, *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.* Accessed 31 July 2026.

[14] Center for Clinical Standards and Quality. ''QSO–22–05-Hospitals (ADVISORY).'' *Centers for Medicare & Medicaid Services,* 7 Dec. 2021, *https://www.cms.gov/files/document/qso-22-05-hospitals.pdf.*

[15] 89 FR 93912.

[16] 68 FR 3437.

[17] 84 FR 51776.

[18] 89 FR 94484.

2025 deregulatory RFI [19] from interested parties. Commenters, including physician organizations, medical associations, and rural health advocates, specifically raised concerns about the OB QAPI requirements at § 482.21(b)(4) and (e) as well as the broader OB services CoPs (§ 482.59) finalized in the CY 2025 OPPS/ASC final rule. Commenters indicated that these requirements were overly burdensome and costly, particularly for small and rural hospitals, and expressed concern that compliance costs could contribute to the closure of labor and delivery units, which would worsen access to maternity care and potentially exacerbate maternal health disparities.

While we originally disagreed with these types of comments in the CY 2025 OPPS/ASC final rule, we have since refined our understanding of the issues that hospitals are facing in diverting resources away from direct patient care to comply with administrative standards. Upon further consideration, including input received through the 2025 deregulatory RFI and the policy priorities reflected in E.O. 14219 and E.O. 14192, CMS has reassessed the burden imposed by the OB-specific QAPI requirements and the quality improvement those requirements would achieve, beyond what was previously already required under the existing, broadly applicable QAPI CoPs at § 482.21. In particular, CMS now finds that the existing QAPI CoPs, which require hospitals to maintain an effective, ongoing, facility-wide, data-driven program that measures, analyzes, and tracks quality indicators, including adverse patient events, across all services provides a sufficient foundation for quality oversight of OB care, without the need for OB-specific requirements. In consideration of the above, CMS is proposing to remove the OB QAPI requirements at § 482.21(b)(4) and (e) for hospitals that offer OB services. Hospitals would continue to be required to comply with the remaining QAPI requirements at § 482.21, including with respect to OB services.

CMS also recognizes the compliance costs associated with the OB QAPI requirements, estimated in the CY 2025 OPPS/ASC final rule,[20] are $187,985,440 and 1,110,900 hours of staff time over a ten-year period, or approximately $18,798,544 and 111 staff hours annually. This burden may pose a disproportionate burden on small and rural hospitals, potentially contributing to the closure of labor and delivery units and thereby worsening access to maternity care in underserved communities. Hospitals may have begun taking steps toward compliance with the OB QAPI requirements finalized in the CY 2025 OPPS/ASC final rule, which are not effective until January 1, 2027. CMS has considered these efforts toward achieving compliance and, given that the requirements have not yet taken effect, expects the disruption to hospitals from this proposed change in position to be limited. Although it is unlikely that this proposed rule will be finalized before January 1, 2027, we would request our surveyors that conduct surveys after that date to focus on those CoPs that are not potentially subject to imminent revision. CMS recognizes and affirms the importance of high-quality OB-focused QAPI programs in improving maternal health outcomes and reducing maternal mortality and morbidity. While we are proposing to remove the OB-specific requirements at § 482.21(b) and (e), we strongly encourage hospitals that offer OB services to prioritize maternal health as part of their existing QAPI programs. Furthermore, nothing in these proposals prohibits hospitals from establishing and maintaining policies and procedures that go beyond the minimum standards set forth in the CoPs. Hospitals are encouraged to exercise this flexibility to ensure they are meeting the unique needs of their patient populations.

Furthermore, HHS has several existing quality initiatives related to maternal health, including CMS' ''Birthing-Friendly'' designation and state-based National Perinatal Quality Collaboratives (PQCs) supported by the Centers for Disease Control (CDC) and Prevention. The Birthing-Friendly Hospital Designation (hereinafter referred to as ''the Designation''), was created to identify hospitals that demonstrate the delivery of high-quality maternal care and a commitment to improving maternal health outcomes (87 FR 49284 through 49290).[21] The Designation serves as a quality-driven mechanism to incentivize hospitals to adopt and sustain evidence-based maternal health practices, and is one of several tools CMS is leveraging to advance maternal health outcomes. CMS intends to explore, in future rulemaking, opportunities to expand the Designation and similar quality-based programs as a primary vehicle for reducing maternal mortality and morbidity, and we invite public comment on how such programs could be structured or expanded to address maternal health disparities. CMS is also actively refining the Designation program, including through a recent Request for Information (RFI) in the proposed rule titled, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; and Other Policy Changes (91 FR 19597, April 14, 2026),[22] which sought public input on updates to designation criteria, alignment with other Federal and state maternal health quality initiatives, and strategies to increase hospital participation, particularly among rural and safety-net hospitals.

While the Designation operates at the hospital level, state-based PQCs complement this effort by advancing standardized best practices at the state and regional level, serving as another tool for advancing maternal health. As of March 2026, there are 52 state- and territory-based PQCs,[23] of which 36 are funded by the CDC.[24] Through Federal grants and cooperative agreements with the CDC and/or funding and support from state and local governments, PQCs have achieved notable improvements in maternal health and safety, including in severe pregnancy complications.[25] For example, the Illinois Perinatal Quality Collaborative launched the Severe Maternal Hypertension Initiative helped raise timely treatment rates for sever hypertension from 41 percent to 87 percent within 2 years.[26] Together, this regulatory approach ensures flexibility and reduces burden while maintaining strong support for maternal and infant health.

CMS acknowledges that U.S. maternal mortality remains elevated relative to peer nations and that the majority of

[19] ''Medicare Regulatory Relief | CMS.'' *Cms.gov*, 2025, *https://www.cms.gov/files/document/unleashing-prosperity-through-deregulation-medicare-program-request-information.pdf* Accessed September 2025.

[20] 89 FR 94577.

[21] 87 FR 48780.

[22] 91 FR 19312.

[23] ''National Network of Perinatal Quality Collaboratives.'' *The National Institute for Children's Health Quality*, National Institute for Children's Health Quality, *https://nichq.org/projects/national-network-of-perinatal-quality-collaboratives/*. Accessed 30 March 2026.

[24] ''State Perinatal Quality Collaboratives.'' *Centers for Disease Control and Prevention*, 15 May 2024, *https://www.cdc.gov/maternal-infant-health/pqc/state-pqcs.html*. Accessed 24 September 2025.

[25] ''Perinatal Quality Collaboratives.'' *Centers for Disease Control and Prevention*, 15 May 2024, *https://www.cdc.gov/maternal-infant-health/pqc/index.html*. Accessed 24 September 2025.

[26] Centers for Disease Control and Prevention. ''PQC Impacts: Reducing Pregnancy Complications From High Blood Pressure.'' *Maternal Infant Health*, 20 May 2024, *https://www.cdc.gov/maternal-infant-health/pqc/success-stories-illinois.html*.

pregnancy-related deaths are considered preventable. According to data from MMRCs in 45 states, 85.7 percent of pregnancy-related deaths occurring in 2022 were preventable, with clinical skill and quality of care, lack of continuity of care, and knowledge identified as the most common contributing factors.[27] MMRC prevention recommendations were directed at the provider level (32.2 percent), facility level (18.6 percent), and system level (38.0 percent),[28] underscoring the importance of facility-level responsiveness to MMRC findings. Comprehensive strategies for improving maternal health quality, such as engaging with State PQCs, utilizing AIM resources, and seeking the CMS Birthing-Friendly designation, can significantly enhance outcomes in maternal health. CMS encourages hospitals that offer OB services to incorporate maternal health quality improvement activities, including review of publicly available MMRC data and recommendations where available, into their existing QAPI programs under § 482.41.

2. Proposal To Remove Transfer Protocol Staff Training (§ 482.43(c))

The hospital discharge planning requirements at § 482.43, ''Discharge planning,'' were originally published on December 13, 1994,[29] including the requirement that hospitals must maintain a written discharge planning process for all patients that supports safe, timely transitions from hospital care. This includes early identification of patients at risk of adverse outcomes and timely discharge planning evaluations by qualified personnel to assess post-hospital care needs, service availability, and the patient's capacity for self-care or appropriateness of the discharge setting (§ 482.43). When needed, hospitals must document and communicate evaluation results, develop and implement discharge plans, reassess plans as patient needs change, ensure appropriate transfer or referral, and regularly review their discharge planning process.

In the September 30, 2019 final rule, ''Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care,'' [30] CMS established additional discharge planning requirements requiring hospitals to assist patients and their caregivers in selecting post-acute care providers by sharing relevant quality and resource use data that are relevant to the patient's goals of care and treatment preferences, and to document this sharing of information in the medical record (§ 482.43(a)(8)).

The discharge planning CoP was last updated in the CY 2025 OPPS/ASC final rule. Effective July 1, 2025, all hospitals must have written policies and procedures for transferring patients under their care (§ 482.43(c)). This requirement is inclusive of hospital inpatients, such as transfers from the emergency department to inpatient admission, transfers between inpatient units in the same hospital, as well as transfers between inpatient units at different hospitals. In addition, hospitals are required to provide annual training to the relevant staff (as determined by the facility) regarding the hospital policies and procedures for transferring patients under its care.

In the CY 2025 OPPS/ASC final rule, CMS specifically agreed with commenters that supported inclusion on annual training on transfer protocols in the hospital CoPs to promote consistency in transfer processes and ensure that transfers are conducted safely by minimizing errors.[31] In light of additional public comments received through the 2025 deregulatory RFI [32] and the issuance of E.O. 14192 and E.O. 14219, CMS is now reconsidering that position. CMS received comments on the 2025 deregulatory RFI stating that transfer protocols are already built into existing regulations, and that the additional formal annual staff training requirement is unnecessarily prescriptive, as staff engage with transfer processes routinely as part of daily clinical operations and maintain familiarity through regular practice, including through electronic health record systems that facilitate unit-to-unit and facility-to-facility transfer processes. CMS agrees that a separate, prescriptive annual training requirement is not necessary to ensure staff familiarity with transfer policies and procedures. CMS also recognizes that the broader existing regulatory requirements, including Emergency Medical Treatment and Labor Act (EMTALA) requirements for emergency department transfers, the existing discharge planning CoP requirements (§ 482.43), and accrediting organization (AO) standards collectively support staff competency in transfer processes without the need for a separate annual training requirement.

CMS acknowledges that hospitals were required to undertake compliance efforts, including conducting initial annual training sessions and documenting staff completion in personnel records, since the July 1, 2025, effective date of § 482.43(c). However, CMS has determined that the ongoing annual compliance burden of maintaining and documenting a separate staff training requirement on transfer protocols outweighs the benefit of retaining this requirement, given that the written policies and procedures requirement remains in place and the existing operational and regulatory requirements support staff knowledge of transfer protocols.

Specifically, the compliance costs associated with the emergency services readiness staff training requirements, estimated in the CY 2025 OPPS/ASC final rule,[33] are more than $862 million and 5.1 million hours of staff time over a ten-year period, or approximately $86 million and 505,213 staff hours annually.

Removing the annual transfer protocol staff training requirement may allow clinicians to spend more time with patients and prioritize high-quality patient care, while maintaining flexibility in how hospitals ensure staff familiarity with transfer policies and reduce regulatory compliance burden. As patient transfers require coordinated clinical decision-making across settings and levels of care, maintaining written transfer policies support consistent transfer decision-making, including critical or infrequent situations. Removing this annual training requirement would not prevent hospitals, states or AOs from independently establishing and enforcing facility policies requiring annual training.

3. Proposal To Remove Emergency Services Readiness Staff Training (§ 482.55(c))

In the CY 2025 OPPS/ASC final rule,[34] CMS finalized emergency services readiness staff training

[27] CDC. ''Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees.'' *Maternal Mortality Prevention,* 28 Aug. 2025, *www.cdc.gov/maternal-mortality/php/data-research/mmrc/index.html?cove-tab=4.* Accessed 28 May 2026.

[28] ''Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees.'' *Maternal Mortality Prevention,* 28 Aug. 2025, *www.cdc.gov/maternal-mortality/php/data-research/mmrc/index.html?cove-tab=5.* Accessed 28 May 2026.

[29] 59 FR 64142.

[30] 84 FR 51836.

[31] 89 FR 94481.

[32] ''Medicare Regulatory Relief | CMS.'' *Cms.gov,* 2025, *https://www.cms.gov/files/document/unleashing-prosperity-through-deregulation-medicare-program-request-information.pdf.* Accessed September 2025.

[33] 89 FR 94481.

[34] 89 FR 93912.

requirements for hospitals (89 FR 94592). As of July 1, 2025, § 482.55(c)(3) requires hospitals to train applicable staff annually on the protocols and provisions implemented pursuant to the emergency services readiness requirements at § 482.55(c). Specifically, in accordance with the complexity and scope of services offered by the facility, the hospital must have adequate provisions and protocols to meet the emergency needs of patients. These protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with OB emergencies, complications, and immediate post-delivery care. The hospital's governing body is responsible for identifying and documenting which staff must complete training on emergency services readiness protocols and procedures. Additionally, the hospital must document in their personnel records that the training was successfully completed and demonstrate staff knowledge on emergency services readiness topics. Further, the hospital must use findings from their QAPI programs to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

In the CY 2025 OPPS/ASC final rule, CMS disagreed with commenters who contended that the emergency services readiness staff training requirements at § 485.618(e)(2) were duplicative of existing CoPs (89 FR 94472). CMS is now reconsidering that position in light of public comments we received through the 2025 deregulatory RFI [35] and E.O. 14219 and E.O. 14192, which direct agencies to reduce regulatory burdens. Commenters stated that this requirement is duplicative, as most hospitals have internal standards and protocols to ensure compliance with nationally accepted guidelines for emergency care and readiness including OB emergencies, complications, immediate post-delivery care, and other patient health and safety events. Other commenters noted that the emergency services readiness requirements at § 482.55(c) will impose large burdens on hospitals and health care professionals, particularly for small and rural hospitals with limited staffing and financial resources. CMS agrees that the combination of existing CoP requirements (including those for QAPI under § 482.21), EMTALA requirements, AO accreditation standards, specialty board certification requirements, and nationally recognized clinical resources ensure staff competency in emergency services readiness without the need for a separate, prescriptive annual training requirement. This determination is further supported by the role of state licensing boards, which require clinicians to meet continuing education and competency standards for licensure renewal, as well as private-sector patient safety organizations that advance national clinical readiness and safety practices.

CMS acknowledges that hospitals were required to undertake compliance efforts since the July 1, 2025, effective date, however, CMS has determined that the ongoing annual compliance burden outweighs the incremental benefit of retaining this requirement given the robust existing structure of other applicable regulations, AO standards, board certifications, EMTALA requirements, and QAPI requirements. Specifically, the compliance costs associated with the emergency services readiness staff training requirements, estimated in the CY 2025 OPPS/ASC final rule [36] at $1.73 billion and 16.4 million hours of staff time over a 10-year period, or approximately $173 million and 1.6 million hours annually.

The financial pressures facing rural hospitals further underscore the need for this reconsideration. Rural hospitals are experiencing significant and worsening financial challenges that threaten patient access to care, including emergency services. According to the North Carolina Rural Health Research Program's financial distress index, a model that assesses rural hospital vulnerability across financial performance, government reimbursement, organizational traits, and market characteristics,[37] there are currently 86 rural hospitals in the highest financial risk category and an additional 329 are in the mid-highest risk category.[38] For rural hospitals already experiencing financial strain, the recurring annual cost associated with implementing, documenting, and maintaining separate staff training requirements is an additional burden, further worsening existing financial constraints. The financial challenges rural hospitals face may impact access to care as shown by expanding ambulance and health care deserts,[39] and the absence of hospital-based obstetric services in 60 percent of rural counties.[40] The compounding financial and operational challenges rural hospitals experience highlight the disproportionate burden of retaining a requirement that CMS has determined is duplicative of similar regulations, AO accreditation standards, specialty board certifications, and EMTALA requirements. Therefore, removing this staff training requirement may allow clinicians to spend more time with patients and prioritize providing high-quality patient care, while maintaining flexibility in how hospitals ensure staff competency and reducing regulatory compliance expenditures.

Existing requirements for hospitals that provide emergency services, located at § 482.55, require hospitals to meet each patient's emergency care needs in accordance with acceptable standards of practice through appropriate oversight, integration, and staffing. Hospitals must also have adequate provisions and protocols to meet the emergency needs of patients. Further, hospitals may incorporate emergency services readiness and staff competency activities into their QAPI programs under § 482.21, which require hospitals to evaluate and improve the quality of all services furnished, including emergency and OB services. Considering the duplicative nature of these requirements, and in alignment with both E.O. 14192 and E.O. 14219, we are proposing to remove the emergency services readiness staff training requirement at § 482.55(c)(3). This change would streamline regulatory requirements while preserving patient safety, allowing clinicians to spend more time delivering high-quality care to patients.

In meeting the existing emergency services CoP requirements at § 482.55, hospitals commonly rely on AO standards, voluntary certification programs, and nationally recognized clinical resources that include staff training and competency expectations

[35] ''Medicare Regulatory Relief | CMS.'' *Cms.gov,* 2025, *https://www.cms.gov/files/document/unleashing-prosperity-through-deregulation-medicare-program-request-information.pdf.* Accessed September 2025.

[36] 89 FR 94545 to 94546.

[37] Malone, Tyler L, et al. ''An Updated Model of Rural Hospital Financial Distress.'' *The Journal of Rural Health,* vol. 41, no. 2, 3 Oct. 2024, *onlinelibrary.wiley.com/doi/full/10.1111/jrh.12882, https://doi.org/10.1111/jrh.12882.* Accessed 27 May 2026.

[38] Malone, Tyler, et al. ''Rural Hospital Financial Distress: Relative Risk in 2025.'' North Carolina Rural Health Research Program, Nov. 2025, *www.ruralhealthresearch.org/publications/1742.* Accessed 28 May 2026.

[39] Jonk, Y., Milkowski, C., Croll, Z., & Pearson, K. (2023). Ambulance Deserts: Geographic Disparities in the Provision of Ambulance Services [Chartbook]. University of Southern Maine, Muskie School, Maine Rural Health Research Center.

[40] Interrante JD, O'Hanlon K, Kozhimannil KB. Availability of Hospital-Based Obstetric Services in the United States by County, 2010–2023: A State-by-State Report. University of Minnesota Rural Health Research Center. January 2026. *https://rhrc.umn.edu/publication/availability-of-hospital-based-obstetric-services-in-the-united-states-by-county-2010-2023-a-state-by-state-report/.*

related to emergency services readiness. AOs have staff training requirements pertaining to emergency services readiness for patients with critical illnesses. For example, The Joint Commission (TJC) offers facility certification programs in managing critical illnesses, such as heart attacks and stroke, through its comprehensive heart attack and stroke centers programs in collaboration with the American Heart Association and American Stroke Association.

Additionally, professional health care societies offer facility credentialing opportunities and free resources to improve emergency services readiness. For example, the American College of Emergency Physicians (ACEP) offers a geriatric emergency department (ED) accreditation program, with the aim of promoting best clinical practices for older adults, coordinating care more efficiently, and reducing the cost of care.[41] ACEP also offers an ED accreditation program to establish transparency and improve patient care through the implementation of evidence-based policies and practices.[42] EDs also have access to free educational resources such as the American College of Obstetricians and Gynecologists' (ACOG's) toolkit for OB emergencies in non-obstetric settings and the Alliance for Innovation on Maternal Health (AIM) Obstetric Emergency Readiness Kit, including guidance for rural facilities, to improve their obstetrical readiness.[43] [44] CMS also recognizes that risk-appropriate care, a strategy to ensure that pregnant women and infants receive the right care in the right place at the right time, is an important framework for rural hospitals, including those without dedicated OB services.[45] Under this approach, healthy patients can safely deliver in their communities, while complex pregnancies are delivered in hospitals with the personnel and resources to support higher risk conditions. Having formal transfer policies and protocols in place beyond individual hospital systems is foundational to providing risk-appropriate care. Hospitals, including those without dedicated OB services, may find it beneficial to ensure that providers have the skills necessary to stabilize and transport, or potentially deliver, a high-risk pregnancy, and are encouraged to explore the range of training resources available to support obstetric emergency preparedness in non-obstetric settings. Similarly, the National Pediatric Readiness Project, developed in partnership with ACEP, the Emergency Nurses Association (ENA), and the American Academy of Pediatrics, empowers EDs nationwide to improve their ''pediatric readiness'' or capability to care for acutely ill and injured children through free assessment and toolkit resources.[46]

In addition, hospitals commonly rely on existing specialty board certification and continuing education requirements to ensure that emergency services staff are qualified and prepared to deliver care in accordance with acceptable standards of practice, consistent with § 482.55. Notably, specialty board certification is a key component of physician education and required by a majority of hospital-based employers. For example, physicians can pursue board certification in emergency medicine from organizations such as the American Board of Emergency Medicine (ABEM) or the Board of Certification in Emergency Medicine (BCEM).[47] Emergency Medicine board certification requires physicians to demonstrate and maintain knowledge of key emergency topics, including OB emergencies.[48] ACEP also offers Continuing Medical Education (CME) in best practice updates for managing common and critical emergency conditions through conferences, online modules, and seminars and requires its members to earn 150 CME hours every 3 years.[49] [50] The Board of Certification of Emergency Nursing offers nurses credentialling as a certified emergency nurse (CEN), while the ENA offers nurses continuing education courses in managing critical patients, including pediatrics, obstetrics, geriatrics, and trauma.[51]

The extensive nature of these resources and the nature of hospital expectations for clinician training would continue to drive improvements in clinician training in the absence of the emergency services staff training requirements that we propose to remove from the hospital regulations.

4. Proposal To Remove OB Services Staff Training (§ 482.59(c))

In the CY 2025 OPPS/ASC final rule,[52] we finalized OB services staff training requirements for hospitals. Effective January 1, 2027, section § 482.59(c) requires hospitals to ''develop policies and procedures to ensure that relevant staff are trained on select topics for improving the delivery of maternal care.'' The training topics must reflect the scope and complexity of the services offered within the facility, including facility-identified, evidence-based best practices and protocols. Hospitals will also be required to use findings from their QAPI programs to inform staff training needs and any additions to the training topics on an ongoing basis and provide relevant new staff with initial training. In addition, the governing body will be required to identify and document which staff must complete an initial training and subsequent biennial (every 2 years) training. Additionally, the hospital must document in the staff personnel records that the training was successfully completed and must be able to demonstrate staff knowledge on the aforementioned topics.

As part of the regulatory review conducted in response to the E.O 14219 and E.O. 14192, we solicited and received interested parties input through the 2025 deregulatory RFI.[53] Commenters expressed several concerns about the OB services CoP staff training requirements at § 482.59(c). Several commenters requested that rural hospitals be exempt from the new OB services and QAPI requirements, noting that REHs, a provider type with its own unique care model and standards, are exempt and that small, rural hospitals require flexibility given their unique operational constraints. Commenters

[41] ''Accreditation Programs.'' American College of Emergency Physicians, *www.acep.org/patient-care/accreditation-programs.* Accessed 4 February 2026.

[42] ''Accreditation Programs.'' American College of Emergency Physicians, *www.acep.org/patient-care/accreditation-programs.* Accessed 4 February 2026.

[43] ''Obstetric Emergencies in Nonobstetric Settings.'' *www.acog.org, www.acog.org/programs/obstetric-emergencies-in-nonobstetric-settings.* Accessed 4 February 2026.

[44] ''AIM | Alliance for Innovation on Maternal Health.'' Saferbirth.org, *saferbirth.org/.* Accessed 4 February 2026.

[45] CDC. ''CDC Levels of Care Assessment Tool (CDC LOCATe®).'' *Maternal Mortality Prevention,* 13 Feb. 2026, *www.cdc.gov/maternal-infant-health/php/cdc-locate/index.html#cdc_toolkit_main_purpose-risk-appropriate-care.* Accessed 28 May 2026.

[46] ''National Pediatric Readiness Project.'' *Emergency Medical Services for Children Innovation and Improvement Center (EIIC), emscimprovement.center/domains/pediatric-readiness-project/.* Accessed 4 February 2026.

[47] ''Emergency Medicine Board Certification | ABPS.'' *American Board of Physician Specialties,* 7 October 2025, *www.abpsus.org/specializations/emergency-medicine.* Accessed 4 February 2026.

[48] ''Continuing Medical Education.'' American College of Emergency Physicians, *www.acep.org/education/cme.* Accessed 4 February 2026.

[49] ''ACEP26—Chicago, Illinois—October 5–8, 2026.'' *Acep.org,* ACEP's Scientific Assembly, 2026, *www.acep.org/sa.* Accessed 4 February 2026.

[50] ''Continuing Medical Education.'' American College of Emergency Physicians, *www.acep.org/education/cme.* Accessed 4 February 2026.

[51] ''CEN—Certified Emergency Nurse Specialization.'' Board of Certification for Emergency Nursing, *bcen.org/cen.* Accessed 4 February 2026.

[52] 89 FR 93912.

[53] ''Medicare Regulatory Relief | CMS.'' *Cms.gov,* 2025, *https://www.cms.gov/files/document/unleashing-prosperity-through-deregulation-medicare-program-request-information.pdf.* Accessed September 2025.

also raised concerns about the requirement that the governing body identify and document which staff must complete training on maternal care protocols, suggesting that decisions regarding the frequency, content, and scope of staff training are more appropriately made at the facility leadership level and that prescriptive training requirements take staff away from direct patient care while increasing the cost of care. More broadly, commenters expressed concern that the staff training requirements, as currently designed, are highly unlikely to reduce maternal mortality or morbidity while significantly increasing administrative burden, and that they risk exacerbating access to care challenges, particularly in rural and underserved areas, by contributing to hospitals reducing or discontinuing OB services. Several commenters also noted that the requirements are duplicative of standards hospitals are already held to under existing requirements, including EMTALA, AO standards, and existing staff training and quality monitoring requirements.

CMS previously considered similar concerns in the CY 2025 OPPS/ASC final rule (89 FR 94480 to 94483). At that time, we concluded that the patient safety benefits of the staff training requirements outweighed the operational and financial burdens on hospitals, and that existing AO standards and CME requirements did not fully substitute for the specific, QAPI-informed, facility-level training we were establishing. We reviewed both of those conclusions in accordance with the deregulatory directives set forth in E.O. 14219 and E.O. 14192, and the additional input received through the 2025 deregulatory RFI to reassess the relative costs and benefits of the requirement. Upon further review, and consistent with concerns raised by commenters through the 2025 deregulatory RFI and the CY 2025 OPPS/ASC final rule, we find that the staff time and administrative costs associated with § 482.59(c), when added to existing financial and workforce pressures, could affect some hospitals' decisions to continue providing OB services at their current level, particularly in areas with limited access to maternity care. We further find that existing AO accreditation standards, board certification requirements, and voluntary professional society training opportunities together provide a robust and sufficient foundation for ensuring staff competency in OB care, such that the incremental benefit of the additional CoP requirement does not justify its associated burden. Specifically, the compliance costs associated with the OB services staff training requirement for hospitals, estimated in the CY 2025 OPPS/ASC final rule,[54] are $242 million and 1.8 million hours of staff time over a 10-year period, translating to approximately $24.2 million and 176,600 staff hours annually. Due to these concerns, and to reduce unnecessary regulatory burden while preserving patient safety, we are proposing to remove the OB services staff training requirement at § 482.59(c). We also note that, since this requirement does not take effect until January 1, 2027, hospitals are not yet required to comply and are unlikely to have made significant investments or actions in preparation for meeting this requirement. To the extent that any hospitals have already begun investing resources in implementing these requirements in anticipation of the effective date, we acknowledge those efforts and note that the training infrastructure developed may continue to serve facilities under existing AO standards and voluntary initiatives. As noted previously, although it is unlikely that this proposed rule will be finalized before January 1, 2027, we would request that our surveyors conducting surveys after that date focus on those CoPs that are not potentially subject to imminent revision. CMS recognizes and affirms the critical importance of high-quality, evidence-based OB staff training programs in improving maternal health outcomes and reducing maternal mortality and morbidity. While we are proposing to remove the requirement at § 482.59(c) we strongly encourage hospitals to continue investing in these activities. Hospitals have the flexibility to exceed the health and safety standards set forth by CMS by establishing additional policies and procedures as needed to address the specific needs of their patients.

If the proposed changes are finalized, hospitals that provide OB services would still need to continue to meet all applicable CoPs related to the organization of services, staffing, delivery of care, and emergency preparedness to ensure safe, high-quality care for pregnant, birthing, and postpartum patients. In meeting these ongoing requirements, hospitals accredited by a CMS-approved accrediting organization would continue to comply with the standards of their AO, which may include staff competency and readiness to safely care for pregnant and postpartum patients. AOs have staff training requirements pertaining to maternal health. For example, TJC requires facilities to provide role-specific education to all staff and providers who treat pregnant and postpartum patients on their OB hemorrhage procedure (Standard PC.06.01.01 EP 4) and to develop written, evidence-based procedures for managing pregnant and postpartum patients with severe hypertension/preeclampsia procedures (Standard PC.06.03.01 EP 3). Under TJC standards, this education must occur at orientation, whenever there are changes to the processes or procedures, or at least every 2 years (Standard PC.06.01.01 EP 4, Standard PC.06.03.01 EP 3). Facilities must also conduct drills at least annually to determine system issues, followed by a team debrief (Standard OC.06.01.01 EP 5).[55]

Hospitals accredited by TJC may voluntarily seek assessment and confirmation of their maternal care capabilities through TJC's ''Maternal Levels of Care Verification'' program, developed in collaboration with ACOG.[56] The program evaluates whether a facility has the expertise, equipment, and resources necessary to provide risk-appropriate care. It also helps hospitals identify and address capability gaps, clarify which patients they are equipped to manage and when transfer is appropriate, and strengthen collaborative relationships with other facilities, supporting broader efforts to reduce maternal mortality and severe maternal morbidity.[57]

Additionally, hospital clinicians may choose to pursue and maintain board certification to demonstrate their expertise and commitment to their specialty and evidence-based medicine. Medical specialty board certification is a key component of physician education and required by a majority of hospital-based employers. Although certification requires an investment of time and resources, this process may enhance physicians' employment opportunities, professional standing, and increase patient trust. Hospitals may also support board certification as part of their credentialing and quality improvement

[54] 89 FR 94542 to 94543.

[55] ''Comprehensive Accreditation Manual for Hospitals.'' The Joint Commission, 1 July 2025, *https://acrobat.adobe.com/id/urn:aaid:sc:VA6C2:843eea61-ae7f-4a8f-b413-fb52d44317b7.* Accessed 4 February 2026.

[56] ''Maternal Levels of Care Verification.'' *www.jointcommission.org, www.jointcommission.org/what-we-offer/verification/maternal-levels-of-care-verification/.* Accessed 4 February 2026.

[57] ''Maternal Levels of Care Verification.'' *www.jointcommission.org, www.jointcommission.org/what-we-offer/verification/maternal-levels-of-care-verification/.* Accessed 4 February 2026.

activities, as it can assist in verifying physician qualifications, meeting accreditation standards, and promoting high-quality patient care.

In addition to AO standards and board certification, several professional health care societies offer training opportunities related to improving management of OB emergencies to protect the health of mothers. For example, ACOG's ''Emergencies in Clinical Obstetrics'' course covers a variety of OB emergencies including breech vaginal delivery, shoulder dystocia, postpartum hemorrhage, and teamwork and communication.[58] Further, ACOG provides CME for physicians and health care professionals practicing obstetrics and gynecology through eModules, conferences, simulations, courses, and webinars.[59] The American Academy of Family Physicians' (AAFP) ''Advanced Life Support in Obstetrics (ALSO) Program'' equips the entire pregnancy care team with skills to effectively manage OB emergencies and positively impact maternal outcomes.[60]

Patient advocacy groups and nursing associations also offer maternal health educational opportunities. March of Dimes offers several educational programs that include continuing nursing education (CNE) and CME in maternal health and provide peer-reviewed and clinically relevant content.[61] Additionally, the American Nurses Association supports professional development by offering resources and opportunities for nurses to enhance their skills and knowledge in various nursing specialties, including obstetrics.[62] [63] [64] The Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN) offers the ''Obstetric Patient Safety: OB Emergencies Workshop'' to disseminate best practices to help clinicians identify, assess, and manage the care for patients with OB emergencies.[65] We believe that this robust set of external resources and standards can be used by hospitals to comply with the existing CoPs related to the organization of services, staffing, delivery of care, and emergency preparedness to ensure safe, high-quality care for pregnant, birthing, and postpartum patients in the absence of the specific OB services staff training requirement that we are proposing to remove.

We invite the public to comment on these proposals, and on any alternatives to our approach. Also, we are interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. Additionally, we seek comments on whether and how such training and quality improvement initiatives could be more effectively advanced through the Birthing-Friendly hospital designation program or similar voluntary, incentive-based frameworks, rather than through the CoPs. The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

5. Patients' Rights for Birth Tissue Collection in Hospitals (Proposed § 482.59(c))

a. Background on Birth Tissues Uses

Birth tissues are solely generated as a direct result of pregnancy, labor, and delivery and may be discarded, retained by the patient, stored, donated, banked for potential future medical use, and/or transferred to a third party for research or commercial purposes. These tissues can include umbilical cord blood, umbilical cord tissue, umbilical veins, placenta, amniotic membrane, chorionic membrane, amniotic fluid, and Wharton's jelly.[66] Currently, the vast majority of birth tissue—approximately 96 percent—is disposed of following delivery.[67] If intended for future medical purposes, such tissue must be collected promptly and handled in a manner designed to minimize contamination.[68] For our analysis, it is helpful to separate our discussion of the collection of cord blood from consideration of other birth tissues.

Cord blood is the most commonly collected birth tissue for future medical use (approximately 110,000 collections annually, or about 3 percent of births, with 75 to 80 percent stored in private banks).[69] It is also the most researched and regulated birth tissue, at both the federal and state level. Cord blood is unique in that families can pursue either public or private cord banking. Public cord blood banking has an established role in hematopoietic stem cell transplantation for certain malignant, hematologic, immunologic, and metabolic disorders.[70] Public cord banking is free to the family as part of a national transplant registry. HRSA oversees the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory.[71] These programs were established under the Stem Cell Therapeutic and Research Acts to expand donor and cord blood availability to fund and coordinate the collection, banking, and distribution of cord blood units to increase access for transplantation and research.[72] Yet only approximately 180 facilities participate in public cord banks nationwide due to costs associated with collection, processing, and storage.[73] Conversely, private cord banks allow families to retain exclusive access to their stored cord blood for potential future personal or family use with collection and storage costs paid out of pocket by the family, which can total several thousand dollars initially, followed by annual storage costs of several hundred dollars.[74] [75] [76]

Professional organizations have emphasized the importance of accurate information, informed consent, and

[58] ''Emergencies in Clinical Obstetrics.'' *www.acog.org, www.acog.org/education-and-events/simulations/eco.* Accessed 4 February 2026.

[59] ''Continuing Medical Education Program.'' *www.acog.org, www.acog.org/education-and-events/cme-program.* Accessed 4 February 2026.

[60] ''Advanced Life Support in Obstetrics (ALSO) Program.'' Aafp.org, 2020, *www.aafp.org/cme/programs/also.html.* Accessed 4 February 2026.

[61] ''Continuing Education Courses.'' Marchofdimes.org, 2024, *www.marchofdimes.org/our-work/health-professionals/continuing-education-courses.* Accessed 4 February 2026.

[62] American Nurses Association. ''About ANA.'' American Nurses Association, 2025, *www.nursingworld.org/ana/about-ana/.* Accessed 4 February 2026.

[63] American Nurses Association. ''About ANA.'' American Nurses Association, 2025, *www.nursingworld.org/ana/about-ana/.* Accessed 4 February 2026.

[64] ''Continuing Education for Nurses (CE) | ANA Enterprise.'' American Nurses Association, 2024, *www.nursingworld.org/continuing-education/.* Accessed 4 February 2026.

[65] ''Getting Started with OPS.'' Association of Women's Health, Obstetric and Neonatal Nurses, *www.awhonn.org/education/hospital-products/ops/getting-started-with-ops/www.awhonn.org/education/hospital-products/ops/getting-started-with-ops/.* Accessed 4 February 2026.

[66] The gelatinous connective tissue that protects vessels within the umbilical cord.

[67] *https://pmc.ncbi.nlm.nih.gov/articles/PMC3477280/.*

[68] *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking.*

[69] *https://www.consumeraffairs.com/health/cord-blood-banking-statistics.html.*

[70] *https://publications.aap.org/pediatrics/article/140/5/e20172695/37866/Cord-Blood-Banking-for-Potential-Future.*

[71] Health Resources and Services Administration, Donation and Transplantation Statistics, Blood Stem Cell, *https://bloodstemcell.hrsa.gov/data/donation-and-transplantation-statistics* (last visited June 2026).

[72] *https://bloodstemcell.hrsa.gov/about/legislation.*

[73] *https://pmc.ncbi.nlm.nih.gov/articles/PMC3477280/.*

[74] *https://publications.aap.org/pediatrics/article/140/5/e20172695/37866/Cord-Blood-Banking-for-Potential-Future.*

[75] *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking.*

[76] *https://www.cordbloodbanking.com/banking/cost/.*

conflict-of-interest disclosure in cord blood banking. ACOG states that public cord blood banking is the recommended method of obtaining cord blood for transplantation, immune therapies, or other medically validated indications and that routine private cord blood banking is not supported by available evidence and that ''there is no current evidence to support the use of an autologous umbilical cord blood sample in regenerative medicine.'' [77] The American Academy of Pediatrics has similarly noted that public cord blood banking is highly regulated, while private banking may be costly and rarely used for treatment, and has recommended ethical and operational standards addressing informed consent, financial disclosures, and conflicts of interest.[78] The American Medical Association (AMA) Code of Medical Ethics states that physicians who provide OB care should be prepared to inform pregnant women of options regarding cord blood donation or storage and potential uses, and should obtain informed consent before the onset of labor whenever feasible when participating in collection.[79]

Data on collection rates of other birth tissue (non-cord blood) for future medical uses are limited due to a lack of standardized national data. Parent's Guide to Cord Blood, a patient advocacy group, estimates approximately 100,000 placentas are collected by birth tissue procurement organizations (BTPOs) each year and distributed to research and/or commercial entities.[80] Unlike cord blood, there is no public banking infrastructure for other birth tissues. The Food and Drug Administration (FDA) regulates such tissues either under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 [81] or under Section 351 of the PHS Act and relevant sections of the Federal Food, Drug and Cosmetic Act.[82] These tissues are often marketed to the public in a misleading manner and without following applicable statutory and/or regulatory requirements.[83]

Regenerative medicine products derived from human cells or tissues, including stem cells, umbilical cord blood, amniotic tissue, and related products that meet all of the criteria in 21 CFR 1271.10(a) are subject only to regulation under section 361 of the PHS Act and the regulations in 21 CFR part 1271. If such a product does not meet all the criteria set out in 21 CFR 1271.10(a), and the establishment that manufactures the HCT/P does not qualify for any of the exceptions listed in 21 CFR 1271.15, the HCT/P will be regulated under section 351 of the PHS Act and/or the FD&C Act, and applicable regulations, including 21 CFR part 1271, and FDA approval will generally be required.[84] Specifically, the FDA issues warning letters to companies regarding the marketing of unapproved biological products and regarding manufacturing and quality system deficiencies. Additionally, FDA has stated that unapproved regenerative medicine therapies can pose serious safety risks. Adverse events associated with the use of unapproved regenerative medicine products have included bacterial infections, blindness, tumor formation, inflammatory reactions, and other harms.[85] [86] [87] These regulations, company communications, and public safety communications provide additional context regarding FDA's oversight of regenerative medicine products, including birth tissues, and the potential risks associated with products that do not comply with applicable statutory and regulatory requirements.

Investigative reporting has also described commercialization of birth tissues and the potential for donations made in connection with childbirth to enter supply chains for unapproved or unproven products. In a 2019 investigation, *The New Yorker* and *ProPublica* reported that some patients who donated birth tissue understood the donation to be for a beneficial purpose, but did not recall the details of the donation process, and described a broader market for birth tissue products used in unproven commercial uses, often without families' awareness.[88] [89]

National data on the number of placentas or other birth tissues released to or taken home by families each year is not available. The limited available evidence consists primarily of small surveys of hospital/pathology practices and non-national studies of placentophagy or community birth populations.[90] [91] [92] We are aware that mothers and families may have significant cultural, religious, spiritual, or personal interests in birth tissues, especially the placenta and umbilical cord.[93] Although birth tissues are often treated as medical waste within healthcare settings, scholarly literature describes numerous traditions and cultural practices, in the United States and internationally, involving the retention, burial, preservation, or other uses of birth tissue following childbirth.[94] Scholars have further observed that patient preferences regarding the disposition of birth tissues are not always reflected in institutional policies or informed consent practices, and that families may face inconsistent policies or practices when seeking to retain their placentas and other birth tissues.[95] [96] One limited survey in 2013

[77] American College of Obstetricians and Gynecologists, Committee Opinion No. 771, Umbilical Cord Blood Banking (Mar. 2019), *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking.*

[78] William T. Shearer et al., Cord Blood Banking for Potential Future Transplantation, 140 Pediatrics e20172695 (2017), *https://publications.aap.org/pediatrics/article/140/5/e20172695/37866/Cord-Blood-Banking-for-Potential-Future.*

[79] American Medical Association, Code of Medical Ethics Opinion 6.1.5, Umbilical Cord Blood Banking, *https://code-medical-ethics.ama-assn.org/ethics-opinions/umbilical-cord-blood-banking.*

[80] *https://parentsguidecordblood.org/en/news/its-morning-your-c-section-and-someone-wants-you-donate-your-placenta.*

[81] 21 CFR part 1271, includes requirements related to collection, processing, storage, and distribution of certain tissues HCT/Ps (including placenta, amniotic membrane, and cord tissue).

[82] Section 361 of the Public Health Service Act, 42 U.S.C. 264; Section 351 of the Public Health Service Act, 42 U.S.C. 262; 21 CFR part 1271; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*

[83] Food and Drug Administration, Consumer Alert on Regenerative Medicine Products Including Stem Cells and Exosomes, *https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/consumer-alert-regenerative-medicine-products-including-stem-cells-and-exosomes.*

[84] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal.*

[85] *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/patient-and-consumer-warning-about-potential-serious-risks-harm-following-use-unapproved-products.*

[86] Food and Drug Administration, Important Patient and Consumer Information About Regenerative Medicine Therapies (June 3, 2021), *https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies.*

[87] *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products.*

[88] Caroline Chen, The Birth-Tissue Profiteers, The New Yorker and ProPublica (May 7, 2019), *https://www.newyorker.com/news/news-desk/the-birth-tissue-profiteers.*

[89] Mathilde Cohen, The Law of Placenta, 31 Yale Journal of Law and Feminism 337 (2020).

[90] *https://journals.sagepub.com/doi/10.2350/13-05-1338-OA.1.*

[91] *https://pubmed.ncbi.nlm.nih.gov/29722066/.*

[92] Although Cohen's analysis draws on international case studies, including examples from Brazil, CMS cites the article because it addresses ethical, legal, and commercial issues associated with birth tissue procurement and use that have received comparatively limited attention in the U.S. literature.

[93] Mathilde Cohen, The Law of Placenta, 31 Yale Journal of Law and Feminism 337 (2020).

[94] Mathilde Cohen, The Law of Placenta, 31 Yale Journal of Law and Feminism 337 (2020).

[95] Mathilde Cohen, The Law of Placenta, 31 Yale Journal of Law and Feminism 337 (2020).

[96] *https://parentsguidecordblood.org/en/news/your-placenta-rights-under-us-state-laws.*

found that 61 percent of hospitals allow for placenta release to families, and most hospitals had an interdisciplinary policy supporting it.[97]

b. Need for New Hospital Standards

As discussed in section II. A. of this proposed rule, section 1861(e)(9) of the Act authorizes the Secretary to establish additional requirements necessary for the health and safety of patients served by Medicare-participating hospitals. Existing hospital CoPs establish the framework for protecting patient rights, promoting informed decision-making, and ensuring accurate medical and clinical record documentation. Together, the requirements safeguard patient health and safety and promote quality care for all patients in Medicare- and Medicaid-participating hospitals. Specifically, patient rights CoPs for hospitals at § 482.13(a) and (b) provide that patients or their representatives have the right to make informed decisions regarding their care, including being informed of their health status, being involved in care planning and treatment, and being able to request or refuse treatment. The hospital medical records CoP at § 482.24(c)(4)(v) requires the medical record to contain properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable. However, there are no existing CoPs related specifically to the collection of birth tissues.

We note that this differs from the regulatory framework applicable to organs and tissues collected for transplantation. For example, § 482.45 establishes specific requirements for organ, tissue, and eye procurement, including requirements related to hospitals' agreements with organ procurement organizations, tissue banks, and eye banks and policies governing the donation process. Of note, hospitals are not required to have a relationship with birth tissue procurement organizations or birth tissue banks. Organs and tissues collected for transplantation are therefore subject to an established regulatory framework and associated donation and consent process. The existing hospital CoPs do not establish comparable requirements specifically addressing the collection and disposition of birth tissues following a live birth, including circumstances in which tissues may be retained by the patient or collected, donated, transferred, stores, or used for purposes other than transplantation.

We believe that decisions involving the collection, storage, donation, banking, transfer, release, or discarding of birth tissues may implicate important patient interests and rights and therefore warrant additional transparency and informed decision-making protections. Unlike many other biological materials generated during the course of medical care, birth tissues may have unique cultural, religious, personal, or familial significance to patients and their families.[98] At the same time, birth tissues may also have medical, research, or other uses that can involve their collection or transfer to entities outside of the hospital. These characteristics distinguish birth tissues from both biological materials routinely discarded in the course of medical care and organs and tissues collected through established transplantation and donation processes. Therefore, families giving birth at hospitals may reasonably wish to understand whether such tissues will be discarded, available for them to retain, used for research purposes, transferred to third parties, stored for future use, or otherwise utilized in commercial activities.

Moreover, because of the concerns discussed previously about inappropriate clinical use and profiteering, transparency is particularly important when a hospital participates in a program or arrangement through which birth tissues may be donated, transferred, banked, stored, or used by a third party and/or for commercial purposes. We believe that patients have the right to the information necessary to make an informed decision about consenting to these uses of their personal birth tissues and biological materials.

CMS understands that many hospitals may already have policies around informed consent and allow patients to request retention or release of birth tissues, subject to State law, infection prevention and control requirements, and clinical circumstances.[99] However, practices may vary, and patients may not know whether, when, or how to make such a request. Some hospitals may rely on general consent forms or medical waste policies that do not clearly inform patients about possible collection, transfer, storage, donation, commercial use, or other disposition of birth tissues. Variation in these processes can create uncertainty for patients, staff, and hospitals.

We believe that establishing new requirements to address these variations would strike the appropriate balance between improving transparency, creating consistent patient expectations and ensuring that no hospital is compelled to collect, bank, donate, or release tissues in circumstances that would be unsafe, unlawful, or inconsistent with clinical care.

c. Proposed Scope and Definition of Birth Tissues (§ 482.59(c))

Mothers who give birth in hospitals that furnish OB services should have baseline protections regarding informed decision-making, documentation, and safe handling of their birth tissues when the hospital engages in birth tissue collection, storage, donation, banking, transfer, or release. To advance this goal, we propose to add new standards at § 482.59(c). As noted earlier in this section, we are proposing to remove the current requirements at § 482.59(c) and replace them with new standards that build on the CoPs for obstetrical services. These new standards address informed consent for birth tissue collection and patient requests for retention or release of birth tissues.

We propose to add a new standard to the OB Services CoP at § 482.59(c), titled ''Birth tissue collection.'' Facilities that furnish obstetrical services vary widely in their involvement with birth tissues. For example, some hospitals are deeply involved in birth tissue activities, including operating or sponsoring public cord blood donation programs, contracting with third-party collection or tissue procurement entities, or facilitating private banking arrangements. Others have more limited involvement, such as occasionally receiving requests to retain or release birth tissues to the patient for cultural, religious, or personal uses or to a private third-party for personal future medical uses, research, or donation, even where no formal relationship exists between the hospital and the third party. To account for this variation, the proposed standard would apply to only those hospitals that furnish obstetrical services and participate in one or more activities related to birth tissues including collection, storage, donation, banking, transfer, or release to patient. For purposes of this standard, we interpret participation to include hospital-sponsored, hospital-operated, or hospital-facilitated activities, that is, any instance in which the hospital's personnel, premises, policies, or processes are used in connection with the collection, packaging, storage, transfer, banking, donation, or release

[97] *https://journals.sagepub.com/doi/10.2350/13-05-1338-OA.1.*

[98] Mathilde Cohen, The Law of Placenta, 31 Yale Journal of Law and Feminism 337 (2020).

[99] *https://journals.sagepub.com/doi/10.2350/13-05-1338-OA.1.*

birth tissues. Facilities that do not engage in any of these activities would not be subject to the proposed standard.

Furthermore at § 482.59(c), we propose to define ''birth tissues'' to capture the materials most commonly associated with live childbirth that may be collected, retained, stored, donated, banked, transferred, or released for personal, clinical, research, and/or commercial purposes. For purposes of this proposed rule, birth tissue is limited to tissue or biological material obtained in connection with labor and delivery resulting in a live birth. This proposal does not apply to tissue or biological material obtained in other clinical circumstances. Specifically, we propose to define ''birth tissue'' as ''human cells, tissues, and cellular and tissue-based products obtained during or immediately following labor and delivery, (including cesarean-section delivery), such as umbilical cord blood, umbilical cord tissue, placenta, amniotic membrane, amniotic fluid,[100] and other tissues or biological materials associated with live childbirth.'' This definition is intended to avoid gaps in patient protections that could arise if the rule addressed only one category of birth tissue, such as cord blood, while other tissues were collected, transferred, released, or disposed of under less transparent processes. This definition is also intended to be flexible enough to accommodate changes in collection practices and terminology over time. NIH has issued policy describing additional requirements related to research uses of such tissue.[101] Importantly, our definition is not intended to conflict with or alter FDA definitions or classifications of human cells, tissues, and cellular or tissue-based products (HCT/Ps) under FDA authorities or other similar FDA terminology, which remain controlling for purposes of FDA regulation.[102] Similarly, CMS' definition of birth tissues is not intended to conflict with or alter NIH's definitions or policies as it relates to this or similar topics. Lastly, we note that nothing in this proposal limits or impairs a family's ability to receive their stillborn child for the purposes of holding, mourning, or making funeral arrangements. Such activities are regulated under state and local law, and hospital specific policies.[103] Furthermore, such scenarios are beyond the scope of this regulation, which applies only to live births.

d. Proposals for Informed Consent (§ 482.59(c)(1))

At proposed § 482.59(c)(1), we would require that the hospital ensure that it obtains informed consent from the patient or the patient's representative prior to the collection, storage, donation, transfer, banking, or release to patients of birth tissues, consistent with the hospital's scope of services and role in those activities. The consent must be documented consistent with the medical records requirements at § 482.24(c)(4)(v).

Consistent with the phrase ''scope of services and role in those activities'' in proposed § 482.59(c)(1), the obligations under this proposal would be tailored to the specific activities in which the hospital participates. The proposal would not require hospitals to offer new services, to purchase or provide new equipment, or initiate or sponsor a collection program, private banking arrangement, or other birth tissue collection program. Rather, it would require only that when a hospital furnishes obstetrical services and participates in a covered birth tissue activity, the hospital maintains appropriate consent, documentation, policies, procedures, and safe handling processes commensurate with its scope of services and role in that activity. For example, a hospital that operates a public cord blood collection program would be expected to ensure that its consent process includes the information and disclosures applicable to public donation. In contrast, a hospital that does not participate in a public cord blood collection program and is only collecting birth tissue in response to an individual mother's request for release of a placenta for personal or cultural reasons would be expected to document the request and release decision consistent with its policies and provide safe handling instructions.

We propose that the informed consent process include, as applicable, six categories of information: (1) a description of the birth tissues to be collected; (2) the intended use, including commercial and research uses, of the birth tissues; (3) disclosure of any third-party involvement and conflicts of interest; (4) information regarding risks, limitations, and infection prevention and quality control considerations; (5) notice that a patient's refusal to provide informed consent will not affect access to care or treatment; (6) and any other information required under applicable Federal or State law. These elements establish a baseline and are not intended to prescribe a single consent form or process for all hospitals or activities. For example for relevant research purposes, HHS' Federal Policy for the Protection of Human Subjects (also known as the Common Rule; codified at 45 CFR part 46 (Authority: 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v–1(b)) [104] [105] may also apply, such as Institutional Review Board (IRB) review, additional informed consent requirements, and specific protections for pregnant women, fetuses, and neonates (subparts B and D), inclusive of certain birth tissues such as the

[100] CMS acknowledges that the inclusion of amniotic fluid within ''birth tissues'' definition differs from FDA's definition of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P). Namely, that amniotic fluid is not an HCT/P for FDA regulatory purposes. See 21 CFR 1271.3(d)(3). See also FDA's July 2020 guidance entitled ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal*), on page 15 states ''Secreted body fluids (*e.g.* amniotic fluid) are generally not considered HCT/Ps'' per the definition of HCT/P in 21 CFR 1271.3(d). However, CMS for its regulatory purposes includes amniotic fluid within its definition of ''birth tissue'' based on current practices regarding collection of such material and the CMS definition is not intended to incorporate FDA's definition in 1271.

[101] *https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.15_human_fetal_tissue_research.htm.*

[102] FDA regulations define human cells, tissues, or cellular or tissue-based products (HCT/Ps) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. See 21 CFR 1271.3(d). FDA does not define or use the term ''birth tissue'' in 21 CFR part 1271, its 2007 Donor Eligibility Guidance (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/eligibility-determination-donors-human-cells-tissues-and-cellular-and-tissue-based-products*), or its Minimal Manipulation/Homologous Use guidance (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal*). In January 2025, FDA issued draft guidance entitled ''Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-determining-eligibility-donors-human-cells-tissues-and-cellular-and-tissue-based*). This document uses the term ''gestational cells or tissues.'' Differences may exist between FDA's definitions of HCT/Ps and ''gestational cells or tissues'' and CMS' definition of ''birth tissues,'' as CMS is not intending to incorporate FDA's definition into this rulemaking. CMS chose to define and use the term ''birth tissue'' because it is already familiar to tissue establishments and to hospitals that contract with them. Since this proposed CoP would regulate facility-patient interactions, as well as facility policies, documentation, and processes related to informed decision-making and the safe release of birth tissues, CMS chose terminology that is familiar to the affected industry.

[103] *https://stacks.cdc.gov/view/cdc/80634/cdc_80634_DS1.pdf.*

[104] *https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.*

[105] *https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.*

placenta.[106] CMS acknowledges the importance of research related to birth tissues [107] [108] and views this proposal as in alignment with the Common Rule and not as a replacement for such standards. This proposed rule would therefore defer to Common Rule standards related to exempted or waived research activities. Additionally, facilities retain the flexibility to adapt their consent processes to reflect their specific scope of services and patient needs in alignment with local, state, and federal law and regulations. Birth tissues may move through complex supply chains and may have research, clinical, manufacturing, or commercial value. We propose at § 482.59(c)(1)(i) and (ii) requirements for disclosure to ensure that patients and families fully understand how collected tissues may be transferred to a third party, processed into a product, sold, used in research, banked for future use, or discarded if quality criteria are not met. Patients must be informed if a hospital and/or third party will be financially compensated for the procurement, facilitation, transfer, end use or other activity regarding collected tissues. Providing this information supports patient autonomy and empowers the patient to make a decision that reflects the patient's values and preferences.

We propose at § 482.59(c)(1)(iii) to require disclosure of (both not-for-profit and for-profit) third-party involvement and conflicts of interest. ACOG and AMA both recognize the importance of conflict-of-interest disclosure in cord blood banking.[109] Disclosure is particularly important when a hospital, practitioner, or other staff member has a financial, contractual, ownership, employment, research, or other business relationship with a third party that could reasonably be viewed as influencing the presentation of delivery options to the patient (such as recommending a cesarean-section over a vaginal delivery) or when such a relationship could result in profit from the processing and sale of birth materials). Patients must receive sufficient information to understand third-party involvement and potential conflicts when they are making decisions about birth tissues from their deliveries. The components of the informed consent as required at proposed § 482.59(c)(1)(i) through (vi) are consistent with general informed consent principles and with professional guidance that emphasizes disclosure of financial interests.[110]

We propose at § 482.59(c)(1)(iv) to require information regarding risks, limitations, infection prevention, and quality control considerations. Depending on the activity, relevant information could include the possibility that collection may not be feasible because of maternal or neonatal clinical circumstances, that a specimen may fail to meet volume or quality criteria, that stored birth tissues may not be clinically useful in the future, or that releasing tissue for personal handling may involve infection prevention and storage considerations.

We also propose at § 482.59(c)(1)(v) that the patient be informed that refusal to provide informed consent will not affect access to care or treatment. Patients in labor or experiencing obstetrical emergencies may be vulnerable to time pressure or perceived pressure from clinicians, hospital staff, or third parties. Equally, the patient's decision to request collection or release of birth tissues does not obligate the hospital to provide services that are unsafe, unavailable, or inconsistent with State law or hospital policy. This is consistent with patient exercise of rights at § 482.13(b)(2).

We recognize that timing of consent in the labor and delivery context can be challenging. As previously discussed, the proposed requirements apply to birth tissue obtained during or immediately following labor and delivery resulting in live birth. The timing of the informed consent process does not alter the scope of tissues subject to this proposal. Prenatal education and consent are preferable when feasible, especially for planned donation or banking arrangements, but patients may present without prior knowledge of their options or make key requests at admission or after delivery. Under these proposals, hospitals retain flexibility to design processes that are consistent with clinical practice, patient needs, State law, and the hospital's role provided that consent is obtained before the applicable birth tissue activity occurs whenever possible, and that collection or release activities does not interfere with clinical care (for example, pathologic examination of the placenta). Patient safety takes precedence in high-acuity or emergent circumstances.

Finally, we also recognize that, in some circumstances, a patient may independently arrange with a third-party tissue bank, private bank, courier, or other entity and may ask the hospital solely to accommodate collection or release. In such cases, the hospital is not expected to become an expert in the third party's products, business practices, marketing claims, or downstream uses. The hospital should have a process, consistent with its policies, to document the patient's request; confirm, as appropriate to the hospital's role, that the patient has provided authorization or evidence of the applicable third-party consent; and document the actions taken by the hospital to accommodate, accommodate subject to reasonable conditions, delay, or deny the request based on clinical circumstances, infection prevention, and legal requirements. This approach supports patient choice while ensuring that the hospital's obligations remain proportional to the hospital's actual role and involvement. We note that FDA regulates human cells, tissues, and cellular and tissue-based products, including birth tissues.

e. Policies and Procedures for Cultural, Religious, or Personal Uses (§ 482.59(c)(2))

At § 482.59(c)(2), we propose to require the hospital to have written policies and procedures that permit patients to request retention or release of birth tissues for cultural, religious, or personal reasons, consistent with State law and the hospital's infection prevention and control program requirements under § 482.42. Such policies and procedures would not require patients to provide justification or documentation for their respective cultural, religious, or personal reasons. We propose this requirement because patient requests for retention or release may arise in routine deliveries, scheduled cesarean deliveries, emergent deliveries, or other clinical contexts, and families and staff need clear procedures for safe, consistent collection and release of birth tissues.

The proposed policies and procedures would address four core topics. First, policies must address processes for patient requests for retention or release of birth tissues. We expect hospitals to specify how and when a patient or representative may make a request, who

[106] *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-B/section-46.206.*

[107] *https://www.nichd.nih.gov/sites/default/files/inline-files/STILLBIRTH_WG_REPORT_03152023.pdf.*

[108] *https://pubmed.ncbi.nlm.nih.gov/36180175/*" *https://pubmed.ncbi.nlm.nih.gov/36180175.*

[109] American College of Obstetricians and Gynecologists, Committee Opinion No. 771, Umbilical Cord Blood Banking (Mar. 2019), *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking;* American Medical Association, Code of Medical Ethics Opinion 6.1.5, Umbilical Cord Blood Banking, *https://code-medical-ethics.ama-assn.org/ethics-opinions/umbilical-cord-blood-banking.*

[110] American College of Obstetricians and Gynecologists, Committee Opinion No. 771, Umbilical Cord Blood Banking (Mar. 2019), *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking.*

is responsible for receiving and documenting the request, what forms or authorizations must be completed, and how the hospital will communicate decisions regarding release to the patient. Hospitals should design processes that are easily understandable and accessible for their patient population and align with clinical operations.

Second, the policies and procedures must address safe handling, packaging, storage, and release practices of birth tissues. For example, we expect hospitals to identify the personnel responsible for handling birth tissues, provide appropriate containers or packaging as needed in alignment with safe handling, clearly label each tissue container or package as appropriate, accommodate tissue storage pending release as requested by the patient, establish chain-of-custody or handoff processes where needed, and implement protocols for circumstances requiring consultation with infection prevention personnel, pathology, risk management, or clinical leadership. These procedures should reflect the type of tissue, the intended use, the clinical circumstances, and the hospital's infection prevention and control program. Third, we propose that policies and procedures must address circumstances under which retention or release may be limited or denied, including infection prevention and control concerns, biohazard risks, certain clinical conditions, emergency cases, or other applicable legal requirements, as discussed below.

• Infection Prevention and Control Concerns and Biohazard Risks

Suspected or confirmed infection, contamination, or other biohazard concerns may create unacceptable risks that warrant limiting or denying retention or release. Occupational Safety and Health Administration (OSHA) classifies human blood, certain body fluids, and unfixed human tissues and organs as potentially infectious materials.[111] Because placental and related birth tissues may contain blood and other biological material, hospitals would need to implement handling and packaging procedures to protect patients, staff, and others from potential exposure to bloodborne pathogens (for example, HIV, hepatitis B, hepatitis C, or other infectious agents).[112] Hospitals must have processes to address safe handling, packaging, storage, and release when patients request retention or release of birth tissues. Hospitals should also identify circumstances in which release may be limited or denied due to infection prevention and control concerns consistent with the hospital's infection prevention and control program under § 482.42.

• Certain Clinical Conditions

Retention or release may also be limited when tissue is needed for pathology review or other clinically appropriate diagnostic evaluation. Placental pathology may assist in the evaluation of adverse maternal, fetal, or neonatal outcomes, including fetal growth restriction, stillbirth,[113] infection, congenital abnormalities, preterm birth, placental insufficiency, maternal hypertensive disorders, or other complications of pregnancy and delivery. Hospitals should identify in their policies the clinical circumstances under which retention for diagnostic purposes would take precedence over patient's requests for release. To the extent possible, patient requests should take precedence over circumstances under which hospitals may want to retain the placenta or other birth tissues for elective evaluation, research, or other purposes. Unless there are circumstances such as infection prevention concerns or a need for the hospital to retain the birth tissue for appropriate diagnostic evaluation, the patient's autonomy over their biological materials related to delivery should be prioritized.

• Emergency Cases

Patient safety takes precedence in all emergency circumstances in which staff cannot safely collect, process, or release birth tissues due to emergent patient care needs. Collection, storage, donation, banking, transfer, or release activities of birth tissues should not delay emergency care, interfere with the clinical management of labor and delivery, or alter medically appropriate obstetric or neonatal practice.[114] [115] A hospital would not be expected to delay necessary clinical intervention to complete a birth tissue consent process or collection activity, and failure to collect birth tissue due to emergent clinical circumstances would not, by itself, constitute noncompliance. To the extent necessary, such consents may be obtained following resolution of the emergency and stabilization of the patient's condition.

• Other Applicable Legal Requirements

Retention, testing, handling, or disposition of birth tissue may also be limited or governed by applicable Federal, State, Tribal, territorial, or local law (See discussion of relevant State laws in section II.A.5. of this proposed rule.) By defining these criteria in advance, hospitals provide patients and staff with clear expectations and transparent and consistent processes. These proposed requirements are intended to complement, not interfere with, a hospital's existing authority to retain birth tissues when clinically appropriate or otherwise required by law.

Fourth, at § 482.59(c)(2)(i)(D), we propose that the policies and procedures must address staff education regarding the hospital's procedures for responding to patient requests. This education is intended to be focused and practical. Staff who may receive or respond to requests to know how to identify the applicable policy, document the request, process the request safely and within their scope of services, and provide safe handling instructions when tissue is released.

Lastly, we propose at § 482.59(c)(2)(ii) that the hospital provide patients who request retention or release of birth tissues with instructions for safe handling, transport, storage, and disposition of the tissues, as applicable. These instructions should be understandable, practical, and tailored to the birth tissue and release context. For example, instructions might address the need to maintain tissue in a leak-proof container, avoid exposure to other patients or staff, refrigerate or otherwise store tissue as directed, use appropriate personal protective measures, or comply with applicable local disposition requirements. The proposed requirement would not require hospitals to supervise the patient's use after release, but it does require the hospital to provide instructions that support safe decision-making at the point of release.

In summary, these proposed requirements are intended to operate alongside, not in place of, other existing Federal and State authorities. FDA regulates human cells, tissue and cellular and tissue-based products (HCT/Ps) either under Section 361 of the Public Health Service Act and 21

[111] OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030. *https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030.*

[112] *https://www.cdc.gov/pregnancy-hiv-std-tb-hepatitis/php/screening/index.html.*

[113] *https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2020/03/management-of-stillbirth.*

[114] American College of Obstetricians and Gynecologists, Committee Opinion No. 771, Umbilical Cord Blood Banking (Mar. 2019), *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking.*

[115] American Medical Association, Code of Medical Ethics Opinion 6.1.5, Umbilical Cord Blood Banking, *https://code-medical-ethics.ama-assn.org/ethics-opinions/umbilical-cord-blood-banking.*

CFR part 1271 or under Section 351 of the PHS Act and relevant sections of the Federal Food, Drug, and Cosmetic (FD&C) Act and applicable regulations. FDA has issued guidance on minimal manipulation and homologous use and has stated that HCT/Ps that do not meet the criteria to be regulated solely under section 361 of the Public Health Service Act and 21 CFR part 1271 are regulated as drugs, devices, and/or biological products.[116] FDA also has taken compliance and enforcement actions addressing unapproved HCT/Ps, including products derived from birth tissues.

The proposed CoPs at § 482.59(c) occupies a narrower and distinct role, regulating the facility-patient interaction, facility policies, documentation, and processes for informed decision-making and safe release in Medicare and Medicaid participating hospitals. Nothing in this proposal determines whether any product is lawfully marketed or subject to FDA premarket review. Rather the purpose of the CoPs is to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals. In accordance with section 1864 of the Act, State surveyors assess hospital compliance with the conditions as part of the process of determining whether a hospital qualifies for a provider agreement under Medicare. Alternatively, under section 1865 of the Act, hospitals can elect to be reviewed instead by private accrediting organizations approved by CMS as having standards that meet or exceed the applicable Medicare standards and survey procedures comparable to those CMS requires for State survey agencies. Examples of survey and enforcement activities include review of facility policies and procedures, auditing of patient medical records, and interviewing facility leadership and staff.

We invite public comment on proposed § 482.59(c), including the scope of hospitals and activities to which the standard should apply; the proposed definition of birth tissues; the proposed informed consent standard; and the proposed policies and procedures for cultural, religious, or personal uses.

[116] Food and Drug Administration, Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff (July 2020), *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal.*

B. Long-Term Care Facilities

LTC facilities, meaning SNFs and NFs, are institutions or distinct parts of an institution that are primarily engaged in providing skilled nursing care and related services to patients that require medical or nursing care or rehabilitation services due to an injury, disability, or illness. As of January 2026, there are around 15,000 LTC facilities caring for about 1.25 million residents daily.[117] LTC facilities seeking to be Medicare and Medicaid providers of services must be certified as meeting Federal participation requirements set forth at 42 CFR part 483 (hereafter, ''LTC requirements''), which set out the resident health and safety protections established by the Secretary. The specific statutory authority for LTC facilities is set forth in section 1819 and 1919 of the Act. Sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act explicitly authorize the Secretary to issue any regulations he deems necessary to protect the health and safety of residents of LTC facilities. Under sections 1866 and 1902 of the Act, LTC facilities seeking to participate in the Medicare or Medicaid program, respectively, or both, must enter into an agreement with the Secretary or the State Medicaid agency, as appropriate.

1. Proposal To Amend Transfer Notice to Ombudsman (§ 483.15(c))

In 2016 CMS finalized revised requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs.[118] This comprehensive update of the regulations focused on quality of healthcare furnished through Federal programs, patient safety and reducing procedural burdens on providers. Among other things, this 2016 final rule emphasized the importance of protection to residents from being inappropriately transferred or discharged, providing residents with access to an advocate who can inform them of their options and rights, and ensuring that the Office of the State LTC Ombudsman is aware of facility activities related to transfers and discharges. Specifically, as a part of ensuring resident rights at § 483.15(c), we require LTC facilities to provide notice to the resident and the resident's representative(s) before transfer or discharges. The facility must also send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

[117] Centers for Medicare & Medicaid Services. Quality, Certification and Oversight Reports (QCOR), Nursing home provider reports, Active Provider and Supplier Counts Report, FY 2025. Accessed February 2, 2026. *https://qcor.cms.gov/main.jsp.*

[118] 81 FR 68688.

In accordance with the January 30, 2017, E.O. ''Reducing Regulation and Controlling Regulatory Costs'' (E.O. 13771), on July 18, 2019, we published a proposed rule entitled, ''Requirements for LTC Facilities: Provisions to Promote Efficiency and Transparency.'' [119] In that rule we proposed changes to § 483.15 related to admission, transfer, and discharge rights. Specifically, we proposed to revise the requirement for facilities to send transfer and discharge notices to the State LTC ombudsman to apply only to ''involuntary transfers and discharges.'' In response to the proposed rule, we received comments from a wide range of individual health care professionals, various healthcare associations, LTC facilities, organizations representing providers of LTC and senior service, LTC Ombudsmen, advocacy groups for LTC consumers, and LTC consumers and their family representatives. Many commenters supported the proposed change to remove Ombudsman notifications for hospitalizations where the facility has every intention of accepting the resident back following the hospitalization. However, some commenters suggested that this should be addressed in the sub-regulatory guidance, rather than through regulatory revisions. Furthermore, these commenters indicated that the use of the terms ''involuntary'' or ''facility-initiated'' in the regulations is confusing and suggest that a notice would not be required unless a resident actively objects to the transfer or discharge. Due to circumstances surrounding the COVID–19 pandemic and the rapidly evolving needs and concerns of the LTC community at that time, we did not finalize the proposal to restrict Ombudsman notices to involuntary transfers and discharges only.

While the original intent of this requirement as finalized in the 2016 rule was to enable Ombudsman officials to intervene in cases of inappropriate resident discharges, the volume of paperwork related to notice for every transfer of care and discharge has prevented Ombudsman officials from effectively focusing their efforts on inappropriate discharges, thereby negating the purpose of the regulation. In an emergent care situation, the urgency of the transfer of a resident to an acute care hospital for emergent care must be the primary focus of LTC facility staff, with a notice of transfer provided to the resident and resident's representative(s) as soon as practicable

[119] 84 FR 34737.

before the transfer in accordance with the requirements set forth at § 483.15(c)(4)(ii)(D). Copies of notices for emergency transfers must be sent to the Ombudsman, however the practicalities of implementing this requirement have led to the permitted practice of submitting a monthly list of residents who experienced a transfer to receive emergency care. This current practice does not meet the original intent of the regulations to prevent residents from being inappropriately transferred or discharged, as a transfer for emergency care services is inherently appropriate, nor does the practice as implemented lend itself to actionable efforts on the part of the Ombudsman officials.

We are aware that Ombudsman offices have expressed concerns about the issue of large numbers of notices and the difficulties of sorting notices in a timely manner so that problematic notices can be identified and acted upon. Responses to the 2025 deregulatory RFI [120] indicate that transfer and discharge notice requirements create administrative burden for nursing homes, particularly during emergent resident hospital transfers. Commenters indicated that while these notices may be necessary for planned discharges, they are excessive and are low priority for urgent hospital visits. Commenters recommend eliminating transfer notices for emergent care and eliminating the requirement to send a copy of the notice to the Ombudsman to reduce administrative burden and confusion for the families.

In light of the public comments and the misalignment between our original regulatory goals and the way in which LTC facilities and Ombudsman offices have complied with the regulations, we propose to modify the requirement at § 483.15(c)(3)(i) for LTC facilities to provide Ombudsman notice of resident transfers, except for transfers related to emergent care, as a way to focus Ombudsman official efforts on the reduction of inappropriate transfers and discharges and to alleviate the burdens of sending and processing these notices for both LTC facilities and Ombudsman officials.

The transfer and discharge facility requirements at § 483.15(c) would continue to require that the facility must permit each resident to remain in the facility and not transfer or discharge the resident from the facility unless certain circumstances are present. The circumstances center around the resident's welfare, whether the resident has improved sufficiently that the resident no longer needs the services provided by the facility, safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident, payment issues and/or the facility ceases to operate. In addition, the resident has the right to appeal a transfer or discharge. The robust nature of the facility requirements around transfer and discharge, specifically the timing of the notice at least 30 days before the resident is transferred or discharged, would continue to assure that residents receive appropriate protection in the transfer and discharge process. The requirements would also continue to require that if the information in the notice changes prior to affecting the transfer or discharge, the facility must update the recipients of the notice as soon as practicable once the updated information becomes available. We invite comments on how to reduce burden while supporting sharing the most current, updated information related to transfer and discharge notices.

2. Proposal To Amend Facility Assessment Requirement (§ 483.71)

In May 2024 CMS finalized changes to the LTC facility requirements.[121] Among other things, these changes moved the existing facility assessment requirements from § 483.70(e) to their own requirement at § 483.71. As part of this revision, CMS expanded the facility assessment requirements to require the active involvement of certain categories of staff and others in the facility assessment process. One of those new categories is direct care staff, including but not limited to, RNs, LPNs/LVNs, NAs, and representatives of the direct care staff, if applicable. Most commenters at the time of the proposed rule supported the inclusion of direct care staff; however, some commenters opposed including third party representatives of direct care staff, such as union representatives.

Commenters contended that inclusion of representatives of direct care staff would be inappropriate since the facility assessment is an operational document for the facility. They also suggested that the inclusion of third parties, especially union representatives, could be disruptive, divisive, and render the facility assessment ineffective. In addition, commenters raised concerns that third parties, especially union representatives, would be primarily concerned about the well-being of the workers they represent instead of the quality of residents' care. CMS acknowledged these counter arguments to the proposal but subsequently finalized the provision, and we have continued to review and reevaluate all aspects of the facility assessment regulation. Upon review of these changes, conducted in light of recent E.O. 14192 ''Unleashing Prosperity Through Deregulation'' [122] and E.O. 14219 ''Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative,'' [123] CMS identified the provision related to ensuring the active involvement of representatives of direct care staff as being operationally and logistically burdensome without direct benefits to resident care. LTC facilities do not have any authority over the actions or inactions of direct care staff representatives; therefore, requiring LTC facilities to be responsible for assuring their active involvement in the facility assessment process is impracticable. We have determined that holding LTC facilities responsible for the actions of those that do not have employment or contractual obligations with the facility is not an appropriate requirement for LTC facility regulations. As such, we propose to remove this provision from the requirements. We would retain the remainder of the facility assessment requirements without change.

The facility assessment is a foundational element of the LTC requirements, providing the basis for ensuring residents receive safe and appropriate care. LTC facilities are required to conduct and document a facility-wide assessment to determine what resources are necessary to competently care for their residents during both day-to-day operations and emergencies, including an evaluation of the resident population and the resources needed to serve them. The facility assessment informs several key areas of LTC facility operations, including nursing services (§ 483.35), food and nutrition services (§ 483.60), quality assurance and performance improvement (§ 483.75), infection control (§ 483.80), and training (§ 483.95). We recognize that LTC facilities serve a uniquely vulnerable population with complex, chronic, and often rapidly changing care needs. Unlike other provider types, LTC facilities serve as the permanent residence for their residents, requiring a level of individualized, continuous care planning that necessitates a structured,

[120] ''Medicare Regulatory Relief | CMS.'' *Cms.gov,* 2025, *https://www.cms.gov/files/document/unleashing-prosperity-through-deregulation-medicare-program-request-information.pdf.* Accessed September 2025.

[121] 89 FR 40876.

[122] 90 FR 9065.

[123] 90 FR 10583.

facility-wide assessment. The facility assessment requirement reflects this distinct care environment and is intended to ensure that facilities have the resources, staffing, and systems in place to meet the needs of their specific resident population.

Although we are proposing to remove the prescriptive requirement regarding the inclusion of representatives of direct care staff in the facility assessment, we encourage LTC facilities to consider the input of any individuals the facility deems appropriate as part of a comprehensive and meaningful facility assessment. We recognize the facility assessment as an essential tool for effective LTC facility planning. While we remain committed to ensuring that facility assessments are comprehensive and meaningful, we also acknowledge the administrative burden this process may place on LTC facilities. Therefore, we invite public comments on approaches to streamline and reduce burden associated with the facility assessment process, without compromising its integrity or effectiveness. Specifically, we seek input on the following:

- What process improvements or best practices have LTC facilities found effective in conducting facility assessments efficiently?
- Are there existing or emerging technological tools that could assist LTC facilities in completing this process more efficiently?
- How can CMS support facilities in leveraging these tools while maintaining the quality and comprehensiveness of the assessment?

3. Infection Control (§ 483.80(d) and (g))

The COVID–19 Public Health Emergency (PHE) placed unprecedented strain on the Nation's healthcare system, particularly LTC facilities, which faced severe staffing shortages and limited access to personal protective equipment (PPE) and critical supplies. Protecting LTC residents under these conditions required enhanced visibility into the spread and impact of infectious diseases within these settings. To address this need, CMS published a series of interim final rules with comment period (IFCs) and subsequent final rules during and after the PHE to establish and refine data reporting, testing, vaccination, and infection control requirements for LTC facilities. The data informed coordination of operations and were especially important to anticipate and prepare for surge conditions.

Beginning on May 8, 2020, CMS issued an IFC[124] revising infection prevention and control requirements to better respond to COVID–19, including electronic reporting of confirmed and suspected COVID–19 cases to the Centers for Disease and Control and Prevention and notification requirements for residents and their representatives. These reporting requirements enabled CMS and CDC to identify national epidemiological trends in LTC facilities. On September 2, 2020, CMS issued a second IFC[125] establishing COVID–19 testing requirements for LTC facilities, including documentation and response protocols following positive test results. On May 13, 2021, CMS issued an additional IFC[126] further revising infection control requirements by requiring LTC facilities and ICFs-IID to provide education about COVID–19 vaccines and to offer vaccination to residents, clients, and staff, as well as to report resident and staff vaccination status to CDC.

To ensure continuity of critical data collection beyond the end of the PHE, CMS finalized the COVID–19 reporting requirements from the May 2020 and May 2021 IFCs in a November 9, 2021 final rule.[127] This rule modified and streamlined reporting requirements, reduced reporting frequency, and required LTC facilities to continue reporting standardized COVID–19 data elements through December 31, 2024, with ongoing reporting of vaccination status without a sunset date. On June 5, 2023, CMS issued a final rule[128] removing expired COVID–19 testing requirements, withdrawing the COVID–19 staff vaccination mandate issued in an earlier IFC, ''Medicare and Medicaid Programs; Omnibus COVID–19 Health Care Staff Vaccination Interim Final Rule'' dated November 5, 2021 (hereafter ''Staff Vaccination IFC''),[129] and finalizing requirements for LTC facilities and ICFs-IID to continue providing vaccine education and offering COVID–19 vaccinations to residents, clients, and staff. Together, these actions reflect CMS' evolving regulatory approach to monitoring and mitigating the impact of COVID–19 in LTC settings while reducing unnecessary burden as conditions changed following the PHE.

In November 2024, CMS finalized the current iteration of these requirements, as part of the ''Medicare Program; Calendar Year (CY) 2025 Home Health Prospective Payment System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies'' (henceforth referred to as CY 2025 HH PPS final rule)[130] which included ongoing respiratory illness data reporting requirements as well as requirements for reporting during a Secretary-declared PHE (89 FR 88459). These requirements further reduced compliance burden when compared to the data reporting that was required during the PHE. Specifically, we decreased the scope of data categories required to be reported (including, total deaths and COVID–19 deaths among patients and staff, ventilator capacity, access to COVID–19 testing, and staff vaccination status).

In the CY 2025 HH PPS final rule, CMS finalized requirements at § 483.80(g) for LTC facilities to report respiratory illness data on an ongoing basis as well as additional reporting requirements during a declared national, State, or local PHE (89 FR 88458). We revised the requirements related to LTC facility infection prevention and control and antibiotic stewardship program to extend a modified form of the COVID–19 and influenza reporting requirements that included data for RSV and reduced the frequency of reporting compared to prior rules. Specifically, we required LTC facilities to report a facility census as well as information on acute respiratory illnesses (including influenza, COVID–19, and RSV), related to resident vaccination status, confirmed resident cases, and hospitalized residents in a standardized format and frequency specified by the Secretary, through the CDC's NHSN on an ongoing basis (§ 483.80(g)(1)(i) (89 FR 88485). We also established that during a declared Federal, State, or local PHE, the Secretary could require LTC facilities to report additional or modified data elements relevant to an acute infectious illness, up to a frequency of daily reporting, without going through additional notice and comment rulemaking. We also established that during a declared PHE the Secretary may require LTC facilities to report supply inventory shortages, staffing shortages, relevant medical countermeasures and therapeutic inventories usage, and relevant confirmed infections for staff (§ 483.80(g)(2)).

[124] 85 FR 27550.

[125] 85 FR 54820.

[126] 86 FR 26306.

[127] 86 FR 62240.

[128] 88 FR 36485.

[129] 86 FR 61555.

[130] 89 FR 88354.

a. Proposal To Remove Staff Covid–19 Vaccine Educate, Offer and Documentation Requirements (§ 483.80(d))

During the COVID–19 PHE, CMS, in consultation with the CDC, issued an evolving series of requirements to address emerging concerns. As part of the response, CMS required LTC facilities to educate and offer COVID–19 vaccination to staff. On May 13, 2021, CMS published an IFC,[131] which revised the health and safety requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. The IFC established requirements at § 483.80(d)(3), requiring that LTC facilities provide COVID–19 vaccination education to staff, and offer COVID–19 vaccines to staff, and document these activities, referred to as the ''educate and offer'' provisions. The IFC also established similar requirements related to educating and offering COVID–19 vaccinations to residents. On June 5, 2023, CMS finalized the educate and offer provisions. Specifically, LTC facilities are required to develop and implement policies and procedures to ensure that all of the requirements set forth within that section are followed. For residents and staff members, the facility maintains documentation related to COVID–19 vaccination that includes, at a minimum, that residents and staff were provided education regarding the benefits and potential risks associated with COVID–19 vaccines; were offered a COVID–19 vaccine or information on obtaining a COVID–19 vaccine; and the COVID–19 vaccine status of residents and staff and related information as indicated by the CDC's NHSN. These educate and offer provisions, supported quality measures that included healthcare providers that were adopted in the 2024 SNF Prospective Payment System rule.[132]

Similar to the requirement that LTC facilities must educate their staffs about the COVID–19 vaccine and offer it to them, issued on November 5, 2021, we issued the Staff Vaccination IFC.[133] This IFC revised the requirements that most Medicare- and Medicaid-certified providers and suppliers were required to meet to participate in the Medicare and Medicaid programs to include requirements regarding development and implementation of policies and procedures to ensure COVID–19 vaccination of staff. At that time evidence continued to demonstrate that unvaccinated healthcare staff presented risks to patient safety across healthcare settings, and that too few healthcare staff were getting vaccinated. While the requirements established by the staff vaccination IFC were necessary to protect the health and safety of residents at that time, circumstances of the COVID–19 pandemic evolved with the eventual lifting of the PHE. On June 5, 2023, we issued a final rule[134] that ultimately withdrew the requirements regarding development and implementation of policies and procedures to ensure COVID–19 vaccination of staff, noting that declining infection rates, deaths, and decreasing severity of disease were important reasons for withdrawing the healthcare staff COVID–19 vaccination provisions.

We find the same reasoning to be true when examining the necessity and appropriateness of the requirement that LTC facilities must educate staff about the COVID–19 vaccine, offer it to them, and document these actions. During the COVID–19 PHE, there was value in these requirements as we sought to protect vulnerable residents from the risks of infection with the COVID–19 virus through reduced transmission from facility staff members. We expect that, if finalized, eliminating the staff COVID–19 education requirements found at § 483.80(d)(3), would free up resources that LTC facilities could use to implement best practices for infection control and prevention.

We would retain the COVID–19 educate and offer requirements applicable to LTC facility residents currently codified at § 483.80(d)(3). This is consistent with the resident-specific immunization requirements at § 483.80(d) that are specific to influenza and pneumococcal immunizations that also apply to just residents and not staff.

To further streamline and simplify the documentation requirements for residents regarding COVID–19 immunization, we are proposing to align the regulatory text with the influenza and pneumococcal immunization requirements at § 483.80(d)(1) and (d)(2). Specifically, we are proposing to revise the language at § 483.80(d)(3). While the current requirement includes documentation in the resident's medical record of each individual dose of the COVID–19 vaccine, the proposed changes would consolidate documentation into two concise elements: education and immunization status. The proposed regulatory text for COVID–19 immunizations at 483.80(d)(3) would follow the sequence for influenza and pneumococcal immunizations at § 483.80(d)(1) and (d)(2). The regulation sequence starts with education regarding the benefits and potential side effects of immunization, offering the option to refuse immunization, and documentation requirements that fall into two categories, education provided and whether the resident received the immunization. This streamlined regulatory text should be familiar to providers. We are also proposing to remove the requirements at § 483.80(d)(3) for education regarding multi-dose vaccine series. We are proposing at § 483.80(d)(3)(i) to require education of vaccine requirements to be more flexible, as vaccines formulations can change over time. We are also proposing to revise the documentation requirements for immunization status to include that the resident was either immunized or not immunized. If the resident is not immunized, documentation would be required to indicate if this was due to medical contraindication or refusal.

Research demonstrates that LTC facility residents are highly susceptible to COVID–19 infection because of their age, comorbidities, and frailty.[135] Vaccination of residents in LTC facilities against respiratory diseases including influenza, pneumococcal disease, and COVID–19 is a simple, inexpensive, and effective means to reduce the burden of infection in this segment of the population.[136] In fall 2024 COVID–19 vaccination coverage among LTC facility residents, as reported to NHSN, was lower than coverage of community dwelling older adults, while influenza vaccination coverage among LTC facility residents was similar to that of the general adult population aged 65 years and older.[137] While LTC facility residents faced increased risks from these infections, their vaccination rates for RSV and COVID–19 lagged behind their community dwelling counterparts. This vaccination gap may reflect vaccination barriers in LTC facilities that have real consequences for resident health and safety. During each week of October 2024, approximately 5,500 LTC facility residents received a diagnosis of

[131] 86 FR 61555.

[132] 88 FR 53200.

[133] 86 FR 61555.

[134] 88 FR 36485.

[135] Nursing homes used unproven COVID measures and didn't use vaccines, antivirals enough, review finds. CIDRAP.

[136] *Gerontology* (2024) 70 (3): 241–247. *https://doi.org/10.1159/000534998.*

[137] Reses HE, Segovia G, Dubendris H, et al. Coverage with Influenza, Respiratory Syncytial Virus, and COVID–19 Vaccines Among Nursing Home Residents—National Healthcare Safety Network, United States, November 2024. MMWR Morb Mortal Wkly Rep 2024;73:1052–1057. DOI: *http://dx.doi.org/10.15585/mmwr.mm7346a2.*

COVID–19 and 360 were hospitalized after having received a positive COVID–19 test result.[138] During the 2023 to 2024 respiratory virus season, approximately one in six adults hospitalized with COVID–19 was a LTC facility resident, and their peak weekly hospitalization rate was approximately eight times the peak weekly rate of all U.S. adults aged 70 years and older.[139] CMS continues to believe that LTC residents have the right to be informed and exercise their right to self-determination by making informed decisions about the care they receive, and that LTC facilities should be required to facilitate informed decision making among residents and their representatives. Residents and their representatives would continue to have the right to refuse all offered vaccines. Additionally, LTC facilities would continue to be required to document information regarding the education and offering of the vaccine to each resident.

We note that while we are proposing to eliminate the staff COVID–19 educate and offer requirements, adherence to proper infection control guidelines, including current CMS infection control requirements, continues to be an effective strategy to prevent COVID–19 cases and deaths. For example, one study found that in nursing homes with higher adherence to CDC infection prevention guidelines, including hand hygiene, disinfection, PPE use, and screenings for symptoms and elevated temperature, there were lower incidences of COVID–19 vis-à-vis nursing homes with lower adherence.[140] A broader literature review found an association between proper mask use and proper donning of PPE and a lower prevalence of COVID–19 infections.[141] Another literature review centered on influenza in LTC facilities and the need for robust infection prevention and control practices to minimize outbreaks. Prevention and control of influenza in LTC facilities requires a multifaceted approach that includes infection prevention and control policies, strong managerial leadership, outbreak planning and a well-trained workforce.[142] Leading organizations, including the Society for Healthcare Epidemiology of America (SHEA) and the Association for Professional in Infection Control and Epidemiology (APIC) have also recently released updated guidelines for best practices related to infection prevention and control policies in nursing homes that are an important source of information to help providers protect vulnerable residents.[143] CMS recognizes these guidelines recommend that staff should receive recommended vaccinations or have documented evidence of immunity against vaccine-preventable diseases. Also, the guidelines recommend that LTC facilities should identify and implement multimodal interventions to increase vaccine acceptance by LTC facility staff.

We expect that eliminating the staff COVID–19 education requirements would help LTC facilities realign resource allocation to implement best practices for infection control and prevention. LTC facility residents are at risk for becoming infected with and experiencing complications from respiratory viruses, protecting residents against respiratory illness by continuing to educate and offer them vaccinations coupled with supporting their rights for informed choices will promote quality of life.

b. Proposal To Remove Ongoing Data Reporting Requirements (§ 483.80(g))

As part of regulatory review conducted in response to E.O. 14219 and E.O. 14192, CMS solicited and received interested parties' input through the 2025 deregulatory RFI.[144] Some comments focused on the ongoing acute respiratory illness data reporting requirement. Commenters stated that this provision is duplicative of State and local requirements, noting that these requirements—including reporting clusters of respiratory symptoms and confirmed cases to local public health agencies as required under infection control regulations, as well as data reported through the CMS Minimum Data Set (MDS)—already impose excessive burden on facilities through time consumed in, data collection, verification, and submission. Moreover, the reporting creates technical challenges operating reporting software. While we received comments noting similar concerns during the CY 2025 HH PPS final rule comment period, such concerns are common when implementing new regulations and at that time we believed that facilities could overcome these challenges and the data would be used to protect the health and safety of residents. Since the implementation of this final rule, facilities have reported continuing to struggle with data reporting to the extent that they are unable to comply.

Furthermore, based on feedback on the 2025 deregulatory RFI from providers and interested parties, we have come to understand that current expenditures related to ongoing data reporting are likely diverting staff from direct resident care.

Most notably, CMS estimates that maintaining the current reporting requirement would impose approximately $61 million in average annual costs and require over 600,000 average annual staff hours. We have not identified corresponding improvements in resident health or safety that would justify this burden. In brief, the ongoing cost and administrative burden to LTC facilities outweigh any demonstrated benefit.

The burden of data reporting includes labor costs associated with developing policies and procedures to report the required information, as well as costs associated with gathering, reviewing, and organizing the data used to compile the reported information. At this time, CMS does not believe that the benefits of ongoing data reporting outweigh the costs of complying with these requirements, and interested parties have requested removal of the existing requirements.

Given these considerations, CMS proposes to remove the ongoing reporting requirements currently found at § 483.80(g)(1) while retaining the authority to require specific reporting during a future Secretary declared PHE. This approach does not impose new costs, as PHE reporting requirements are already established in regulation. Preserving the Secretary's authority ensures the ability to require targeted reporting for emerging infectious diseases without additional rulemaking.

[138] Reses HE, Segovia G, Dubendris H, et al. Coverage with Influenza, Respiratory Syncytial Virus, and COVID–19 Vaccines Among Nursing Home Residents—National Healthcare Safety Network, United States, November 2024. MMWR Morb Mortal Wkly Rep 2024;73:1052–1057. DOI:

[139] Reses HE, Segovia G, Dubendris H, et al. Coverage with Influenza, Respiratory Syncytial Virus, and COVID–19 Vaccines Among Nursing Home Residents—National Healthcare Safety Network, United States, November 2024. MMWR Morb Mortal Wkly Rep 2024;73:1052–1057. DOI:

[140] Telford, Carson T et al. ''COVID–19 Infection Prevention and Control Adherence in Long-Term Care Facilities, Atlanta, Georgia.'' *Journal of the American Geriatrics Society* vol. 69,3 (2021): 581–586. doi:10.1111/jgs.17001.

[141] Henriques, H.R., Sousa, D., Faria, J. *et al.* Learning from the covid-19 outbreaks in long-term care facilities: a systematic review. *BMC Geriatr* 23, 618 (2023). *https://doi.org/10.1186/s12877-023-04319-w.*

[142] Lansbury LE, Brown CS, Nguyen-Van-Tam JS. Influenza in long-term care facilities. Influenza Other Respir Viruses. 2017 Sep;11(5):356–366. doi: 10.1111/irv.12464. Epub 2017 Jul 26. PMID: 28691237; PMCID: PMC5596516.

[143] Mody L, Advani SD, Ashraf MS, et al. Multisociety guidance for infection prevention and control in nursing homes. *Infection Control & Hospital Epidemiology.* 2025;46(11):1069–1096. doi:10.1017/ice.2025.10252.

[144] ''Medicare Regulatory Relief | CMS.'' *Cms.gov,* 2025, *https://www.cms.gov/files/document/unleashing-prosperity-through-deregulation-medicare-program-request-information.pdf.* Accessed September 2025.

Infection prevention and control is a primary goal and responsibility of facilities in their normal day-to-day operations. While we propose to remove both the requirements for educating staff about the COVID–19 vaccine and offering it to them and the requirements for ongoing data reporting related to respiratory illnesses from the LTC infection prevention and control requirements, the remaining infection control requirements would continue to remain in effect. Sections 1819(d)(3) and 1919(d)(3) the Act explicitly require LTC facilities to develop and maintain an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public. Existing requirements for LTC facilities at § 483.80 require facilities to establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. This program must include, among other things, an antibiotic stewardship program with antibiotic use protocols and a system to monitor antibiotic use and at least one designated infection preventionist, who is responsible for the facility's infection prevention and control programs. Specifically, the infection control officer(s) are required to develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of residents and personnel. Furthermore, § 483.71 requires that LTC facilities conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations (including nights and weekends) and emergencies. This includes determining the infection prevention and control needs in their facility. In addition, issues identified in the all-facilities' infection prevention and control programs must be addressed in facility-wide QAPI programs (§ 483.75). All of these requirements would remain in place if CMS were to finalize the proposed removal of the ongoing data reporting requirement to ensure patient health and safety. As such, we believe that there would be adequate minimum infection prevention and control practices in the absence of the ongoing respiratory illness data reporting requirements and staff COVID–19 vaccination requirements.

In addition to complying with the robust LTC facility requirements, facilities may have other measures in place to address infectious disease outbreaks in response to State and local governments laws. For example, some States may have regulations for communicating information to local public health agencies. We believe that these ongoing requirements provide the necessary protection for residents from infections within the LTC environment. We understand that data from healthcare providers remain a key driver to identify and respond to resident needs and public health threats.

The CDC has continued to refine data collection and promote electronic data collection directly from electronic health records, like fast healthcare interoperability resources (FHIR) enabled data reporting from hospitals. These activities help to reduce voluntary reporting burden and build a foundation for conducting surveillance in all clinical settings that may incentivize LTC facilities to voluntarily report data. We encourage LTC facilities to continue submitting data to the NHSN on an ongoing basis to contribute to greater public health efforts.

We also remind LTC facilities that, while we are proposing to remove the ongoing acute respiratory illness data reporting, we are proposing to retain the requirements for facilities to report specified acute infectious illness data during a declared PHE, in the standardized format and frequency specified by the Secretary, as currently required at § 483.80(g)(2). During the comment period for the CY 2025 PPS/HH final rule, healthcare facilities and interested parties noted that the value of data reporting during a PHE outweighed the administrative burden. During a PHE, insight into facility capacity helps to ensure capabilities are available to meet patient needs with quality care through enhanced planning, technical assistance, resource allocation, and coordination. Retaining the current PHE data reporting requirements enables facilities to maintain a functional reporting capacity. This data can be used to inform and guide response efforts at the local, State, and Federal levels to protect residents and their communities, including resource allocation and load balancing within and across facilities during emergencies when system capacity is most critical.

We propose to modify the current regulations for acute infectious illness data reporting during a PHE for LTC facilities because some of the necessary data elements are listed within the ongoing data reporting section that we propose to remove. All of the elements that we propose to include in the data reporting requirements during a PHE are already required by the current regulations for ongoing reporting and would provide a response-ready foundation for LTC facilities and the broader health system.

The proposed regulatory revisions would retain the Secretary's authority to require reporting during a declared PHE, without naming the yet-unknown infectious disease pathogen(s), while reducing the overall burden on facilities. This approach provides CMS with the flexibility to respond to a broad range of future public health threats without the need for additional rulemaking, while imposing reporting obligations for only those circumstances necessary to protect patient health and safety. Specifically, we propose to retain requirements that LTC facilities must report (1) facility census (currently § 483.80(g)(1)(ii)(A)); (2) confirmed, resident cases (currently § 483.80(g)(1)(ii)(C)); (3) hospitalized residents with confirmed cases (currently § 483.80(g)(1)(ii)(D)); (4) confirmed infections for staff (currently § 483.80 (g)(2)(i)); (5) supply inventory shortages (currently § 483.80 (g)(2)(ii)); (6) staffing shortages (currently § 483.80 (g)(2)(iii)); and (7) medical countermeasures and therapeutic inventories (currently § 483.80 (g)(2)(iv)) during a PHE. We are proposing to rescind the reporting of resident vaccination status (currently § 483.80(g)(1)(ii)(B)).

To facilitate LTC facility compliance with the proposed data reporting requirements during a PHE, the Secretary would provide clear, standardized definitions for any data to be reported, as well as instructions for the effective reporting date. HHS would provide notification to LTC facility to activate PHE reporting and indicate the frequency and required elements based on the specific circumstances at the time. We expect that we would use existing communication mechanism, such a Quality Safety and Oversight (QSO) Memorandum, that is readily available to the public, nationally accessible, and familiar to interested parties, to ensure clarity and access to necessary information.

We invite public comment on these proposals, and on any alternatives to our approach. Also, we are interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions. We also request comments on how to reduce burden related to capturing

information related to supply inventory shortages, staffing shortages, and medical countermeasures and therapeutic inventories.

4. Revisions to Existing LTC Facilities' Resident Room Occupancy and Bathroom Facility Requirements § 483.90(e)(1)(i) and (f)

LTC facilities newly certified after November 28, 2016, must meet the current resident occupancy and bathroom facility standards—specifically, the requirements to accommodate no more than two residents per bedroom and to provide each resident room with its own bathroom equipped with a commode and sink. These requirements can create significant barriers for new providers seeking to take over operations and re-open a facility, as large-scale renovations—particularly for older buildings—may be required to comply with these standards. Such renovations may create significant financial challenges, potentially deterring new providers from re-opening facilities, particularly in areas that already have limited access to long-term care services. To address these concerns and reduce barriers related to the certification of new providers, we propose to amend resident room occupancy (proposed to be redesignated as § 483.90(d)(1)(i)) and bathroom facility standards (proposed to be redesignated as § 483.90(e)), both of which set standards for ''newly certified'' facilities. We propose to remove the term ''newly certified ''from the resident room occupancy and bathroom facility standards, thereby eliminating certification status as the trigger for compliance with the requirements to accommodate no more than two residents per bedroom and to provide each resident room with its own bathroom equipped with a commode and sink.

Specifically, we propose that for facilities that receive approval of building construction and reconstruction plans by the State and local authorities after November 28, 2016, each bedroom must accommodate no more than two residents per room. We also propose that for facilities that receive approval of building construction plans by the State and local authorities after November 28, 2016, each resident room must be provided with its own bathroom with at least a commode and sink.

This change would exempt existing facilities from being required to meet the current room occupancy (no more than two residents per room) and bathroom standards (commode and sink per room) because the facility changed ownership or experienced a gap in operations. Even with this exemption, LTC facilities must still comply with the CoPs, which are intended to protect the health and safety of residents and ensure that high-quality care is provided to all residents. LTC facilities must also comply with Title III of the Americans with Disabilities Act (ADA), which prohibits discrimination based on disability in public accommodations and commercial facilities, and requires businesses and non-profit service providers to ensure equal access to their goods, services, and facilities. In addition, sections 1819(b)(1)(A) and 1919(b)(1)(A) of the Act explicitly require Medicare and Medicaid LTC facilities to care for their residents in a manner and environment that promotes the maintenance or enhancement of the safety and quality of life of each resident. We invite public comment on these proposals, and on any alternatives to our approach as well as the risks and potential unintended consequences.

5. Additional LTC Comment Solicitation

We are seeking public comments related to information regarding resident preferences on sending discharge notice to the State Ombudsman office, specifically when the discharge is initiated by the resident or resident's representative. Second, we are seeking information regarding expanding the scope of practice of physician assistants and nurse practitioners providing care in SNFs, especially as it pertains to performing visits currently required to be made by a physician.

a. Ombudsman Notice of Discharge Opt Out

The current requirement at § 483.15(c)(3)(i) requires that LTC facilities provide a notice of transfer or discharge prior to transferring or discharging a resident. Facilities must notify the resident and the resident representative(s), in writing and in a language and manner they understand, of the transfer or discharge and the reasons for the move. Facilities are also required to send a copy of this notice to a representative of the Office of the State Long-Term Care Ombudsman. The regulation specifies both the timing of the notice and the required content.

As part of safeguarding resident rights, LTC facilities must notify the State Ombudsman office of all resident discharges and transfers. As previously discussed, several interested parties have indicated that this requirement results in a significant volume of paperwork for facilities to generate and distribute, as well as a substantial administrative workload for Ombudsman offices to receive and review these notices. Based on recent input from interested parties, we are seeking comments on whether residents should be permitted to opt out of having their discharge notice sent to the Ombudsman, and the facility must document the resident's preference in the medical record. We believe that residents and resident representatives that initiate a transfer or discharge may not need or want review of their decisions by Ombudsman officials. This option could increase resident self-determination and privacy, decrease paperwork for LTC facilities, and reduce the number of notices received by Ombudsman offices, while maintaining existing notice requirements for residents and their representatives. In consideration of this idea, we request public comments on the following questions:

- What types of communications occur between LTC facilities and the Ombudsman office for discharges and how is the notice process currently managed?
- What types of training or guidance would LTC facility staff need to properly explain the opt-out option to residents and resident representatives?
- How would LTC facilities document for surveyors to verify that a discharge was initiated by a resident or the resident's representative?
- Are there any unintended consequences to opting out of discharge notices being sent to the Ombudsman? For example, how would LTC facilities ensure that residents understand their rights in relation to notifying the Ombudsman office of their discharge prior to opting out of having a notice sent?

b. Comment Solicitation on Expanding the Scope of Practice of Physician Assistants and Nurse Practitioners

According to the U.S. Census Bureau,[145] the number of Americans over 65 is expected to nearly double, jumping from 54 million in 2019 to 95 million by 2060. With an aging population, we expect an increasing demand for skilled nursing care, and we are aware of concerns regarding access to skilled nursing care and long wait times for admission to LTC facilities. Nearly every nursing home and assisted living community in the United State are facing workforce shortages.[146] The

[145] *https://www.census.gov/topics/population/older-aging.html.*

[146] State of the Long-Term Care Industry. American Health Care Association. National Cetner for Assisted Living. September 2021. Accessed February 2026. *https://www.ahcancal.org/News-*

number of board-certified geriatricians in the US fell from 10,270 in 2000 to 7,413 in 2022;[147] this drop has been further exacerbated by recruitment and retention challenges for specialists involved in geriatrics—the geriatricians, nurses, and home health aides— which face considerable excess demand relative to supply.[148]

In certain cases, Federal statute limits our ability to make changes through regulation. For SNFs, the Act defines a licensed health professional[149] as ''a physician, physician assistant, nurse practitioner, physical, speech, or occupational therapist, physical or occupational therapy assistant, registered professional nurse, licensed practical nurse, or licensed certified social worker, registered respiratory therapist, or certified respiratory therapy technician''. However, the Act also requires that the care of every resident be provided under the supervision of a physician.[150] For Medicaid NFs, the Act allows, at the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) to also be satisfied when supervised by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.[151] We note that the Act does not allow for this delegation in SNFs.

The current regulations at § 483.20(a), ''Resident assessment,'' requires physician's orders for the resident's immediate care. The physician is solely responsible for certifying the need for skilled care. Section 483.30, ''Physician services,'' requires that the initial comprehensive visit in a SNF must be performed by a physician. At the option of the physician, required visits in SNFs after the initial visit may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner, or clinical nurse specialist. Section 483.30(e)(1) through (4), ''Physician delegation of tasks in SNFs,'' lists details of what can be delegated, such as allowing dietary orders and therapy orders to be issued by these professionals with various qualifiers. Section 483.30(f) lists the requirements for performance of physician tasks in NFs. There is a notable difference in what is allowed in Federal regulations regarding physician services for SNFs and NFs. We are requesting comments on expanding the scope of practice of physician assistants and nurse practitioners in SNFs, within our current statutory limitations. Specifically, we request public comments on the following:

- Factors that influence access to care issues for admissions to SNFs.
- The roles that physician assistants and nurse practitioners currently fill and the potential for their use in addressing the identified factors influencing SNF resident access to care.
- Specific examples of collaboration between nursing home physicians and physician assistants and nurse practitioners, and the measurable impact on residents' health outcomes and safety. The roles of physician assistants and nurse practitioners in performing SNF visits following the initial visit by a physician.
- Information about the preferences of residents and their representatives regarding the type of clinician that provides care, such as a physician, physician assistant or nurse practitioner.

Current State and local restrictions that may affect a facility's ability to implement any new flexibilities regarding physician assistant and nurse practitioner services in LTC facilities, and how these restrictions impact resident care quality and access.

C. Intermediate Care Facilities for Individuals With Intellectual Disabilities

Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID) are institutions with four or more beds that serve people with intellectual disabilities or other related conditions. As of January 2026, there are 5,215 ICFs/IID with 55,321 beds.[152] Under section 1902 of the Act, ICFs/IID seeking to be Medicaid providers of services must enter into an agreement with the State Medicaid agency. They must also be certified as meeting federal participation requirements set forth at 42 CFR part 483, subpart I. The CoPs set out the client health and safety protections established by the Secretary, as authorized by § 1905(d)(1) of the Act.

1. Proposal To Remove Staff COVID–19 Vaccine Educate and Offer Requirements (§ 483.460(a)(4)(i) and (ii)))

The COVID–19 PHE placed unprecedented strain on the Nation's healthcare system, including ICFs/IID, which faced severe staffing shortages and limited access to PPE and necessary supplies for infection prevention and control. In ICFs/IID, clients often live in close quarters, and some may not understand the dangers of the virus or be able to independently comply with mitigation measures. Those who need help with activities of daily living may not have been able to maintain their distance from staff and caregivers. During the PHE some facilities struggled to retain staff and some staff working in these facilities may also have had more than one job, putting them at higher risk.[153]

Protecting ICF/IID clients under these conditions required enhanced infection control measures to decrease the spread and impact of infectious diseases within these settings. On May 13, 2021, CMS published an IFC,[154] which revised the health and safety requirements that ICFs/IID must meet to participate in the state Medicaid programs. The IFC established standards at § 483.460 that required ICFs/IID to provide COVID–19 vaccination education to staff and offer COVID–19 vaccines to staff, referred to as the ''educate and offer'' provisions (86 FR 26317 to 26318). The IFC also established similar requirements related to educating and offering COVID–19 vaccinations to clients (86 FR 26318 to 26319).

Building upon the requirement that ICFs/IID must educate their staffs about the COVID–19 vaccine and offer it to them, on November 5, 2021, we published additional COVID–19 staff vaccination requirements in an IFC titled ''Medicare and Medicaid Programs; Omnibus COVID–19 Health Care Staff Vaccination,'' [155] otherwise known as the ''staff vaccination IFC.'' This IFC revised the requirements that most Medicare and Medicaid-certified providers and suppliers were required to meet to participate in the Medicare and Medicaid programs to include requirements regarding development and implementation of policies and

and-Communications/Press-Releases/Pages/Survey-Nearly-Every-U-S--Nursing-Home-And-Assisted-Living-Community-Is-Facing-A-Workforce-Crisis.aspx.

[147] Gurwitz JH. The Paradoxical Decline of Geriatric Medicine as a Profession. JAMA. 2023;330(8):693–694. doi:10.1001/jama.2023.11110.

[148] Katherine E.M. Miller, Chase Mulholland Green, Abigail Fassinger, Jennifer L. Wolff. 2025. Long-Term Care Services and Supports Needed for Successful Aging-in-Place: A Critical Review. *Annual Review Public Health*. 46:487–505. *https://doi.org/10.1146/annurev-publhealth-071823-113604.*

[149] Section 1819 (b)(5)(G) [42 U.S.C. 1395i–3].

[150] Section 1819(b)(6).

[151] Section 1919(b)(6).

[152] Centers for Medicare & Medicaid Services. Quality, Certification and Oversight Reports (QCOR), Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) Provider Reports, Active Provider and Supplier Counts Report, FY 2025. Accessed February 2, 2026. *https://qcor.cms.gov/main.jsp.*

[153] Centers for Medicare & Medicaid Services. ''Medicaid Home | Medicaid.gov.'' *Medicaid.gov,* 22 March 2019, *www.medicaid.gov/.*

[154] 86 FR 26306.

[155] 86 FR 61555.

procedures to ensure COVID–19 vaccination of staff. The previous IFC was aimed at achieving widespread vaccination among ICF/IID staff to protect clients; this IFC required ICFs/IID to establish and implement policies and procedures for COVID–19 vaccination of all staff, including employees; licensed practitioners; students, trainees, and volunteers; and other individuals who provide care, treatment, or other services for the ICF/IID or its clients.

At that time evidence demonstrated unvaccinated healthcare staff presented risks to patient safety across healthcare settings, and that too few healthcare staff were getting vaccinated to reduce those risks. While the requirements established by the staff vaccination IFC were necessary to protect the health and safety of ICF/IID clients at that time, circumstances of the COVID–19 pandemic evolved with the eventual lifting of the PHE.

On June 5, 2023, CMS issued a final rule [156] that, among other things, withdrew the COVID–19 staff vaccination mandate.[157] In this final rule [158] CMS noted declining infection rates and deaths, declining severity, and significant vaccination uptake as important reasons for withdrawing the healthcare staff COVID–19 vaccination provisions.

We find the same reasoning of declining rates, deaths, and severity when examining the necessity and appropriateness of the requirement established that ICFs/IID must educate staff about the COVID–19 vaccine and offer it to them (§ 483.460(a)(4)(i) and (ii)). During the COVID–19 PHE there was value in these requirements as we sought to protect vulnerable clients from the risks of infection with the COVID–19 virus through reduced transmission from facility staff members who dwell in the community and had the potential to contract COVID–19 and spread the infection to vulnerable ICF/IID clients. In light of the declining infection rates and deaths, declining severity, and vaccination uptake that provides a base level of protection, we find that this regulatory focus on staff vaccination for COVID–19 is no longer needed and propose to remove these requirements.

We note that while we are proposing to eliminate the staff COVID–19 education and offer requirements, we would retain the requirements related to continued education and offering of the COVID–19 vaccinations to clients and their representatives, supporting their right to make informed choices and promoting overall quality of life for clients. We would also retain the requirements related to infection control, including providing a sanitary environment, and prohibiting staff that have symptoms or signs of a communicable disease from direct contact with clients and their food. Adherence to proper infection control guidelines, including current CMS infection control requirements, continues to be an effective strategy to prevent COVID–19 cases and deaths. ICF/IID clients continue to be at increased risk of infection and complications from respiratory viruses. For example, one study found that in nursing homes with higher adherence to CDC infection prevention guidelines, including hand hygiene, disinfection, PPE use, and screenings for symptoms and elevated temperature, there were lower incidences of infection with COVID–19 compared to nursing homes with lower adherence. While the study focused on nursing homes, we find it applicable to ICFs/IID in that both share strong similarities as communal living environments with shared dining and activity spaces that facilitate person -to-person spread of infectious diseases, shared ventilation systems for spread of airborne disease, and vulnerable populations for whom the risk of disease may be magnified due to comorbidities. A broader literature review found an association between proper mask use and proper donning of PPE and a lower prevalence of COVID–19 infections. Leading organizations, including the Society for Healthcare Epidemiology of America (SHEA) and the Association for Professionals in Infection Control and Epidemiology (APIC) have also recently released updated guidelines for best practices related to infection prevention and control policies in nursing homes that are an important source of information to help providers protect vulnerable residents and, by extension, vulnerable ICF/IID clients. CMS recognizes these guidelines recommend that healthcare personnel should receive recommended vaccinations or have documented evidence of immunity against vaccine-preventable diseases. Also, the guidelines recommend identifying and implementing multimodal interventions to increase vaccine acceptance by healthcare personnel.

We expect eliminating the staff COVID–19 offer and educate requirements may free up resources that ICFs/IID can use to implement best practices for infection control and prevention. Furthermore, resources will also be made available so that staff can focus more directly on clients for things like assisting with activities of daily living, engaging clients in activities, and delivering care and services in accordance with the medical care plan, if applicable.

Though research demonstrates that ICF/IID clients are highly susceptible to COVID–19 infection because of their comorbidities and close living quarters,[159] the emergency circumstances which occasioned the staff vaccination education provisions no longer exist. However, it is important that the client and the client's representative receive information necessary to make healthcare decisions, including clear information on the benefits and risks of the vaccine. Because individuals in ICFs/IID face a heightened risk of COVID–19 due to comorbidities, close living arrangements, and functional impairments, prevention and coping strategies must account for these limitations. Physical distancing and masking may be difficult for non-ambulatory clients or those with behavioral challenges, making vaccination the most effective protection. Educating clients and their representatives about vaccine benefits and safety is essential to informed decision-making. Offering vaccines to clients directly within facilities addresses mobility barriers and ensures timely access, reducing the risk of severe illness and outbreaks. Clients and their representatives would continue to have the right to refuse the vaccine.

To further streamline and simplify the documentation requirements for clients regarding COVID–19 immunization, we are also proposing to streamline and simplify the regulatory text at § 483.460(a)(4). Specifically, we are proposing to revise the regulatory language at § 483.460(a)(4)(i)–(vi). This revision would streamline the existing six standards into four, with the resulting provisions renumbered as § 483.460(a)(4)(i) through (iv). While the current requirement includes documentation in the client's medical record of each individual dose of the COVID–19 vaccine, the proposed changes would consolidate documentation into two concise elements: education and immunization status. We are proposing to revise the documentation requirements for immunization status to include that the client was either immunized or not

[156] 88 FR 36485.

[157] 86 FR 61555.

[158] 88 FR 36503.

[159] Musumeci M. and Chidambaram P. ''COVID–19 Vaccine Access for People with Disabilities.'' *KFF*. Published March 1, 2021. Accessed February 12, 2026. *https://www.kff.org/medicaid/covid-19-vaccine-access-for-people-with-disabilities/*.

immunized. If the client is not immunized, documentation would be required to indicate if this was due to medical contraindication or refusal.

We invite public comment on the proposed revision of § 483.460(a)(4), and on any alternatives to our approach. Also, we are interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

D. Rural Emergency Hospitals (REHs)

REHs are a Medicare provider type established in the Consolidated Appropriations Act, 2021 (CAA, 2021; Pub. L. 116–260, Dec. 27, 2020) to address barriers in access to healthcare, particularly emergency services, that result from rural hospital closures. REHs are former CAHs or rural hospitals with not more than 50 beds and do not provide any acute care inpatient services. Rather, they are required to furnish emergency department and observation care through a staffed emergency department 24 hours a day, 7 days a week. They may also provide other specified outpatient medical and health services, as elected by the REH. The average annual length of stay across all services per patient may not exceed 24 hours. As of April 2026, there are 51 currently operating REHs.[160]

Under sections 1866 and 1902 of the Act, REHs seeking to participate in the Medicare program, must enter into an agreement with the Secretary. REHs seeking to be Medicare providers of services must be certified as meeting Federal participation requirements set forth at 42 CFR part 485, subpart E. The Secretary established these CoPs to ensure the health and safety of patients receiving services furnished by an REH under the specific statutory authority set forth in section 1861(kkk) of the Act. Section 1861(kkk)(2)(D)(v) of the Act authorizes the Secretary to issue any regulations necessary to protect the health and safety of patients receiving services at REHs. On November 23, 2022, CMS published a final rule in the **Federal Register** titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19,'' [161] henceforth referred to as ''CY 2022 OPPS/ASC final rule'' which established CoPs for REHs at part 485 subpart E. We propose to revise the existing REH requirements by making technical changes to update outdated information and removing regulatory provisions that implement Federal requirements that are no longer in effect.

1. Technical Change of Cross-Reference at § 485.516(c)(5)

As part of the REH CoPs for emergency services (§ 485.516), we require these facilities to be in compliance with specific CAH Requirements at § 485.618. In 2024, CMS published a final rule that revised the regulations for CAHs [162] and, in doing so, changed the numbering of the section that is referred to in § 485.516(c) of the CoPs for REHs. Specifically, we finalized a new standard entitled ''Emergency Services Readiness'' (89 FR 94488) within the existing Emergency Services CoP for CAHs (§ 485.618(e)) to set clear expectations as well as improve facility readiness in caring for emergency services patients, including pregnant, birthing, and postpartum patients. When placing these regulations in the Code of Federal Regulations, we redesignated § 485.618(e) as (f) and added a new paragraph (e). However, REH regulations at § 485.516(c)(5) contain a cross reference to § 485.618(e), and that cross-reference was not updated when the previous content of § 485.618(e) was redesignated as § 485.618(f). Originally, this cross reference correctly referred to CAH standard for coordination with emergency response systems. With the 2024 CAH regulatory update, it now refers to the standard on emergency service readiness, and this reference is not accurate or appropriate. We propose to correct the cross reference at § 485.516(c)(5) to update the citation from § 485.618(e) to (f), which is where the CAH coordination with emergency response systems requirement is now located.

2. Infection Prevention and Control and Antibiotic Stewardship Programs

During the COVID–19 PHE, CMS, in consultation with the CDC, issued an evolving series of requirements to obtain data through several interim final rules with comment period to understand epidemiological trends. The COVID–19 PHE placed unprecedented strain on the Nation's healthcare system, particularly REHs, which faced severe staffing shortages and limited access to PPE and critical supplies. Protecting patients under these conditions required enhanced visibility into the spread and impact of infectious diseases within these settings. To address this need, CMS, issued infection prevention and control requirements during the PHE to establish data reporting, testing, vaccination, and infection control requirements for Medicare and Medicaid suppliers. The data informed coordination of operations and was especially important to anticipate and prepare for surge conditions. In the 2022 Final Rule, ''Medicare Program; Hospital Outpatient Prospective Payment'' (87 FR 71748, 72293, November 23, 2022), we finalized data reporting requirements within the infection control and prevention requirements for REHs that were similar to the data reporting requirements for hospitals and CAHs at that time at 42 CFR 485.526(e).

a. Proposal To Remove COVID–19 Sunset Requirements (§ 485.526(e) and (g))

The CY 2022 OPPS/ASC final rule requires REHs to electronically report information about COVID–19 and seasonal influenza in a standardized format specified by the Secretary, including the REH's current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the REH and the current usage rate for those therapeutics beginning at the conclusion of the COVID–19 PHE (at § 485.526(e)).

Section 485.526(e) provides that ongoing data reporting requirements would be in effect through April 30, 2024, unless the Secretary specified an earlier end date. Because this reporting requirement has now expired, we propose removing §485.526(e) from the REH CoPs. Additionally, in the CY 2022

[160] *https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/hospital-enrollments/data?query=%7B%22filters%22%3A%7B%22list%22%3A%5B%7B%22conditions%22%3A%5B%7B%22column%22%3A%7B%22value%22%3A%22PROVIDER+TYPE+TEXT%22%7D%2C%22comparator%22%3A%7B%22value%22%3A%22%3D%22%7D%2C%22filterValue%22%3A%5B%22PART+A+PROVIDER+-+RURAL+EMERGENCY+HOSPITAL+%28REH%29%22%5D%7D%5D%7D%5D%2C%22rootConjunction%22%3A%7B%22value%22%3A%22AND%22%7D%7D%2C%22keywords%22%3A%22%22%2C%22offset%22%3A0%2C%22limit%22%3A10%2C%22sort%22%3A%7B%22sortBy%22%3A%22PROVIDER+TYPE+TEXT%22%2C%22sortOrder%22%3A%22DESC%22%7D%2C%22columns%22%3A%5B%5D%7D* Cecil G. Sheps Center for Health Services Research The University of North Carolina at Chapel Hill. Accessed May 2026.

[161] 87 FR 71748.

[162] 89 FR 93921.

OPPS/ASC final rule, CMS included a COVID–19 staff vaccination requirement in the REH infection prevention and control and antibiotic stewardship program CoP, set forth at § 485.526(g). Until November 4, 2024, REHs were required to develop and implement policies and procedures to ensure that all non-exempt staff were fully vaccinated against COVID–19. Effective November 4, 2024, this vaccination requirement expired. Accordingly, because REHs are no longer required to meet this standard, we are proposing to remove § 485.526(g) relating to the COVID–19 healthcare staff vaccination requirements.

Although we are proposing to remove these expired requirements from the regulations, the prevention and control of infections remain primary goals in REHs and are the responsibility of facilities in their normal day-to-day operations. The current required infection prevention and control program, as described at § 485.526, includes general infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions which must adhere to nationally recognized guidelines. In addition to complying with the robust REH infection prevention and control CoP requirements, facilities may have other measures in place to address infectious disease outbreaks in response to AOs accreditation standards, as well as state and local governments laws.

b. Proposal To Remove REH Data Reporting Requirements During a PHE (§ 485.526(f))

REHs are currently required to report data related to acute respiratory illness and other viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential under a Secretary-declared PHE (§ 485.526(f)). The REH PHE data reporting requirements became effective January 1, 2023, and at this time, exceed the requirements for hospitals and CAHs for certain data elements.[163] Under § 485.526(f)(1), REHs are required to report suspected infections, total deaths attributed to the PHE, vaccine administration data, and key co-morbidities or exposure risk factors related to the disease of interest, which is not currently required for hospitals or CAHs. The data elements for REHs also have a more detailed format than hospitals or CAHs. Specifically, our provisions at § 485.526(f)(2)) require REHs to provide person-level information, including medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients.

The REH designation was created to address concerns about rural hospital closures by giving facilities an option to continue providing emergency and outpatient services without having to maintain inpatient beds. These facilities typically employ a limited staff as they were primarily intended to provide rural areas with emergency services for stabilization and transfer with minimal administrative load. We believe the requirements for data reporting during a PHE are overly burdensome for REHs. Therefore, we propose to remove the data reporting requirements for REHs during a PHE found at § 485.526(f).

We note that we are retaining the requirement for hospitals and CAHs to report data on infectious illnesses during a PHE. As a result, when a patient is stabilized at an REH and subsequently transferred to a hospital or CAH, that patient's relevant data would be captured in the receiving facility's reporting.

We invite public comment on this proposal and on any alternatives to our approach. Also, we are interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

3. Proposed Revisions to Physical Environment and Emergency Preparedness Incorporation by Reference (§§ 485.542(g) & 485.544(e))

In the CY 2022 OPPS/ASC final rule (87 FR 72202), the physical environment and emergency preparedness CoPs each include a standard in which CMS incorporated by reference three National Fire Protection Association (NFPA) codes. These requirements, codified at §§485.542(g) and 485.544(e), outline procedures for enforcing updated editions and provide contact information for accessing materials through CMS and the National Archives and Records Administration (NARA). However, the listed CMS contact is no longer current. We propose to remove the outdated CMS contact information and update the NARA contact information for access to the incorporated materials. We would state that the materials incorporated by reference are available for inspection at CMS, located at 7500 Security Boulevard, Baltimore, MD 21244.

We invite public comment on these proposals, and on any alternatives to our approach. Also, we are interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations or offer particular additions.

E. Critical Access Hospitals (CAHs)

A CAH is a Medicare-certified hospital that meets specified criteria required for designation as a CAH by CMS. CAHs were established as a provider-type to help ensure access to health care services in rural communities. The statutory authority for CAHs is set forth in section 1820(e) of the Act and includes statutory authority for the Secretary to issue such criteria as required at section 1820(e)(3) of the Act. Under sections 1866 and 1902 of the Act, CAHs seeking to participate in the Medicare or Medicaid program, respectively, or both, must enter into an agreement with the Secretary or the State Medicaid agency, as appropriate. CAHs seeking to be Medicare and Medicaid providers of services must be certified as meeting Federal participation requirements as set forth at 42 CFR part 485, subpart F. Our CoPs set out the patient health and safety protections established by the Secretary for various types of providers and suppliers.

In accordance with section 1864 of the Act, State surveyors assess CAH compliance with the CoPs as part of the process of determining whether a CAH qualifies for a provider agreement under Medicare. However, under section 1865 of the Act, CAHs can elect to be reviewed instead by private accrediting organizations approved by CMS as having standards that meet or exceed the applicable Medicare standards and survey procedures comparable to those CMS requires for State survey agencies.

Under section 1820(c)(2)(B)(iii) of the Act, as implemented in our regulations at § 485.620(a), a CAH can have no more than 25 beds that may be used for acute care inpatient services or swing-bed services (post-hospital skilled nursing care), except as permitted for CAHs having distinct part units under § 485.647, in which case, beds in the distinct part unit are excluded from the 25-bed limit specified in § 485.620(a). Section 1820(c) of the Act also requires that CAHs be located in a State that has established a Medicare Rural Hospital Flexibility Program and generally must be more than a 35-mile drive on primary

[163] 89 FR 68986.

roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH. If prior to January 1, 2006, a facility was designated by the State as a ''necessary provider'' of health care services to residents in the area, the facility is exempt from the distance requirements relative to hospitals and other CAHs that are otherwise applicable to CAHs under § 485.610(c). CAHs must provide emergency care services 24 hours a day, 7 days a week and maintain an average annual length of stay of 96 hours or less. They may be granted approval to provide ''swing bed'' post-hospital skilled nursing care, may provide inpatient care to individuals under the care of a hospice, and may operate a psychiatric and/or rehabilitation distinct part unit of up to 10 beds each. CAHs may operate as independent institutions or as part of a larger health care system. As of January 2026, there were approximately 1,400 CAHs.[164]

1. Proposals To Amend Certain Status and Location Requirements (§ 485.610(c) and (e))

Section 1820(c)(2)(B)(i)(I) of the Act, codified into the CoPs at § 485.610(c)(1), requires that a CAH be located more than a 35-mile drive (or a 15-mile drive on secondary roads or mountainous terrain) from a hospital or another CAH. Section 4201 of the Balanced Budget Act of 1997 (Pub. L. 105–33) established the CAH designation to help reduce the financial risks faced by rural hospitals and to improve health care access in rural areas. CAHs are acute care facilities that provide outpatient, emergency, and limited inpatient services in communities that cannot support a full-service hospital. To achieve this, Medicare reimburses CAHs a reasonable cost-based reimbursement for their services. Under section 1820(c)(2)(B) of the Act, CAHs must meet location-related requirements that aim to limit designation to facilities serving geographically isolated communities and support appropriate distribution of hospital services. In addition, 1820(c)(2)(E) of the Act authorizes CAHs to establish psychiatric and rehabilitation units as distinct parts of the CAH.

Since 2004, the Medicare program requires hospitals seeking CAH designation to be located more than 35 miles from the nearest similar hospital.[165] However, the regulatory text at § 485.610(c) did not specify which types of hospitals are relevant to that distance determination, resulting in uncertainty regarding the application of this requirement. In 2013, the HHS Office of Inspector General (OIG) released a report entitled ''Most Critical Access Hospitals Would Not Meet the Location Requirements If Required to Re-Enroll in Medicare'' (OEI–05–12–00080),[166] which found that approximately 64 percent of CAHs would not meet the distance requirement if they were required to re-enroll in Medicare. The report also found that CMS may not have the authority to revoke the CAH designation from most of these facilities based on failure to meet the distance requirement, as a majority of these CAHs are designated as ''necessary providers'' and are therefore exempt from the distance requirement as noted in section 1820(h)(3) of the Act. The OIG report also recommended that CMS periodically reassess CAHs for compliance with the location-related CoPs. In response, CMS began evaluating its policies concerning the definitions of several key concepts used in enforcing the CAH regulations at § 485.610, including which types of hospitals should be considered when determining whether a hospital applying for CAH status has met the applicable distance requirement under § 485.610(c)(1) and (e)(2), as the regulation does not specify which hospital types are relevant to that determination. Following this evaluation, CMS published a Survey and Certification letter on February 12, 2016 (S&C–16–08–CAH),[167] which was later revised on September 2, 2016, clarifying that distance eligibility determinations must be based on the proximity of the nearest hospital furnishing comparable acute care services, and that psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals (LTCHs) would not considered ''like hospitals'' for the purpose of determining CAH eligibility. CMS has since expired S&C–16–08–CAH and replaced it with QSO–26–15–CAH, ''Critical Access Hospital (CAH) Evaluation of Compliance with the Rural and Distance Requirements,'' issued August 21, 2026.[168] QSO–26–15–CAH reaffirms the ''like hospital'' exclusions established under S&C–16–08–CAH and provides CMS with a process for evaluating a CAH's necessary provider status. CMS believes it is appropriate to revise § 485.610(c)(1) and (e)(2) to make permanent existing policy clarifying how the CAH distance requirement is applied. We propose to amend the regulations at § 485.610(c)(1) to codify our policy that CAHs would need to be located more than a 35-mile drive on primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from an acute care hospital or another CAH. Consistent with current CMS guidance on evaluating CAH compliance with the distance requirements, we are also proposing to add a new standard at § 485.610(c)(3) to clarify that, for the purposes of paragraph (c)(1) and (e)(2), an acute care hospital means a hospital as defined under section 1861(e) of the Act, and does not include a psychiatric hospital as defined under section 1861(f) of the Act, a long-term care hospital as described at section 1886(d)(1)(B)(iv) of the Act, or a rehabilitation hospital as described under section 1886(d)(1)(B)(ii) of the Act. We are also proposing to add rural emergency hospital (REH) as described under section 1861(kkk)(2) of the Act, to this exclusion because REHs do not provide acute inpatient care services and therefore would not be considered acute care hospitals for purposes of the location requirements under § 485.610(c)(1) and (e)(2). Therefore, these facilities would not be considered as ''like or similar'' hospitals when evaluating compliance with the location requirements. A CAH designated as a necessary provider on or before December 31, 2005, would still maintain its necessary provider designation after January 1, 2006.

We also propose to amend § 485.610(e)(2), which currently requires that if a CAH (or a necessary provider CAH) operates an off-campus provider-based location, excluding an RHC as defined in § 405.2401(b), but including a department or remote location, as defined in § 413.65(a)(2), or an off-campus distinct part psychiatric or rehabilitation unit, as defined in § 485.647, that was created or acquired on or after January 1, 2008, the off-campus facility must also be located more than a 35-mile drive (or, in the

[164] Centers for Medicare & Medicaid Services. Quality, Certification and Oversight Reports (QCOR), Hospital provider reports, CAHs only, Active Provider and Supplier Counts Report, FY 2025. Accessed February 2, 2026. *https://qcor.cms.gov/main.jsp.*

[165] 69 FR 49107.

[166] Levinson, Daniel. Department of Health and Human Services Office of Inspector General. ''Most Critical Access Hospitals would not meet the location requirements if required to re-enroll in Medicare.'' 2013, *https://oig.hhs.gov/oei/reports/oei-05-12-00080.pdf.*

[167] *Critical Access Hospital (CAH) Recertification Checklist for Evaluation of Compliance with the Location and Distance Requirements.* Centers for Medicare and Medicaid Services, 12 February 2016.

[168] *Critical Access Hospital (CAH) Evaluation of Compliance with the Rural and Distance Requirements.* Centers for Medicare and Medicaid Services, 21 August 2026.

case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH. We propose to codify the existing CMS policy and clarify that CAHs would continue to meet these location requirements if the off-campus provider-based location or off-campus distinct part unit was located more than a 35-mile drive on primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from an *acute care* hospital or another CAH. As with the proposed revision to (c)(1), psychiatric hospitals, LTCHs, rehabilitation hospitals, and REHs would not be considered acute care hospitals and therefore would not be treated as ''like or similar'' hospitals when evaluating compliance with the location requirements. Codifying this policy would confirm that proximity to a specialty hospital does not, by itself, affect compliance with the CAH distance requirement, and would ensure consistent location determinations, including in cases where specialty hospitals are co-located on CAH campuses. Aligning the regulations with established policy will ensure uniform application of the distance requirement nationwide, provide certainty for CAHs and survey agencies, and reduce administrative burden. Most importantly, clarifying that only acute care hospitals and CAHs are included in distance determinations will help safeguard the continued availability of essential health care services in the rural communities served by these CAHs.

In February 2026, section 241 of Division B, Title II, of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) (''CAA 2026''), established that certain CAHs that received termination notices within a specific time frame for failure to meet distance requirements could remain CAHs or re-enroll, as applicable. Specifically, Section 241 of the CAA 2026 states that CMS may not apply the statutory distance requirement at section 1820(c)(2)(B)(i)(I) of the Act to facilities that had a CAH provider agreement and were designated and certified as CAHs as of January 1, 2024, and received a notification letter from CMS between December 1, 2024, and January 1, 2026, indicating noncompliance with the CAH distance requirement at § 485.610(c)(1) or § 485.610(e)(2). For these facilities, CMS is prohibited from enforcing the distance requirement.

Section 241 further reads that, in cases where a provider agreement for such a facility was terminated on or after December 1, 2024, but prior to the date of enactment of CAA 2026 (February 2, 2026), solely because the facility did not meet the distance requirement under section 1820(c)(2)(B)(i)(I) of the Act, the Administrator must recertify the facility as a CAH and reinstate its provider agreement. Furthermore, section 241 clarifies that this provision does not prevent the Administrator from taking other enforcement actions, including terminating a provider agreement, if a facility is found to be out of compliance with federal requirements unrelated to the distance requirement.

To implement section 241 of CAA 2026, we propose to amend the regulations at § 485.610(c)(1) and (e)(2) to add a qualifying statement to each standard stating that a CAH described in section 241 of CAA 2026 will not be subject to the distance requirements of that paragraph. For CAHs that qualify under section 241, we view the exemption from the distance requirement as not being time-limited and as applying to all future distance reviews. The statutory text does not contain a sunset clause or fiscal year limitation, and the provision's reinstatement mechanism for terminated provider agreements appears to provide an ongoing exemption for the defined affected facilities.

CMS performed a detailed analysis to identify how many CAHs would be subject to the exemption from the distance requirement, as outlined in section 241 of CAA 2026. Through this review, CMS determined that four facilities met the necessary criteria; they were designated as CAHs as of January 1, 2024, and received a notification letter from CMS during December 1, 2024 through January 1, 2026, indicating that the facility no longer met the distance requirements under section 1820(c)(2)(B)(i)(I) of the Act, or was actually terminated in that time period.

CAHs often serve as the primary, and sometimes the only source of emergency and acute inpatient care in their communities. By allowing qualifying facilities to retain or regain their CAH status despite no longer meeting the distance requirement relative to other hospitals and CAHs, section 241 of CAA 2026 supports continued access to potentially critical services. Maintaining access to these services protects patient health and safety and promotes continuity of care in underserved areas.

2. Proposal To Remove Emergency Services Readiness Staff Training (§ 485.618(e)(2))

In November 2024, as part of the final rule, ''Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities'' (''CY 2025 OPPS/ASC final rule'') [169] CMS finalized new CoPs for CAHs that offer obstetrical (OB) services. Prior to the CY 2025 OPPS/ASC final rule, CMS had not established CoPs specifically for OB services. Rather those services fell within the scope of broader CoPs applicable to hospitals, including the QAPI requirements. Separate from the CoPs, CMS had also addressed maternal health through sub-regulatory guidance,[170] [171] hospital quality measures, and initiatives such as the Birthing-Friendly Hospital designation.

In the CY 2025 OPPS/ASC final rule, CMS finalized revisions to the CoP related to emergency readiness for CAHs that provide emergency services (§ 485.618(e)(2)), added maternal health QAPI requirements (§ 485.641(d)(4) and (e)(2), and added baseline standards for the organization, staffing, and delivery of OB care, including staff training on evidence-based maternal health practices (§ 485.649). In this section we discuss the proposed changes to the emergency services CoP. Revisions to the CAH QAPI program CoP and Obstetrical services CoP are discussed in sections II.E.3. and II.E.4. of this proposed rule, respectively.

In the CY 2025 OPPS/ASC final rule, we finalized emergency services readiness staff training requirements for CAHs (89 FR 94592 to 94593). As of July 1, 2025, § 485.618(e)(2) requires CAHs to train applicable staff annually on the protocols and provisions implemented pursuant to the emergency services

[169] 89 FR 93912.

[170] Centers for Medicare and Medicaid Services. *State Operations Manual Appendix A -Survey Protocol, Regulations and Interpretive Guidelines for Hospitals Transmittals for Appendix A.* 2024, *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.* Accessed 31 July 2026.

[171] Center for Clinical Standards and Quality . '' QSO–22–05-Hospitals (ADVISORY) .'' *Centers for Medicare & Medicaid Services,* 7 Dec. 2021, *https://www.cms.gov/files/document/qso-22-05-hospitals.pdf.*

readiness requirements at § 485.618(e). Specifically, in accordance with the complexity and scope of services offered by the facility, the CAH must have adequate provisions and protocols to meet the emergency needs of its patients. These protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with OB emergencies, complications, and immediate post-delivery care. The CAH's governing body is responsible for identifying and documenting which staff must complete training on emergency services readiness protocols and procedures. Additionally, the CAH must document in their personnel records that the training was successfully completed and demonstrate staff knowledge on emergency services readiness topics. Further, the CAH must use findings from their QAPI programs to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

In the CY 2025 OPPS/ASC final rule, CMS disagreed with commenters who argued that the emergency services readiness staff training requirements at § 485.618(e)(2) were duplicative of existing CoPs (89 FR 94472). CMS is now reconsidering that position in light of changed circumstances, including the issuance of E.O. 14219 and E.O. 14192, which direct agencies to reduce regulatory burdens, and input received through the 2025 deregulatory RFI.[172] Commenters stated that this requirement is duplicative, as most CAHs have internal standards and protocols to ensure compliance with nationally accepted guidelines for emergency care and readiness including OB emergencies, complications, immediate post-delivery care, and other patient health and safety events. Upon reflection, CMS agrees that the combination of existing CoP requirements (including those for QAPI under § 485.641), EMTALA requirements, AO accreditation standards, specialty board certification requirements, and nationally recognized clinical resources provides a sufficient framework to ensure staff competency in emergency services readiness without the need for a separate, prescriptive annual training requirement. This determination is further supported by the role of state licensing boards, which require clinicians to meet continuing education and competency standards for licensure renewal, as well as private-sector patient safety organizations that advance national clinical readiness and safety practices.

CMS acknowledges that CAHs were required to undertake compliance efforts since the July 1, 2025, effective date of § 485.618(e)(2); however, CMS has determined that the ongoing annual compliance burden, particularly for small and rural CAHs with limited staffing and financial resources, outweighs the incremental benefit of retaining this requirement given the existing structure of other applicable regulations, AO standards, board certifications, EMTALA requirements, and QAPI requirements. Specifically, the compliance costs associated with the emergency services readiness staff training requirements, estimated in the CY 2025 OPPS/ASC final rule,[173] are more than $1.73 billion and 16.4 million hours of staff time over a 10-year period, translating to approximately $173 million and 1,640,108 staff hours annually.

The financial pressures facing rural CAHs further underscore the need for this reconsideration. Rural hospitals are experiencing significant and worsening financial challenges that threaten patient access to care, including emergency services. Between 2010 and May 2026, 51 CAHs either closed completely or ended inpatient services but continue to provide some health care services (for example, primary care, skilled nursing care, long term care). Between 2024 and May 2026, five CAHs closed completely or ended inpatient services to convert to other services.[174] Additionally, since 2023, 23 CAHs have converted to REHs, reflecting a broader trend of rural facilities restructuring to reduce services in response to financial pressures.[175] According to the North Carolina Rural Health Research Program's financial distress index, a model that assesses rural hospital vulnerability across financial performance, government reimbursement, organizational traits, and market characteristics,[176] there are currently 86 rural hospitals in the highest financial risk category and an additional 329 are in the mid-highest risk category.[177] For CAHs already experiencing financial strain, the recurring annual cost associated with implementing, documenting, and maintaining separate staff training requirements is an additional burden, further worsening existing financial constraints. The financial challenges rural hospitals and CAHs face may impact access to care as shown by expanding ambulance and health care deserts.[178] These pressures are also reflected in the absence of hospital-based obstetric services in 60 percent of rural counties, underscoring the consequences of financial distress in rural communities.[179] The compounding financial and operational challenges CAHs experience highlight the disproportionate burden of retaining a requirement that CMS has determined is duplicative of similar regulations, AO accreditation standards, specialty board certifications, and EMTALA requirements. Removing this staff training requirement may allow clinicians to spend more time with patients and prioritize providing high-quality patient care, while maintaining flexibility in how hospitals ensure staff competency and reducing regulatory compliance expenditures.

Existing requirements for CAHs in other subsections of § 485.618 require CAHs to have adequate provisions and protocols to meet the emergency needs of patients. Further, CAHs may incorporate emergency services readiness and staff competency activities into their QAPI programs under § 485.641, which requires CAHs to evaluate and improve the quality of all services furnished, including emergency and OB services. Considering the duplicative nature of these requirements, and in alignment with both E.O. 14192 and E.O. 14219,

[172] Centers for Medicare & Medicaid Services. ''Unleashing Prosperity Through Deregulation of the Medicare Program: Request for Information.'' *CMS.gov,* 2025, *www.cms.gov/medicare-regulatory-relief-rfi.* Accessed September 2025.

[173] 89 FR 94545 to 94546.

[174] ''Rural Hospital Closures.'' *Cecil G. Sheps Center for Health Services Research, www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.* Accessed 21 May 2026.

[175] ''Rural Emergency Hospitals.'' *The Cecil G. Sheps Center for Health Services Research, www.shepscenter.unc.edu/programs-projects/rural-health/rural-emergency-hospitals/.* Accessed 28 May 2026.

[176] Malone, Tyler L, et al. ''An Updated Model of Rural Hospital Financial Distress.'' *The Journal of Rural Health,* vol. 41, no. 2, 3 Oct. 2024, *onlinelibrary.wiley.com/doi/full/10.1111/jrh.12882, https://doi.org/10.1111/jrh.12882.* Accessed 27 May 2026.

[177] Malone, Tyler, et al. ''Rural Hospital Financial Distress: Relative Risk in 2025.'' North Carolina Rural Health Research Program, Nov. 2025, *www.ruralhealthresearch.org/publications/1742.* Accessed 28 May 2026.

[178] Jonk, Y., Milkowski, C., Croll, Z., & Pearson, K. (2023). Ambulance Deserts: Geographic Disparities in the Provision of Ambulance Services [Chartbook]. University of Southern Maine, Muskie School, Maine Rural Health Research Center.

[179] Interrante JD, O'Hanlon K, Kozhimannil KB. Availability of Hospital-Based Obstetric Services in the United States by County, 2010–2023: A State-by-State Report. University of Minnesota Rural Health Research Center. January 2026. *https://rhrc.umn.edu/publication/availability-of-hospital-based-obstetric-services-in-the-united-states-by-county-2010-2023-a-state-by-state-report/.*

we are proposing to remove the emergency services readiness staff training requirement at § 485.618(e)(2). This change would streamline regulatory requirements while preserving patient safety, allowing clinicians to spend more time delivering high-quality care to patients.

In meeting the emergency services CoP requirements at § 485.618 that would remain in place after removal of the emergency services readiness staff training requirements, CAHs may rely on AO standards, voluntary certification programs, and nationally recognized clinical resources that include staff training and competency expectations related to emergency services readiness. AOs may have staff training requirements pertaining to emergency services readiness for patients with critical illnesses. For example, The Joint Commission (TJC) offers facility certification programs in managing critical illnesses, such as heart attacks and stroke, through its comprehensive heart attack and stroke centers programs in collaboration with the American Heart Association and American Stroke Association.[180] [181]

Additionally, professional health care societies offer facility credentialing opportunities and free resources to improve emergency services readiness. The American College of Emergency Physicians (ACEP) offers a geriatric ED accreditation program, with the aim of promoting best clinical practices for older adults, coordinating care more efficiently, and reducing the cost of care.[182] ACEP also offers an ED accreditation program to establish transparency and improve patient care through the implementation of evidence-based policies and practices.[183] EDs also have access to free educational resources such as the American College of Obstetricians and Gynecologists (ACOG's) toolkit for OB emergencies in non-obstetric settings and the AIM Obstetric Emergency Readiness Kit, including guidance for rural facilities to improve their OB readiness.[184] [185] CMS also recognizes that risk-appropriate care, a strategy to ensure that pregnant women and infants receive the right care in the right place at the right time, is an important framework for rural CAHs, including those without dedicated OB services.[186] Under this approach, healthy patients can safely deliver in their communities, while complex pregnancies are delivered in hospitals with the personnel and resources to support higher risk conditions. Rural hospitals and CAHs, including those without dedicated OB services, may find it beneficial to ensure that providers have the skills necessary to stabilize and transport, or potentially deliver, a high-risk pregnancy, and are encouraged to explore the range of training resources available to support obstetric emergency preparedness in non-obstetric settings. Similarly, the National Pediatric Readiness Project, developed in partnership with ACEP, the Emergency Nurses Association (ENA), and the American Academy of Pediatrics) empowers EDs nationwide to improve their ''pediatric readiness'' or capability to care for acutely ill and injured children through free assessment and toolkit resources.[187]

In addition, CAHs commonly rely on existing specialty board certification and continuing education requirements to ensure that emergency services staff are qualified and prepared to deliver care in accordance with acceptable standards of practice, consistent with § 485.618. Notably, specialty board certification is a key component of physician education and required by a majority of hospital-based employers.[188] For example, physicians can pursue board certification in emergency medicine from organizations such as the American Board of Emergency Medicine (ABEM) or the Board of Certification in Emergency Medicine (BCEM).[189] [190] Emergency Medicine board certification requires physicians to demonstrate and maintain knowledge of key emergency topics, including OB emergencies.[191] ACEP also offers Continuing Medical Education (CME) such as, through conferences, online modules, seminars in best practice updates for managing common and critical emergency conditions and requires its members to earn 150 CME hours every 3 years.[192] [193] The Board of Certification of Emergency Nursing offers nurses credentialing as a certified emergency nurse (CEN), while the ENA offers nurses continuing education courses in managing critical patients, including pediatrics, obstetrics, geriatrics, and trauma.[194] The extensive nature of these resources and the nature of hospital expectations for clinician training would continue to drive improvements in clinician training in the absence of the emergency services staff training requirements that we propose to remove from the hospital regulations. CAHs retain the flexibility to provide staff training on emergency services readiness topics as they determine appropriate based on their patient population, institutional needs, and medical staff recommendations.

3. Proposal To Remove OB QAPI Requirements (§ 485.641)(d)(4) and (e)(2))

On September 30, 2019, CMS published the ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' final rule (84 FR 51732), which finalized new CAH QAPI requirements.[195] These new

[180] ''Cardiac Certification.'' *www.jointcommission.org, www.jointcommission.org/what-we-offer/certification/certifications-by-setting/hospital-certifications/cardiac-certification/advanced-cardiac/comprehensive-heart-attack-center/.* Accessed 4 February 2026.

[181] ''Stroke Certification.'' *www.jointcommission.org, www.jointcommission.org/what-we-offer/certification/certifications-by-setting/hospital-certifications/stroke-certification/.* Accessed 4 February 2026.

[182] ''Accreditation Programs.'' American College of Emergency Physicians, *www.acep.org/patient-care/accreditation-programs.* Accessed 4 February 2026.

[183] ''Accreditation Programs.'' American College of Emergency Physicians, *www.acep.org/patient-care/accreditation-programs.* Accessed 4 February 2026.

[184] ''Obstetric Emergencies in Nonobstetric Settings.'' *www.acog.org, www.acog.org/programs/obstetric-emergencies-in-nonobstetric-settings.* Accessed 4 February 2026.

[185] ''AIM | Alliance for Innovation on Maternal Health.'' Saferbirth.org, *https://saferbirth.org/.* Accessed 4 February 2026.

[186] CDC. ''CDC Levels of Care Assessment Tool (CDC LOCATe®).'' *Maternal Mortality Prevention,* 13 February 2026, *www.cdc.gov/maternal-infant-health/php/cdc-locate/index.html#cdc_toolkit_main_purpose-risk-appropriate-care.* Accessed 28 May 2026.

[187] ''National Pediatric Readiness Project.'' Emergency Medical Services for Children Innovation and Improvement Center (EIIC), *https://emscimprovement.center/domains/pediatric-readiness-project/.* Accessed 4 February 2026.

[188] Freed, Gary L. ''Use of Board Certification and Recertification in Hospital Privileging.'' Archives of Surgery, vol. 144, no. 8, 14 Aug. 2009, pp. 746–746. JAMA Network,, *https://doi.org/10.1001/archsurg.2009.28.* Accessed 27 March 2025.

[189] ''ABEM.'' American Board of Emergency Medicine, 12 Nov. 2024, *www.abem.org/.* Accessed 4 February 2026.

[190] ''Emergency Medicine Board Certification | ABPS.'' American Board of Physician Specialties, 7 October 2025, *www.abpsus.org/specializations/emergency-medicine.* Accessed 4 February 2026.

[191] ''MyEMCert Study Points Abdominopelvic Module.'' American Board of Emergency Medicine, August 2025, *www.abem.org/wp-content/uploads/2024/07/Abdominopelvic-Study-Points.pdf.* Accessed 4 February 2026.

[192] ''ACEP26—Chicago, Illinois—October 5–8, 2026.'' Acep.org, ACEP's Scientific Assembly, 2026, *www.acep.org/sa.* Accessed 4 February 2026.

[193] ''Continuing Medical Education.'' American College of Emergency Physicians, *www.acep.org/education/cme.* Accessed 4 February 2026.

[194] ''CEN—Certified Emergency Nurse Specialization.'' Board of Certification for Emergency Nursing, *https://bcen.org/cen/.* Accessed 4 February 2026.

[195] 84 FR 51785.

requirements replaced the long standing ''Periodic evaluation and quality assurance review'' CoP,[196] to reflect then-current industry standards that utilized the QAPI model to assess and improve patient care. The CAH QAPI program CoP (§ 485.641) requires CAHs to develop, implement, and maintain an ongoing, CAH-wide, and data-driven program that is, in part, appropriate to the complexity of the CAH's organization and services and involves all departments and services. The program must also use measures to analyze and track performance, and set priorities that it considers high-volume, high-risk services or problem-prone areas, focus on measures related to improved health outcomes and desired patient outcomes, and operate under the oversight and accountability of the CAH's governing body.

In the CY 2025 OPPS/ASC final rule,[197] we finalized additional QAPI requirements for CAHs that offer OB services (89 FR 94593). Effective January 1, 2027, CAHs that offer OB services are required to have their OB leadership participate in the facility's QAPI program (§ 485.641(d)(4)(i)) and, where a State, local, or tribal maternal mortality review committee (MMRC) exists, the facility must have a process for incorporating publicly available MMRC data and recommendations into its QAPI program (§ 485.641(d)(4)(ii)).

Additionally, § 485.641(e)(2) requires that effective January 1, 2027, CAHs that offer OB services must utilize their QAPI programs to assess and improve health outcomes and disparities among OB patients on an ongoing basis. Specifically, once these requirements are effective the facility at a minimum will be required to: (1) analyze data and quality indicators by diverse subpopulation as determined by the facility; (2) measure, analyze, and track outcomes and disparities in processes of care, services, and outcomes among OB patients; (3) analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained when disparities exist among OB patients; (4) and conduct at least one measurable performance improvement project that focuses on improving health outcomes and maternal health disparities annually.

This proposal to remove OB QAPI requirements at § 485.641(d)(4) and (e)(2) would promote efficiency and reduce waste, consistent with the E.O. 14219 and E.O. 14192. As part of regulatory reviews conducted in response to these E.O.s, CMS received input through the 2025 deregulatory RFI[198] from interested parties. Commenters, including physician organizations, medical associations, and rural health advocates, specifically raised concerns about the OB QAPI requirements at § 485.641(d)(4) and (e)(2), as well as the broader OB services CoPs (§ 485.649) finalized in the CY 2025 OPPS/ASC final rule. Commenters indicated that these requirements were overly burdensome and costly CAHs and expressed concern that compliance costs could contribute to the closure of labor and delivery units, which would worsen access to maternity care and potentially exacerbate maternal health disparities.

CMS acknowledges that in the CY 2025 OPPS/ASC final rule, we disagreed with comments asserting that the OB QAPI requirements were duplicative of existing CoPs and concluded that uniform baseline requirements were necessary to ensure quality maternal care across all participating facilities (89 FR 94483). CMS is now proposing to change that position. Upon further consideration, including input received through the 2025 deregulatory RFI and the policy priorities reflected in E.O. 14219 and E.O. 14192, CMS has reassessed the burden imposed by the OB-specific QAPI requirements and the quality improvement those requirements would achieve beyond what was previously already required under the existing, broadly applicable QAPI CoPs at § 485.641. In particular, CMS now finds that the existing QAPI CoPs, which require CAHs to maintain an effective, ongoing, facility-wide, data-driven program that measures, analyzes, and tracks quality indicators, including adverse patient events, across all services provides a sufficient foundation for quality oversight of OB care, without the need for OB-specific requirements. In consideration of the above, CMS is proposing to remove the OB QAPI requirements at § 485.641(d)(4) and (e)(2) for CAHs that offer OB services. CAHs would continue to be required to comply with the remaining QAPI requirements at § 485.641.

CMS also recognizes the compliance costs associated with the OB QAPI requirements. As further discussed in section III.K. of this proposed rule, the current requirements are expected to cost CAHs $34,398,850 and 203,280 hours of staff time over a 10-year period, or $3,439,885 and 20,328 staff hours annually. This burden may pose a disproportionate burden on CAHs, potentially contributing to the closure of labor and delivery units and thereby worsening access to maternity care in underserved communities. CAHs may have begun taking steps toward compliance with the OB QAPI requirements finalized in the CY 2025 OPPS/ASC final rule, which are not effective until January 1, 2027. CMS has considered these efforts toward achieving compliance and, given that the requirements have not yet taken effect, expects the disruption to CAHs from this proposed change in position to be limited. Although it is unlikely that this proposed rule will be finalized before January 1, 2027, we would request that our surveyors conducting surveys after that date focus on those CoPs that are not potentially subject to imminent revision. CMS recognizes and affirms the importance of high-quality OB-focused QAPI programs in improving maternal health outcomes and reducing maternal mortality and morbidity. While we are proposing to remove the OB-specific requirements at § 485.641(d)(4) and (e)(2), we strongly encourage CAHs that offer OB services to prioritize maternal health as part of their existing QAPI programs. Furthermore, nothing in these proposals prohibits CAHs from establishing and maintaining policies and procedures that go beyond the minimum standards set forth in the CoPs. CAHs are encouraged to exercise this flexibility to ensure they are meeting the unique needs of their patient populations.

Furthermore, HHS has several existing quality initiatives related to maternal health, including CMS' Birthing-Friendly designation and State-based National Perinatal Quality Collaboratives (PQCs) supported by the Centers for Disease Control (CDC).[199] The Birthing-Friendly Hospital Designation (hereinafter referred to as ''the Designation''), was created to identify hospitals and CAHs that demonstrate the delivery of high-quality maternal care and a commitment to improving maternal health outcomes (87 FR 49284 through 49290).[200] The Designation serves as a quality-driven mechanism to incentivize hospitals and CAHs to adopt and sustain evidence-based maternal health practices, and is

[196] 58 FR 30658.

[197] 89 FR 93912.

[198] ''Medicare Regulatory Relief | CMS.'' *Cms.gov,* 2025, *www.cms.gov/medicare-regulatory-relief-rfi, https://www.cms.gov/files/document/unleashing-prosperity-through-deregulation-medicare-program-request-information.pdf.* Accessed September 2025.

[199] ''Birthing-Friendly Hospitals and Health Systems.'' *CMS Provider Data,* Centers for Medicare & Medicaid Services, *https://data.cms.gov/provider-data/birthing-friendly-hospitals-and-health-systems.* Accessed 31 March 2026.

[200] 87 FR 48780.

one of several tools CMS is leveraging to advance maternal health outcomes. CMS intends to explore, in future rulemaking, opportunities to expand the Designation and similar quality-based programs as a primary vehicle for reducing maternal mortality and morbidity, and we invite public comment on how such programs could be structured or expanded to address maternal health disparities. CMS is also actively refining the Designation program, including through a recent Request for Information (RFI) in the FY 2027 IPPS/LTCH proposed rule (91 FR 19597, April 14, 2026),[201] which sought public input on updates to designation criteria, alignment with other Federal and state maternal health quality initiatives, and strategies to increase hospital and CAH participation, particularly among rural and safety-net hospitals.

While the Designation operates at the facility level, state-based PQCs complement this effort by advancing standardized best practices at the state and regional level, serving as another tool for advancing maternal health. As of March 2026, there are 52 State- and territory-based PQCs,[202] of which 36 are funded by the CDC.[203] Through Federal grants and cooperative agreements with the CDC and/or funding and support from State and local governments, PQCs have achieved notable improvements in maternal health and safety, including in severe pregnancy complications.[204] For example, the Illinois Perinatal Quality Collaborative launched the Severe Maternal Hypertension Initiative helped raise timely treatment rates for sever hypertension from 41 percent to 87 percent within 2 years.[205] Together, this regulatory approach ensures flexibility and reduces burden while maintaining strong support for maternal and infant health.

CMS acknowledges that U.S. maternal mortality remains elevated relative to peer nations and that the majority of pregnancy-related deaths are considered preventable. According to data from MMRCs in 45 states, 85.7 percent of pregnancy-related deaths occurring in 2022 were preventable, with clinical skill and quality of care, lack of continuity of care, and knowledge identified as the most common contributing factors.[206] MMRC prevention recommendations were directed at the provider level (32.2 percent), facility level (18.6 percent), and system level (38.0 percent),[207] underscoring the importance of facility-level responsiveness to MMRC findings. Comprehensive strategies for improving maternal health quality, such as engaging with State PQCs, utilizing AIM resources, and seeking the CMS Birthing-Friendly designation, can significantly enhance outcomes in maternal health. CMS encourages CAHs that offer OB services to incorporate maternal health quality improvement activities, including review of publicly available MMRC data and recommendations where available, into their existing QAPI programs under § 485.641.

4. Proposal To Remove OB Services Staff Training (§ 485.649(c))

In the CY 2025 OPPS/ASC final rule,[208] we finalized OB services staff training requirements for CAHs. Effective January 1, 2027, section 485.649(c) requires CAHs to ''develop policies and procedures to ensure that relevant staff are trained on select topics for improving the delivery of maternal care.'' The training topics must reflect the scope and complexity of the services offered within the facility, including facility-identified, evidence-based best practices and protocols. CAHs will also be required to use findings from their QAPI programs to inform staff training needs and any additions to the training topics on an ongoing basis and provide relevant new staff with initial training. In addition, the governing body will be required to identify and document which staff must complete an initial training and subsequent biennial (every 2 years) training. Additionally, the CAH must document in the staff personnel records that the training was successfully completed and must be able to demonstrate staff knowledge on the aforementioned topics.

As part of regulatory review conducted in response to the E.O. 14219 and E.O. 14192, CMS solicited and received interested parties' input through the 2025 deregulatory RFI.[209] Commenters expressed several concerns about the OB services CoP staff training requirements at § 485.649(c). Several commenters requested that CAHs and rural hospitals be exempt from the new OB services and QAPI requirements, noting REHs are already exempt and that CAHs similarly require flexibility given their unique operational constraints. Commenters also raised concerns about the requirement that the governing body identify and document which staff must complete training on maternal care protocols, suggesting that decisions regarding the frequency, content, and scope of staff training are more appropriately made at the facility leadership level and that prescriptive training requirements take staff away from direct patient care while increasing the cost of care. More broadly, commenters expressed concern that the staff training requirements, as currently designed, are highly unlikely to reduce maternal mortality or morbidity while significantly increasing administrative burden, and that they risk exacerbating access to care challenges, particularly in rural and underserved areas, by contributing to CAHs and rural hospitals reducing or discontinuing OB services. Several commenters also noted that the requirements are duplicative of standards CAHs and hospitals are already held to under existing requirements, including the Emergency Medical Treatment and Labor Act (EMTALA), accreditation organization (AO) standards, emergency services requirements (§ 485.618), QAPI requirements (§ 485.641), and specialty board certification and continuing education requirements.

CMS previously considered similar concerns in the CY 2025 OPPS/ASC final rule (89 FR 94480 to 94483). At that time, we concluded that the patient safety benefits of the staff training requirements outweighed the operational and financial burdens on CAHs, and that existing AO standards and CME requirements did not fully substitute for the specific, QAPI-informed, facility-level training we were establishing. We are now revising both

[201] 91 FR 19312.

[202] ''National Network of Perinatal Quality Collaboratives.'' The National Institute for Children's Health Quality, National Institute for Children's Health Quality, *https://nichq.org/projects/national-network-of-perinatal-quality-collaboratives/.* Accessed 30 March 2026.

[203] ''State Perinatal Quality Collaboratives.'' Centers for Disease Control and Prevention, 15 May 2024, *https://www.cdc.gov/maternal-infant-health/pqc/state-pqcs.html.* Accessed 24 September 2025.

[204] ''Perinatal Quality Collaboratives.'' Centers for Disease Control and Prevention, 15 May 2024, *https://www.cdc.gov/maternal-infant-health/pqc/index.html.* Accessed 24 September 2025.

[205] Centers for Disease Control and Prevention. ''PQC Impacts: Reducing Pregnancy Complications From High Blood Pressure.'' *Maternal Infant Health,* 20 May 2024, *https://www.cdc.gov/maternal-infant-health/pqc/success-stories-illinois.html.*

[206] CDC. ''Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees.'' *Maternal Mortality Prevention,* 28 August 2025, *www.cdc.gov/maternal-mortality/php/data-research/mmrc/index.html?cove-tab=4.* Accessed 28 May 2026.

[207] ''Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees.'' *Maternal Mortality Prevention,* 28 Aug. 2025, *www.cdc.gov/maternal-mortality/php/data-research/mmrc/index.html?cove-tab=5.* Accessed 28 May 2026.

[208] 89 FR 93912.

[209] ''Medicare Regulatory Relief | CMS.'' *Cms.gov,* 2025, *https://www.cms.gov/medicare-regulatory-relief-rfi.* Accessed September 2025.*https://www.cms.gov/files/document/unleashing-prosperity-through-deregulation-medicare-program-request-information.pdf.* Accessed September 2025.

of those conclusions given the deregulatory directives set forth in E.O. 14219 and E.O. 14192, the additional input received through the 2025 deregulatory RFI, and a reassessment of the relative costs and benefits of the requirement. Upon further review, and consistent with concerns raised by commenters through the 2025 deregulatory RFI and the CY 2025 OPPS/ASC final rule, we find that the staff time and administrative costs associated with § 485.649(c), when added to existing financial and workforce pressures, could affect some CAHs decisions to continue providing OB services at their current level, particularly in areas with limited access to maternity care. We further find that existing AO accreditation standards, board certification requirements, and voluntary professional society training opportunities together provide a robust and sufficient foundation for ensuring staff competency in OB care, such that the incremental benefit of the additional CoP requirement does not justify its associated burden. Specifically, the compliance costs associated with the OB services staff training requirement for CAHs, estimated in the CY 2025 OPPS/ASC final rule,[210] are more than $28.1 million and 205,200 hours of staff time over a 10-year period across all CAHs, translating to approximately $2.8 million and 20,520 staff hours annually. Due to these concerns, and to reduce unnecessary regulatory burden while preserving patient safety, we are proposing to remove the OB services staff training requirement at § 485.649(c). We also note that, since the requirement at § 485.649(c) does not take effect until January 1, 2027, CAHs are not yet required to comply, which limits reliance interests. To the extent that any CAHs have already begun investing resources in implementing these requirements in anticipation of the effective date, we acknowledge those efforts and note that the training infrastructure developed may continue to serve facilities under existing AO standards and voluntary initiatives. As noted previously, although it is unlikely that this proposed rule will be finalized before January 1, 2027, we would request that our surveyors conducting surveys after that date focus on those CoPs that are not potentially subject to imminent revision. CMS recognizes and affirms the critical importance of high-quality, evidence-based OB staff training programs in improving maternal health outcomes and reducing maternal mortality and morbidity. While we are proposing to remove the requirement at § 485.649(c), we strongly encourage CAHs to continue investing in these activities. CAHs have the flexibility to exceed the health and safety standards set forth by CMS by establishing additional policies and procedures as needed to address the specific needs of their patients.

If the proposed changes are finalized, CAHs that provide OB services would still need to continue to meet all applicable CoPs related to the organization of services, staffing, delivery of care, and emergency preparedness to ensure safe, high-quality care for pregnant, birthing, and postpartum patients. In meeting these ongoing requirements, CAHs accredited by a CMS-approved accrediting organization would continue to comply with the standards of their AO, which may include staff competency and readiness to safely care for pregnant and postpartum patients. AOs have staff training requirements pertaining to maternal health. For example, TJC requires facilities to provide role-specific education to all staff and providers who treat pregnant and postpartum patients on their OB hemorrhage procedure (Standard PC.06.01.01 EP 4) and to develop written, evidence-based procedures for managing pregnant and postpartum patients with severe hypertension/preeclampsia procedures (Standard PC.06.03.01 EP 3). Under TJC standards, this education must occur at orientation, whenever there are changes to the processes or procedures, or at least every 2 years (Standard PC.06.01.01 EP 4, Standard PC.06.03.01 EP 3). Facilities must also conduct drills at least annually to determine system issues, followed by a team debrief (Standard OC.06.01.01 EP 5).[211]

CAHs accredited by TJC may voluntarily seek assessment and confirmation of their maternal care capabilities through TJC's ''Maternal Levels of Care Verification'' program, developed in collaboration with ACOG.[212] The program evaluates whether a facility has the expertise, equipment, and resources necessary to provide risk-appropriate care. It also helps CAHs identify and address capability gaps, clarify which patients they are equipped to manage and when transfer is appropriate, and strengthen collaborative relationships with other facilities, supporting broader efforts to reduce maternal mortality and severe maternal morbidity.

Additionally, CAH clinicians may choose to pursue board certification to demonstrate their expertise and commitment to their specialty and evidence-based medicine. Medical specialty board certification is a key component of physician education and required by a majority of hospital-based employers.[213] Although certification requires an investment of time and resources, this process may enhance physicians' employment opportunities, professional standing, and increase patient trust. CAHs may also support board certification as part of their credentialing and quality improvement activities, as it can assist in verifying physician qualifications, meeting accreditation standards, and promoting high-quality patient care.

In addition to the AO standards and board certification, several professional health care societies offer training opportunities related to improving management of OB emergencies to protect the health of mothers. Specifically, ACOG's ''Emergencies in Clinical Obstetrics'' course covers a variety of OB emergencies including breech vaginal delivery, shoulder dystocia, postpartum hemorrhage, and teamwork and communication.[214] Further, ACOG provides CME for physicians and health care professionals practicing obstetrics and gynecology through eModules, conferences, simulations, courses, and webinars.[215] The American Academy of Family Physicians' (AAFP) ''Advanced Life Support in Obstetrics (ALSO) Program'' equips the entire pregnancy care team with skills to effectively manage OB emergencies and positively impact maternal outcomes.[216]

Patient advocacy groups and nursing associations also offer maternal health educational opportunities. March of

[210] 89 FR 94542 to 94543.

[211] ''Comprehensive Accreditation Manual for Hospitals.'' The Joint Commission, 1 July 2025, *https://acrobat.adobe.com/id/urn:aaid:sc:VA6C2:843eea61-ae7f-4a8f-b413-fb52d44317b7.* Accessed 4 February 2026.

[212] ''Maternal Levels of Care Verification.'' *www.jointcommission.org, www.jointcommission.org/what-we-offer/verification/maternal-levels-of-care-verification/.* Accessed 4 February 2026.

[213] Freed, Gary L. ''Use of Board Certification and Recertification in Hospital Privileging.'' Archives of Surgery, vol. 144, no. 8, 14 Aug. 2009, pp. 746–746. JAMA Network, *jamanetwork.com/journals/jamasurgery/fullarticle/405203, https://doi.org/10.1001/archsurg.2009.28.* Accessed 27 March 2025.

[214] ''Emergencies in Clinical Obstetrics (ECO).'' *American College of Obstetricians and Gynecologists (ACOG), www.acog.org/education-and-events/simulations/eco.* Accessed 4 Feb. 2026.

[215] ''Continuing Medical Education Program.'' *American College of Obstetricians and Gynecologists (ACOG), www.acog.org/education-and-events/cme-program.* Accessed 4 Feb. 2026.

[216] ''Advanced Life Support in Obstetrics (ALSO) Program.'' *American Academy of Family Physicians (AAFP),* 2020, *www.aafp.org/cme/programs/also.html.* Accessed 4 February 2026.

Dimes offers several educational programs that include continuing nursing education (CNE) and CME credits in maternal health and provide peer-reviewed and clinically relevant content.[217] Additionally, the American Nurses Association (ANA) supports professional development by offering resources and opportunities for nurses to enhance their skills and knowledge in various nursing specialties, including obstetrics.[218] [219] [220] The Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN) offers the ''Obstetric Patient Safety: OB Emergencies Workshop'' to disseminate best practices to help clinicians identify, assess, and manage the care for patients with obstetric emergencies.[221] We believe that this robust set of external resources and standards can be used by hospitals to comply with the existing CoPs related to the organization of services, staffing, delivery of care, and emergency preparedness to ensure safe, high-quality care for pregnant, birthing, and postpartum patients in the absence of the specific OB services staff training requirement that we are proposing to remove.

We invite the public to comment on this revision of these requirements, and on any alternatives to our approach. We are also interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. Additionally, we seek comments on whether and how such training and quality improvement initiatives could be more effectively advanced through the Birthing-Friendly hospital designation program or similar voluntary, incentive-based frameworks, rather than through the CoPs. The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

5. Requirements for Patient's Rights for Birth Tissue Collection for CAHs (Proposed § 485.649(c))

a. Background on Birth Tissues Uses

Birth tissues are solely generated as a direct result of pregnancy, labor, and delivery and may be discarded, retained by the patient, stored, donated, banked for potential future medical use, and/or transferred to a third party for research or commercial purposes. These tissues can include umbilical cord blood, umbilical cord tissue, umbilical veins, placenta, amniotic membrane, chorionic membrane, amniotic fluid, and Wharton's jelly.[222] Currently, the vast majority of birth tissue—approximately 96 percent- is disposed of following delivery.[223] If intended for future medical purposes, such tissue must be collected promptly and handled in a manner designed to minimize contamination.[224] For our analysis, it is helpful to separate our discussion of the collection of cord blood from consideration of other birth tissues.

Cord blood is the most commonly collected birth tissue for future medical use (approximately 110,000 collections annually, or about 3 percent of births, with 75 to 80 percent stored in private banks).[225] It is also the most researched and regulated birth tissue, at both the Federal and State level. Cord blood is unique in that families can pursue either public or private cord banking. Public cord blood banking has an established role in hematopoietic stem cell transplantation for certain malignant, hematologic, immunologic, and metabolic disorders.[226] Public cord banking is free to the family as part of a national transplant registry. HRSA oversees the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory.[227] These programs were established under the Stem Cell Therapeutic and Research Acts to expand donor and cord blood availability to fund and coordinate the collection, banking, and distribution of cord blood units to increase access for transplantation and research.[228] Yet only approximately 180 facilities participate in public cord banks nationwide due to costs associated with collection, processing, and storage.[229] Conversely, private cord banks allow families to retain exclusive access to their stored cord blood for potential future personal or family use with collection and storage costs paid out of pocket by the family, which can total several thousand dollars initially, followed by annual storage costs of several hundred dollars.[230] [231] [232]

Professional organizations have emphasized the importance of accurate information, informed consent, and conflict-of-interest disclosure in cord blood banking. ACOG states that public cord blood banking is the recommended method of obtaining cord blood for transplantation, immune therapies, or other medically validated indications. and that routine private cord blood banking is not supported by available evidence and that ''there is no current evidence to support the use of an autologous umbilical cord blood sample in regenerative medicine.'' [233] The American Academy of Pediatrics has similarly noted that public cord blood banking is highly regulated, while private banking may be costly and rarely used for treatment, and has recommended ethical and operational standards addressing informed consent, financial disclosures, and conflicts of interest.[234] The American Medical Association (AMA) Code of Medical Ethics states that physicians who provide OB care should be prepared to inform pregnant women of options regarding cord blood donation or storage and potential uses, and should obtain informed consent before the onset of

[217] ''Continuing Education Courses.'' Marchofdimes.org, 2024, *www.marchofdimes.org/our-work/health-professionals/continuing-education-courses*. Accessed 4 February 2026.

[218] American Nurses Association. ''About ANA.'' American Nurses Association, 2025, *www.nursingworld.org/ana/about-ana/ www.nursingworld.org/ana/about-ana/*. Accessed 4 February 2026.

[219] American Nurses Association. ''About ANA.'' American Nurses Association, 2025, *www.nursingworld.org/ana/about-ana/ www.nursingworld.org/ana/about-ana/*. Accessed 4 February 2026.

[220] ''Continuing Education for Nurses (CE) | ANA Enterprise.'' American Nurses Association, 2024, *www.nursingworld.org/continuing-education/ www.nursingworld.org/continuing-education/*. Accessed 4 February 2026.

[221] ''Getting Started with OPS.'' Association of Women's Health, Obstetric and Neonatal Nurses, *www.awhonn.org/education/hospital-products/ops/getting-started-with-ops/www.awhonn.org/education/hospital-products/ops/getting-started-with-ops/*. Accessed 4 February 2026.

[222] The gelatinous connective tissue that protects vessels within the umbilical cord.

[223] *https://pmc.ncbi.nlm.nih.gov/articles/PMC3477280/.*

[224] *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking.*

[225] *https://www.consumeraffairs.com/health/cord-blood-banking-statistics.html.*

[226] *https://publications.aap.org/pediatrics/article/140/5/e20172695/37866/Cord-Blood-Banking-for-Potential-Future.*

[227] Health Resources and Services Administration, Donation and Transplantation Statistics, Blood Stem Cell, *https://bloodstemcell.hrsa.gov/data/donation-and-transplantation-statistics* (last visited June 2026).

[228] *https://bloodstemcell.hrsa.gov/about/legislation.*

[229] *https://pmc.ncbi.nlm.nih.gov/articles/PMC3477280/.*

[230] *https://publications.aap.org/pediatrics/article/140/5/e20172695/37866/Cord-Blood-Banking-for-Potential-Future.*

[231] *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking.*

[232] *https://www.cordbloodbanking.com/banking/cost/.*

[233] American College of Obstetricians and Gynecologists, Committee Opinion No. 771, Umbilical Cord Blood Banking (Mar. 2019), *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking.*

[234] William T. Shearer et al., Cord Blood Banking for Potential Future Transplantation, 140 Pediatrics e20172695 (2017), *https://publications.aap.org/pediatrics/article/140/5/e20172695/37866/Cord-Blood-Banking-for-Potential-Future.*

labor whenever feasible when participating in collection.[235]

Data on collection rates of other birth tissue (non-cord blood) for future medical uses are limited due to a lack of standardized national data. Parent's Guide to Cord Blood, a patient advocacy group, estimates approximately100,000 placentas are collected by birth tissue procurement organizations (BTPOs) each year and distributed to research and/or commercial entities.[236] Unlike cord blood, there is no public banking infrastructure for other birth tissues. The Food and Drug Administration (FDA) regulates such tissues either under Section 361 of the Public Health Service Act (PHSA) and 21 CFR part 1271 [237] or under Section 351 of the PHSA and relevant sections of the Federal Food, Drug and Cosmetic Act.[238] These tissues are often marketed to the public in a misleading manner and without following applicable statutory and/or regulatory requirements.[239]

Regenerative medicine products derived from human cells or tissues, including stem cells, umbilical cord blood, amniotic tissue, and related products that meet all of the criteria in 21 CFR 1271.10(a) are subject only to regulation under section 361 of the PHS Act and the regulations in 21 CFR part 1271. If such a product does not meet all the criteria set out in 21 CFR 1271.10(a), and the establishment that manufactures the HCT/P does not qualify for any of the exceptions listed in 21 CFR 1271.15, the HCT/P will be regulated under section 351 of the PHS Act and/or the FD&C Act, and applicable regulations, including 21 CFR part 1271, and FDA approval will generally be required.[240] Specifically, the FDA issues warning letters to companies regarding the marketing of unapproved biological products and regarding manufacturing and quality system deficiencies.[241] [242] Additionally, FDA has stated that unapproved regenerative medicine therapies can pose serious safety risks. Adverse events associated with the use of unapproved regenerative medicine products have included bacterial infections, blindness, tumor formation, inflammatory reactions, and other harms.[243] [244] [245] These regulations, company communications, and public safety communications provide additional context regarding FDA's oversight of regenerative medicine products, including birth tissues, and the potential risks associated with products that do not comply with applicable statutory and regulatory requirements.

Investigative reporting has also described commercialization of birth tissues and the potential for donations made in connection with childbirth to enter supply chains for unapproved or unproven products. In a 2019 investigation, *The New Yorker* and *ProPublica* reported that some patients who donated birth tissue understood the donation to be for a beneficial purpose but did not recall the details of the donation process and described a broader market for birth tissue products used in unproven commercial uses, often without families' awareness.[246] [247]

National data on the number of placentas or other birth tissues released to or taken home by families each year is not available. The limited available evidence consists primarily of small surveys of hospital/pathology practices and non-national studies of placentophagy or community birth populations.[248] [249] [250] We are aware that mothers and families may have significant cultural, religious, spiritual, or personal interests in birth tissues, especially the placenta and umbilical cord.[251] Although birth tissues are often treated as medical waste within health care settings, scholarly literature describes numerous traditions and cultural practices, in the United States and internationally, involving the retention, burial, preservation, or other uses of birth tissue following childbirth.[252] Scholars have further observed that patient preferences regarding the disposition of birth tissues are not always reflected in institutional policies or informed consent practices, and that families may face inconsistent policies or practices when seeking to retain their placentas and other birth tissues.[253] [254] One limited survey in 2013 found that 61 percent of hospitals allow for placenta release to families, and most hospitals had an interdisciplinary policy supporting it.[255]

b. Need for New CAH Standards

Section 1820(e)(3) of the Act authorizes the Secretary to establish additional requirements necessary for the health and safety of patients served by Medicare-and Medicaid-participating CAHs. Existing CAH CoPs establish the framework for protecting patient rights, promoting informed decision-making, and ensuring accurate medical and clinical record documentation. Together, the requirements safeguard patient health and safety and promote quality care for all patients in Medicare-and Medicaid-participating CAHs. Specifically, patient rights CoPs for CAHs at § 485.614 (a) and (b) provide that patients or their representatives have the right to make informed decisions regarding their care, including being informed of their health status, being involved in care planning and

[235] American Medical Association, Code of Medical Ethics Opinion 6.1.5, Umbilical Cord Blood Banking, *https://code-medical-ethics.ama-assn.org/ethics-opinions/umbilical-cord-blood-banking.*

[236] *https://parentsguidecordblood.org/en/news/its-morning-your-c-section-and-someone-wants-you-donate-your-placenta.*

[237] 21 CFR part 1271 includes requirements related to collection, processing, storage, and distribution of certain HCT/Ps (including placenta, amniotic membrane, and cord tissue).

Section 361 of the Public Health Service Act, 42 U.S.C. § 264; Section 351 of the Public Health Service Act, 42 U.S.C. § 262; 21 C.F.R. part 1271; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq.

[239] Food and Drug Administration, Consumer Alert on Regenerative Medicine Products Including Stem Cells and Exosomes, *https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/consumer-alert-regenerative-medicine-products-including-stem-cells-and-exosomes.*

[240] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal.*

[241] *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/patient-and-consumer-warning-about-potential-serious-risks-harm-following-use-unapproved-products.*

[242] *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products.*

[243] *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/patient-and-consumer-warning-about-potential-serious-risks-harm-following-use-unapproved-products.*

[244] Food and Drug Administration, Important Patient and Consumer Information About Regenerative Medicine Therapies (June 3, 2021), *https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies.*

[245] *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products.*

[246] Caroline Chen, The Birth-Tissue Profiteers, The New Yorker and ProPublica (May 7, 2019), *https://www.newyorker.com/news/news-desk/the-birth-tissue-profiteers.*

[247] Mathilde Cohen, The Law of Placenta, 31 Yale Journal of Law and Feminism 337 (2020).

[248] *https://journals.sagepub.com/doi/10.2350/13-05-1338-OA.1.*

[249] *https://pubmed.ncbi.nlm.nih.gov/29722066/.*

[250] Although Cohen's analysis draws on international case studies, including examples from Brazil, the Department cites the article because it addresses ethical, legal, and commercial issues associated with birth tissue procurement and use that have received comparatively limited attention in the U.S. literature. The Department relies on the article for its general discussion of these issues and not as evidence of the prevalence or characteristics of practices in the United States.

[251] Mathilde Cohen, The Law of Placenta, 31 Yale Journal of Law and Feminism 337 (2020).

[252] Mathilde Cohen, The Law of Placenta, 31 Yale Journal of Law and Feminism 337 (2020).

[253] Mathilde Cohen, The Law of Placenta, 31 Yale Journal of Law and Feminism 337 (2020).

[254] *https://parentsguidecordblood.org/en/news/your-placenta-rights-under-us-state-laws.*

[255] *https://journals.sagepub.com/doi/10.2350/13-05-1338-OA.1.*

treatment, and being able to request or refuse treatment. The CAH clinical records CoP at § 485.638(a)(4)(i)) requires, for each patient receiving healthcare services, a record that includes, as applicable, evidence of properly executed informed consent forms. However, there are no existing CoPs related specifically to the collection of birth tissues.

This differs from the regulatory framework applicable to organs and tissues collected for transplantation. For example, § 485.643 establishes specific requirements for organ, tissue, and eye procurement, including requirements related to CAH's agreements with organ procurement organizations, tissue banks, and eye banks and policies governing the donation process. Of note, hospitals are not required to have a relationship with birth tissue procurement organizations or birth tissue banks. Organs and tissues collected for transplantation are therefore subject to an established regulatory framework and associated donation and consent process. The existing CAH CoPs do not establish comparable requirements specifically addressing the collection and disposition of birth tissues following a live birth, including circumstances in which tissues may be retained by the patient or collected, donated, transferred, stores, or used for purposes other than transplantation.

We believe that decisions involving the collection, storage, donation, banking, transfer, or release, or discarding of birth tissues may implicate important patient interests and rights and therefore warrant additional transparency and informed decision-making protections. Unlike many other biological materials generated during the course of medical care, birth tissues may have unique cultural, religious, personal, or familial significance to patients and their families.[256] At the same time, birth tissues may also have medical, research, or other uses that can involve their collection or transfer to entities outside of the hospital. These characteristics distinguish birth tissues from both biological materials routinely discarded in the course of medical care and organs and tissues collected through established transplantation and donation processes. Therefore, families giving birth at CAHs may reasonably wish to understand whether such tissues will be discarded, available for them to retain, used for research purposes, transferred to third parties, stored for future use, or otherwise utilized in commercial activities.

Moreover, because of the concerns discussed previously about inappropriate clinical use and profiteering, transparency is particularly important when a CAH participates in a program or arrangement through which birth tissues may be donated, transferred, banked, stored, or used by a third party and/or for commercial purposes. We believe that patients have the right to the information necessary to make an informed decision about consenting to these uses of personal birth tissues and biological materials associated with their deliveries.

CMS understands that many CAHs may already have policies around informed consent and allow patients to request retention or release of birth tissues, subject to State law, infection prevention and control requirements, and clinical circumstances.[257] However, practices may vary, and patients may not know whether, when, or how to make such a request. Some CAHs may rely on general consent forms or internal policies governing the handling and disposal of medical waste that do not clearly inform patients about possible collection, transfer, storage, donation, commercial use, or disposition of birth tissues, or about the options available to request retention. Variation in these processes can create uncertainty for patients, staff, and CAHs.

We believe that establishing new requirements to address these variations would strike the appropriate balance between improving transparency, creating consistent patient expectations and ensuring that no CAH is compelled to collect, bank, donate, or release tissues in circumstances that would be unsafe, unlawful, or inconsistent with clinical care.

c. Proposed Scope and Definition of Birth Tissues (§ 485.649(c))

Mothers who give birth in CAHs that furnish OB services should have baseline protections regarding informed decision-making, documentation, and safe handling of their birth tissues when the hospital engages in birth tissue collection, storage, donation, banking, transfer, or release. To advance this goal, we propose to add new standards at § 485.649(c). As noted earlier in this section, we are proposing to remove the current requirements at § 485.649(c) and replace them with new standards that build on the CoPs for obstetrical services. These new standards address informed consent for birth tissue collection and patient requests for retention or release of birth tissues.

We propose to add a new standard to the OB Services CoP at § 485.649(c), titled ''Birth tissue collection.'' Facilities that furnish obstetrical services vary widely in their involvement with birth tissues. For example, some CAHs are deeply involved in birth tissue activities, including operating or sponsoring public cord blood donation programs, contracting with third-party collection or tissue procurement entities, or facilitating private banking arrangements. Others have more limited involvement, such as occasionally receiving requests to retain or release birth tissues to the patient for cultural, religious, or personal uses or to a private third-party for personal future medical uses, research, or donation, even where no formal relationship exists between the CAH and the third party. To account for this variation, the proposed standard would apply to only those CAHs that furnish obstetrical services and participate in one or more activities related to birth tissues including collection, storage, donation, banking, transfer, or release to patients. For purposes of this standard, we interpret participation to include hospital-sponsored, hospital-operated, or hospital-facilitated activities, that is, any instance in which the CAH's personnel, premises, policies, or processes are used in connection with the collection, packaging, storage, transfer, banking, donation, or release birth tissues. Facilities that do not engage in any of these activities would not be subject to the proposed standard.

Furthermore at § 485.649(c), we propose to define ''birth tissues'' to capture the materials most commonly associated with live childbirth that may be collected, retained, stored, donated, banked, transferred, or released for personal, clinical, research, and/or commercial purposes. For purposes of this proposed rule, birth tissue is limited to tissue or biological material obtained in connection with labor and delivery resulting in a live birth. This proposal does not apply to tissue or biological material obtained in other clinical circumstances. Specifically, we propose to define ''birth tissue'' as ''human cells, tissues, and cellular and tissue-based products obtained during or immediately following labor and delivery, (including cesarean-section delivery), such as umbilical cord blood, umbilical cord tissue, placenta, amniotic membrane, amniotic fluid,[258]

[256] Mathilde Cohen, The Law of Placenta, 31 Yale Journal of Law and Feminism 337 (2020).

[257] *https://journals.sagepub.com/doi/10.2350/13-05-1338-OA.1.*

[258] CMS acknowledges that the inclusion of amniotic fluid within ''birth tissues'' definition

and other tissues or biological materials associated with live childbirth.'' This definition is intended to avoid gaps in patient protections that could arise if the rule addressed only one category of birth tissue, such as cord blood, while other tissues were collected, transferred, released, or disposed of under less transparent processes. This definition is also intended to be flexible enough to accommodate changes in collection practices and terminology over time. Importantly, our definition is not intended to conflict with or alter FDA definitions or classifications of human cells, tissues, and cellular or tissue-based products (HCT/Ps) under FDA authorities or other similar FDA terminology, which remain controlling for purposes of FDA regulation.[259]

Similarly, CMS' definition of birth tissues is not intended to conflict with or alter NIH's definitions or policies as it relates to this or similar topics. Lastly, we note that nothing in this proposal limits or impairs a family's ability to receive their stillborn child for the purposes of holding, mourning, or making funeral arrangements. Such activities are regulated under State and local law, and hospital specific policies.[260] Furthermore, such scenarios are beyond the scope of this regulation, which applies only to live births.

d. Proposals for Informed Consent (§ 485.649(c)(1))

At proposed § 485.649(c)(1), we would require that the CAH ensure that it obtains informed consent from the patient or the patient's representative prior to the collection, storage, donation, transfer, banking, or release to patients of birth tissues, consistent with the CAH's scope of services and role in those activities. The consent must be documented consistent with the clinical records requirements at § 485.638(a)(4)(i).

Consistent with the phrase ''scope of services and role in those activities'' in proposed § 485.649(c)(1), the obligations under this proposal would be tailored to the specific activities in which the hospital participates. The proposal would not require CAHs to offer new services, to purchase or provide new equipment, or initiate or sponsor a collection program, private banking arrangement, or other birth tissue collection program. Rather, it would require only that when a hospital furnishes obstetrical services and participates in a covered birth tissue activity, the hospital maintains appropriate consent, documentation, policies, procedures, and safe handling processes commensurate with its scope of services and role in that activity. For example, a hospital that operates a public cord blood collection program would be expected to ensure that its consent process includes the information and disclosures applicable to public donation. In contrast, a hospital that does not participate in a public cord blood collection program and is only collecting birth tissue in response to an individual patient's request for release of a placenta for personal or cultural reasons would be expected to document the request and release decision consistent with its policies and provide safe handling instructions.

We propose that the informed consent process include, as applicable, six categories of information: (1) a description of the birth tissues to be collected; (2) the intended use, including commercial and research uses, of the birth tissues; (3) disclosure of any third-party involvement and conflicts of interest; (4) information regarding risks, limitations, and infection prevention and quality control considerations; (5) notice that a patient's refusal to provide informed consent will not affect access to care or treatment; (6) and any other information required under applicable Federal or State law. These elements establish a baseline and are not intended to prescribe a single consent form or process for all CAHs or activities. For example for relevant research purposes, HHS' Federal Policy for the Protection of Human Subjects (also known as the Common Rule; codified at 45 CFR part 46 (Authority: 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v–1(b)) [261] [262] may also apply, such as Institutional Review Board (IRB) review, additional informed consent requirements, and specific protections for pregnant women, fetuses, and neonates (subparts B and D), inclusive of certain birth tissues such as the placenta.[263] CMS acknowledges the importance of research related to birth tissues [264] [265] and views this proposed rule as in alignment with the Common Rule and not as a replacement for such standards. This proposed rule would therefore defer to Common Rule standards related to exempted or waived research activities. Additionally, facilities retain the flexibility to adapt their consent processes to reflect their specific scope of services and patient needs in alignment with local, State, and Federal law and regulations.

Birth tissues may move through complex supply chains and may have research, clinical, manufacturing, or commercial value. We propose at § 485.649(c)(1)(i) and (ii) requirements for disclosure to ensure that patients and families fully understand how collected tissues may be transferred to a third party, processed into a product, sold, used in research, banked for future use, or discarded if quality criteria are not met. Patients must be informed if a

differs from FDA's definition of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P). Namely, that amniotic fluid is not an HCT/P for FDA regulatory purposes. See 21 CFR 1271.3(d)(3). See also FDA's July 2020 guidance entitled ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal*), on page 15 states ''Secreted body fluids (*e.g.,* amniotic fluid) are generally not considered HCT/Ps'' per the definition of HCT/P in 21 CFR 1271.3(d). However, CMS for its regulatory purposes includes amniotic fluid within its definition of ''birth tissue'' based on current practices regarding collection of such material and the CMS definition is not intended to incorporate FDA's definition in 1271.

[259] FDA regulations define human cells, tissues, or cellular or tissue-based products (HCT/Ps) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. See 21 CFR 1271.3(d). FDA does not define or use the term ''birth tissue'' in 21 CFR part 1271, its 2007 Donor Eligibility Guidance (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/eligibility-determination-donors-human-cells-tissues-and-cellular-and-tissue-based-products*), or its Minimal Manipulation/Homologous Use guidance (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal*). In January 2025, FDA issued draft guidance entitled ''Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-determining-eligibility-donors-human-cells-tissues-and-cellular-and-tissue-based*). This document uses the term ''gestational cells or tissues.'' Differences may exist between FDA's definitions of HCT/Ps and ''gestational cells or tissues'' and CMS' definition of ''birth tissues,'' as CMS is not intending to incorporate FDA's definition into this rulemaking. CMS chose to define and use the term ''birth tissue'' because it is already familiar to tissue establishments and to hospitals that contract with them. Since this proposed CoP would regulate facility-patient interactions, as well as facility policies, documentation, and processes related to informed decision-making and the safe release of birth tissues, CMS chose terminology that is familiar to the affected industry.

[260] *https://stacks.cdc.gov/view/cdc/80634/cdc_80634_DS1.pdf.*

[261] *https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.*

[262] *https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.*

[263] *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-B/section-46.206.*

[264] *https://www.nichd.nih.gov/sites/default/files/inline-files/STILLBIRTH_WG_REPORT_03152023.pdf.*

[265] *https://pubmed.ncbi.nlm.nih.gov/36180175/*'' *https://pubmed.ncbi.nlm.nih.gov/36180175.*

hospital and/or third party will be financially compensated for the procurement, facilitation, transfer, end use or other activity regarding collected tissues. Providing this information supports patient autonomy and empowers the patient to make a decision that reflects the patient's values and preferences.

We propose at § 485.649(c)(1)(iii) to require disclosure of (both not-for-profit and for-profit) third-party involvement and conflicts of interest. ACOG and AMA both recognize the importance of conflict-of-interest disclosure in cord blood banking.[266] Disclosure is particularly important when a hospital, practitioner, or other staff member has a financial contractual, ownership, employment, research, or other business relationship with a third party that could reasonably be viewed as influencing the presentation of delivery options to the patient (such as recommending a cesarean-section over a vaginal delivery) or when such a relationship could result in profit from the processing and sale of birth materials. Patients must receive sufficient information to understand third-party involvement and potential conflicts when they are making decisions about birth tissues associated with their deliveries. These components of the informed consent as required at proposed § 485.649(c)(1)(i) through (vi) are consistent with general informed consent principles and with professional guidance that emphasizes disclosure of financial interests.[267]

We propose at § 485.649(c)(1)(iv) to require information regarding risks, limitations, infection prevention, and quality control considerations. Depending on the activity, relevant information could include the possibility that collection may not be feasible because of maternal or neonatal clinical circumstances, that a specimen may fail to meet volume or quality criteria, that stored birth tissues may not be clinically useful in the future, or that releasing tissue for personal handling may involve infection prevention and storage considerations.

We also propose at § 485.649(c)(1)(v) that the patient be informed that refusal to provide informed consent will not affect access to care or treatment. Patients in labor or experiencing obstetrical emergencies may be vulnerable to time pressure or perceived pressure from clinicians, hospital staff, or third parties. Equally, the patient's decision to request collection or release of birth tissues does not obligate the hospital to provide services that are unsafe, unavailable, or inconsistent with State law or hospital policy. This is consistent with patient exercise of rights at § 485.614(b)(2).

We recognize that timing of consent in the labor and delivery context can be challenging. As previously discussed, the proposed requirements apply to birth tissue obtained during or immediately following labor and delivery resulting in live birth. The timing of the informed consent process does not alter the scope of tissues subject to this proposal. Prenatal education and consent are preferable when feasible, especially for planned donation or banking arrangements, but patients in labor may present without prior knowledge of their options or make key requests at admission or after delivery. Under these proposals, CAHs retain flexibility to design processes that are consistent with clinical practice, patient needs, State law, and the CAH's role provided that consent is obtained before the applicable birth tissue activity occurs whenever possible, and that collection or release activities does not interfere with clinical care (for example, pathologic examination of the placenta). Patient safety takes precedence in high-acuity or emergent circumstances.

Finally, we also recognize that, in some circumstances, a patient may independently arrange with a third-party tissue bank, private bank, courier, or other entity and may ask the hospital solely to accommodate collection or release. In such cases, the hospital is not expected to become an expert in the third party's products, business practices, marketing claims, or downstream uses. The hospital should have a process, consistent with its policies, to document the patient's request; confirm, as appropriate to the CAH's role, that the patient has provided authorization or evidence of the applicable third-party consent; and document the actions taken by the CAH to accommodate, accommodate subject to reasonable conditions, delay, limit, or deny the request based on clinical circumstances, infection prevention, and legal requirements. This approach supports patient choice while ensuring that the CAHs obligations remain proportional to the CAH's actual role and involvement. We note that FDA regulates human cells, tissues, and cellular-tissue based products, including birth tissues.

e. Proposed Policies and Procedures for Cultural, Religious, or Personal Uses (§ 485.649(c)(2))

At § 485.649(c)(2), we propose to require the CAH to have written policies and procedures that permit patients to request retention or release of birth tissues for cultural, religious, or personal reasons, consistent with State law and the CAH's infection prevention and control program requirements under § 485.640. Such policies and procedures would not require patients to provide justification or documentation for their respective cultural, religious, or personal reasons. We propose this requirement because requests for retention or release may arise in routine deliveries, scheduled cesarean deliveries, emergent deliveries, or other clinical contexts, and families and staff need clear procedures for safe, consistent collection and release of birth tissues.

The proposed policies and procedures would address four core topics. First, policies must address processes for patient requests for retention or release of birth tissues. We expect CAHs to specify how and when a patient or representative may make a request, who is responsible for receiving and documenting the request, what forms or authorizations must be completed, and how the hospital will communicate decisions regarding release to the patient. CAHs should design processes that are easily understandable and accessible for their patient population and align with clinical operations.

Second, the policies and procedures must address safe handling, packaging, storage, and release practices of birth tissues. For example, we expect CAHs to identify the personnel responsible for handling birth tissues, provide appropriate containers or packaging as needed in alignment with safe handling, clearly label each tissue container or package as appropriate, accommodate tissue storage pending release as requested by the patient, establish chain-of-custody or handoff processes where needed, and implement protocols for any circumstances requiring consultation with infection prevention personnel, pathology, risk management, or clinical leadership. These procedures should reflect the type of tissue, the intended use, the clinical circumstances, and the CAH's infection prevention and control program. Third,

[266] American College of Obstetricians and Gynecologists, Committee Opinion No. 771, Umbilical Cord Blood Banking (Mar. 2019), *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking;* American Medical Association, Code of Medical Ethics Opinion 6.1.5, Umbilical Cord Blood Banking, *https://code-medical-ethics.ama-assn.org/ethics-opinions/umbilical-cord-blood-banking.*

[267] American College of Obstetricians and Gynecologists, Committee Opinion No. 771, Umbilical Cord Blood Banking (Mar. 2019), *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking.*

we propose that policies and procedures must address circumstances under which retention or release may be limited or denied, including infection prevention and control concerns, biohazard risks, certain clinical conditions, emergency cases, or other applicable legal requirements, as discussed below:

• Infection Prevention and Control Concerns and Biohazard Risks

Suspected or confirmed infection, contamination, or other biohazard concerns may create unacceptable risks that warrant limiting or denying retention or release. Occupational Safety and Health Administration (OSHA) classifies human blood, certain body fluids, and unfixed human tissues and organs as potentially infectious materials.[268] Because placental and related birth tissues may contain blood and other biological material, CAHs would need to implement handling and packaging procedures to protect patients, staff, and others from potential exposure to bloodborne pathogens (for example, HIV, hepatitis B, hepatitis C, or other infectious agents).[269] CAHs must have processes to address safe handling, packaging, storage, and release when patients request retention or release of birth tissues. CAHs should also identify circumstances in which release may be limited or denied due to infection prevention and control concerns consistent with the CAH's infection prevention and control program under § 485.640.

• Certain Clinical Conditions

Retention or release may also be limited when tissue is needed for pathology review or other clinically appropriate diagnostic evaluation. Placental pathology may assist in the evaluation of adverse maternal, fetal, or neonatal outcomes, including fetal growth restriction, stillbirth,[270] infection, congenital abnormalities, preterm birth, placental insufficiency, maternal hypertensive disorders, or other complications of pregnancy and delivery. CAHs should identify in their policies the clinical circumstances under which retention for diagnostic purposes would take precedence over patient's requests for release. To the extent possible, patient requests should take precedence over circumstances under which hospitals may want to retain the placenta or other birth tissues for elective evaluation, research, or other purposes. Unless there are circumstances such as infection prevention concerns or a need for the hospital to retain the birth tissue for appropriate diagnostic evaluation, the patient's autonomy over their biological materials associated with their delivery should be prioritized.

• Emergency Cases

Patient safety takes precedence in all emergency circumstances in which staff cannot safely collect, process, or release birth tissues due to emergent patient care needs. Collection, storage, donation, banking, transfer, or release activities of birth tissues should not delay emergency care, interfere with the clinical management of labor and delivery, or alter medically appropriate obstetric or neonatal practice.[271] [272] A hospital would not be expected to delay necessary clinical intervention to complete a birth tissue consent process or collection activity, and failure to collect birth tissue due to emergent clinical circumstances would not, by itself, constitute noncompliance. To the extent necessary, such consents may be obtained following resolution of the emergency and stabilization of the patient's condition.

• Other Applicable Legal Requirements

Retention, testing, handling, or disposition of birth tissue may also be limited or governed by applicable Federal, State, Tribal, territorial, or local law (see discussion of relevant state laws in Section II. A.5.). By defining these criteria in advance, CAHs provide patients and staff with clear expectations and transparent and consistent processes. These proposed requirements are intended to complement, not interfere with, a CAH's existing authority to retain birth tissues when clinically appropriate or otherwise required by law.

Fourth, at § 485.649(c)(2)(i)(D), we propose that the policies and procedures must address staff education regarding the CAH's procedures for responding to patient requests. This education is intended to be focused and practical. Staff who may receive or respond to requests to know how to identify the applicable policy, document the request, process the request safely and within their scope of services, and provide safe handling instructions when tissue is released.

Lastly, we propose at § 485.649(c)(2)(ii) that the hospital provide patients who request retention or release of birth tissues with instructions for safe handling, transport, storage, and disposition of the tissues, as applicable. These instructions should be understandable, practical, and tailored to the birth tissue and release context. For example, instructions might address the need to maintain tissue in a leak-proof container, avoid exposure to other patients or staff, refrigerate or otherwise store tissue as directed, use appropriate personal protective measures, or comply with applicable local disposition requirements. The proposed requirement would not require CAHs to supervise the patient's use after release, but it does require the hospital to provide instructions that support safe decision-making at the point of release.

In summary, these proposed requirements are intended to operate alongside, not in place of, other existing Federal and State authorities. FDA regulates human cells, tissue and cellular and tissue-based products (HCT/Ps) either under section 361 of the Public Health Service Act and 21 CFR part 1271 or under section 351 of the PHS Act and relevant sections of the FD&C Act as well as applicable regulations. HCT/Ps that do not meet the criteria to be regulated solely under section 361 of the Public Health Service Act and 21 CFR part 1271 are regulated as drugs, devices, and/or biological products.[273] FDA has issued guidance on minimal manipulation and homologous use. FDA also has taken compliance and enforcement actions addressing unapproved HCT/Ps, including products derived from birth tissues.

The proposed CoPs at § 485.649(c) occupies a narrower and distinct role, regulating the facility-patient interaction, facility policies, documentation, and processes for informed decision-making and safe release in Medicare and Medicaid participating CAHs. Nothing in this

[268] OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030. *https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030.*

[269] *https://www.cdc.gov/pregnancy-hiv-std-tb-hepatitis/php/screening/index.html.*

[270] *https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2020/03/management-of-stillbirth.*

[271] American College of Obstetricians and Gynecologists, Committee Opinion No. 771, Umbilical Cord Blood Banking (Mar. 2019), *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking.*

[272] American Medical Association, Code of Medical Ethics Opinion 6.1.5, Umbilical Cord Blood Banking, *https://code-medical-ethics.ama-assn.org/ethics-opinions/umbilical-cord-blood-banking.*

[273] Food and Drug Administration, Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff (July 2020), *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal.*

proposal determines whether any product is lawfully marketed or subject to FDA premarket review. Rather the purpose of the CoPs is to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating CAHs. In accordance with section 1864 of the Act, State surveyors assess CAH compliance with the conditions as part of the process of determining whether a hospital qualifies for a provider agreement under Medicare. Alternatively, under section 1865 of the Act, CAHs can elect to be reviewed instead by private accrediting organizations approved by CMS as having standards that meet or exceed the applicable Medicare standards and survey procedures comparable to those CMS requires for State survey agencies. Examples of survey and enforcement activities include review of facility policies and procedures, auditing of patient medical records, and interviewing facility leadership and staff.

We invite public comments on proposed § 485.649(c), including the scope of CAHs and activities to which the standard should apply; the proposed definition of birth tissues; the proposed informed consent standard; and the proposed policies and procedures for cultural, religious, or personal uses.

F. Adoption of the 2024 Edition of the Life Safety Code (National Fire Protection Association (NFPA) 101) and the 2024 Edition of the Health Care Facilities Code (National Fire Protection Association (NFPA) 99)

1. Background

a. Overview

CMS' oversight of Medicare and Medicaid-certified facilities includes ensuring the health and safety of patients, which involves establishing physical environment and fire safety standards. Building safety system standards are highly complex, technical, and beyond the expertise of CMS as a regulatory body. The National Fire Protection Association (NFPA) convenes technical experts with a vast breadth and depth of fire and building safety expertise to establish consensus-based standards, such as the Life Safety Code (LSC) (NFPA 101) and the Health Care Facilities Code (HCFC) (NFPA 99), and CMS adopts these standards by following the requirements for incorporation by reference. The LSC is a compilation of fire safety requirements for new and existing buildings and establishes minimum requirements for building design, construction, operation, and maintenance necessary to protect people from fire and related hazards. It is updated and published every 3 years.[274] HCFC is a compilation of requirements for the installation, inspection, testing, maintenance, performance and safe practices for facilities, material, equipment and appliances and is updated and published every 3 years by NFPA.

CMS adopts LSC and HCFC provisions through rulemaking. The Administrative Procedure Act (5 U.S.C. 553) requires CMS to follow notice-and-comment rulemaking before adopting, amending, repealing regulations. Since LSC and HCFC are incorporated into Federal regulations, updating to a newer edition constitutes a regulatory change which must go through rulemaking. The process typically begins when the NFPA issues a new edition of the LSC or HCFC, reflecting updated knowledge, best practices, and safety technologies. CMS then evaluates the provisions of the new codes to determine their applicability and impact on health care facilities that participate in Medicare and Medicaid programs. The LSC and HCFC provisions adopted by CMS establish minimum requirements for fire protection and support the emergency preparedness requirements for health care facilities. The codes adopted by CMS encompass critical areas that include, but are not limited to: building construction, fire detection and suppression systems, alarm and communication systems, electrical systems, medical gas and vacuum systems, and gas and electrical equipment. Compliance with the LSC and HCFC not only supports Federal health and safety requirements but also promotes consistency across facilities, reinforces fire emergency readiness, and upholds CMS' commitment to protecting the well-being of all occupants. The LSC and HCFC codes adopted by CMS in the CoPs apply to hospitals, LTC facilities, CAHs, REHs, ASCs, ICFs/IID, hospice inpatient care facilities, PACE centers, RNHCIs and ESRD facilities.

Participation in Medicare or Medicaid requires most provider and supplier types to be certified by CMS as meeting the Medicare Conditions of Participation (CoPs). The statutory basis for incorporating NFPA's LSC and HCFC into the regulations governing Medicare and, where applicable, Medicaid providers and suppliers rests on the authority of the Secretary general rulemaking authority as set forth at sections 1102 and 1871 of the Act, and more specifically the ''health and safety'' provisions applicable to each provider and supplier type, empowering the Secretary to issue regulations necessary for providing health care services, or more specifically for the health and safety of patients. In addition to these rulemaking authorities, sections 1819(d)(2)(B) and 1919(d)(2)(B) of the Act explicitly require Medicare and Medicaid LTC facilities to meet the provisions of the LSC, as specified by the Secretary in regulation.

On May 4, 2016 (81 FR 26872), we published a final rule, ''Fire Safety Requirements for Certain Health Care Facilities'' [275] that adopted the 2012 edition of the NFPA LSC and the 2012 edition of the HCFC, with the exception of chapters 7, 8, 12 and 13, which were not adopted. As such, facilities are currently required to comply with the 2012 editions of each code as part of the Medicare and Medicaid fire safety requirements. However, since the NFPA published the 2012 editions of the LSC and HCFC, there have been advances in safety and technology, and changes made to the LSC and HCFC. Newer buildings are typically built to comply with newer versions of the LSC and HCFC because State and local jurisdictions, as well as some accreditation programs, may adopt and enforce new versions of the code as they become available. This can result in confusion since, for example, a health care facility that was constructed or renovated in 2025 would likely be required by its State and local authorities to comply with a more recent edition of the LSC and HCFC, while also being required to comply with the 2012 edition of the LSC and HCFC to meet the CMS-established regulatory requirements. Additionally, in accordance with E.O. 14192 and E.O. 14219, CMS solicited and received interested parties' input through the 2025 deregulatory RFI.[276] Commenters stated that complying with two different editions of the LSC and HCFC at the same time can create conflicts, duplications, and inconsistencies that increase construction and compliance costs without any fire safety or patient care benefits. They also stated that since the publication of the 2012 edition of the LSC and HCFC, there have been significant advancements in technology, improved inspection, testing, and maintenance strategies and updated

[274] ''NFPA 101 Standard Development.'' National Fire Protection Association. *https://www.nfpa.org/codes-and-standards/nfpa-101-standard-development/101.* Accessed 5 February 2026.

[275] 81 FR 26872.

[276] ''Medicare Regulatory Relief | CMS.'' *Cms.gov,* 2025, *www.cms.gov/medicare-regulatory-relief-rfi. https://www.cms.gov/files/document/unleashing-prosperity-through-deregulation-medicare-program-request-information.pdf.* Accessed September 2025.

building design standards that have lessened the burden of managing health care facilities without compromising patient safety.

We believe that adopting the 2024 edition of the LSC (NFPA 101) and 2024 edition of the HCFC (NFPA 99), would simplify and modernize the construction and renovation process for affected health care providers and suppliers, reduce compliance-related burdens, and allow for more resources to be used for patient care.

b. Waivers

Specific provisions of the adopted NFPA codes may be waived by CMS, either based on facility-specific needs and circumstances or based on widely applicable variances. First, consistent with statutory authorities, the regulations have historically included Secretarial waiver authority to grant waivers of some provisions of the LSC and HCFC in facility-specific instances. For example, section 1861(e)(9) of the Act allows CMS the authority to determine which requirements are necessary for hospitals in general, based on the discretion implicit within the ''health and safety'' rules. By comparison, sections 1819(d)(2)(B)(i) and 1919(d)(2)(B)(i) of the Act explicitly allow CMS to grant LSC waivers for LTC facilities if such waivers do not adversely affect health and safety. State agencies or CMS-approved accreditation organizations (AO) may recommend a waiver; however, only CMS may grant them. Accordingly, all LSC and HCFC waiver requests recommended for approval by State agencies or AOs must be forwarded to CMS for consideration. A waiver may be granted for a specific LSC or HCFC requirement if we determine that—(1) the waiver would not adversely affect patient/staff health and safety; and (2) if meeting the requirement in question would place an unreasonable hardship on the facility. In cases where a facility has been cited for a LSC or HCFC deficiency during a survey, the provider or supplier may request a waiver recommendation from its State survey agency or CMS-approved AO as part of their certification survey plan of correction. The plan of correction is a written response that a facility must submit to the surveyor after deficiencies are identified. The State survey agency or AO reviews the request and makes a recommendation to CMS. CMS reviews the waiver request and the recommendation, along with any supporting evidence and makes the final decision. CMS would not grant a waiver if patient health and safety is compromised. The LSC recognizes alternative systems, methods, or devices approved as equivalent by the authority having jurisdiction as being in compliance with the LSC. CMS, as the authority having jurisdiction over certification, will determine equivalency through the waiver approval process.

c. Regulatory History

On January 10, 2003, we published a final rule ''Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities,'' [277] adopting the 2000 edition of the LSC. In that final rule, we required that all affected facilities meet the provisions of the 2000 edition of the LSC, with the exception of the code's permission for facilities to utilize roller latches on corridor doors in buildings that are fully protected by a sprinkler system. Regardless of its permissibility in the LSC, it was and remains in our position that roller latches on corridor doors are a safety hazard under all circumstances and we prohibit their use on corridor doors in all Medicare and applicable Medicaid facilities.

On September 22, 2006, we published a final rule ''Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities'' [278] to allow certain health care facilities to place alcohol-based hand rub (ABHR) dispensers in exit corridors under specified conditions. Alcohol-based hand rubs are part of hand hygiene strategies used by health care facilities to improve infection prevention and control efforts.[279]

This rule also required that LTC facilities, at a minimum, install battery-powered single station smoke alarms in resident rooms and common areas if their buildings were not fully sprinklered, or if the building did not have system-based smoke detectors. The smoke alarm policy was based on a Government Accountability Office (GAO) report entitled ''Nursing Home Fire Safety: Recent Fires Highlight Weaknesses in Federal Standards and Oversights,'' which examined two 2003 fires that resulted in 31 total resident deaths. The report specifically cited requiring smoke detectors in these facilities as one way to strengthen the requirements. On August 13, 2008, we published a final rule ''Medicare and Medicaid Programs; Fire Safety Requirements for Long Term Care Facilities, Automatic Sprinkler Systems'' [280] to require all LTC facilities to install automatic sprinkler systems throughout their buildings in accordance with the technical provisions of the 1999 edition of NFPA 13, *Standard for the Installation of Sprinkler Systems,* and to test, inspect, and maintain sprinkler systems in accordance with the technical requirements of the 1998 edition of NFPA 25, *Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems.* The August 2008 final rule required all LTC facilities to be equipped with sprinkler systems by August 13, 2013. This rule was also in response to the July 2004 GAO report on nursing home fire safety. On May 12, 2014 CMS published a final rule, ''Part II Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction'' [281] that allowed CMS to grant extensions of up to 2 years to the effective date of the sprinkler requirement for LTC facilities that were building a replacement facility or undergoing major modifications.

While the LSC is a set of fire protection and safety standards that addresses some aspects of accessibility in covered facilities, CMS must emphasize that the LSC is not an accessibility code, and compliance with the LSC does not ensure compliance with the requirements of section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112, Sept. 26, 1973) or the Americans with Disabilities Act (ADA) (Pub. L. 101–336, July 26, 1990). State and local government entities, including health care facilities, are required to comply with section 504 of the Rehabilitation Act of 1973 and Title II of the ADA. Section 504 of the Rehabilitation Act of 1973 prohibits discrimination against individuals with disabilities in programs and activities that receive Federal financial assistance, while Title II of the ADA prohibits discrimination against individuals with disabilities by State and local governments, requiring all public services, programs, and activities to be accessible. Places of public accommodation such as nursing homes and hospitals are required to comply with Title III of the ADA. Title III of the ADA prohibits discrimination based on disability in public accommodations and commercial facilities, requiring businesses and nonprofit service providers to ensure equal access to their goods, services, and facilities. For more information about the Americans with Disabilities Act (ADA), visit the

[277] 68 FR 1374.

[278] 71 FR 55326.

[279] ''Hand Hygiene in Healthcare Settings''. Centers for Disease Control and Prevention. 18 Mar. 2024, *https://www.cdc.gov/infection-control/hcp/hand-hygiene/.* Accessed 05 February 2026.

[280] 73 FR 47075.

[281] 79 FR 27106.

Department of Justice's ADA website at *https://www.ada.gov* or call 1–800–514–0301 (voice) or 1–833–610–1264 (TTY). For information about Section 504 of the Rehabilitation Act as it applies to recipients of HHS Federal financial assistance, visit the HHS Office for Civil Rights website at *https://www.hhs.gov/ocr.*

2. Proposed Provisions

a. Categorical Waiver Authority

As previously noted, CMS is required to use a notice-and-comment rulemaking process to adopt new editions of the LSC and HCFC, which can be a lengthy process. The NFPA updates each of its codes every 3 years, however, each new edition of the LSC and HCFC may not contain enough significant changes to warrant undergoing the rulemaking process. In the past, CMS has issued public notices in the form of sub-regulatory memoranda related to categorical waivers that permit greater provider flexibility by proactively granting them approval to comply with specific provisions from newer editions of the LSC or HCFC. A categorical waiver is narrowly focused on a single change in a newer edition of a code and is typically a faster alternative to rulemaking, which is used to adopt a newer edition of the LSC and HCFC in their entirety.

We are proposing to codify CMS' authority to issue categorical waivers in the regulatory text of each affected provider type. CMS may evaluate specific provisions of the code, determine that a waiver would arguably apply to all similarly situated facilities, and permit the use of specific provisions of a newer edition of the LSC or HCFC only when the provision would provide an equal or superior means of ensuring patient safety as compared to the provisions of the code editions adopted in regulation at that time. A facility that wishes to use a categorical waiver would have to formally elect to do so and document their decision. Waiver approval in these instances would be subject to CMS' review of documentation maintained by the facility, verification of the applicability of the waiver, and confirmation that the terms and requirements of the waiver have been implemented by the facility. Providers and suppliers that have formally elected and documented their decision to utilize a categorical waiver and are complying with the categorical waiver conditions would not be cited for non-compliance with the specific waived provisions of the edition of the LSC or HCFC adopted by regulation. In most cases such verification of compliance occurs when an onsite survey of the facility is conducted. We would clarify that in those cases where we have issued a prior public notice providing for a categorical waiver, a State survey agency or AO (as applicable) is not required to submit an advance recommendation to CMS for such a waiver to be approved.

b. Incorporation by Reference

In this rule we propose to incorporate by reference the following NFPA codes:

- The 2024 edition of the LSC (NFPA 101), issued August 25, 2023;
- The 2024 edition of the HCFC (NFPA 99), issued August 25, 2023, with the exception of Chapter 7, 8, 12, and 13 (see the discussion in paragraph (h) of this section);
- Tentative Interim Amendment (TIA)-24–1 to NFPA 99, issued August 25, 2023;
- TIA–24–2 to NFPA 99, issued August 25, 2023 and;
- The 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A), issued April 22, 2024.

The materials that we propose to incorporate by reference would be reasonably available to interested parties for inspection at CMS, 7500 Security Boulevard, Baltimore, MD 21244. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169–7471, *www.nfpa.org,* 1–800–344–3555. If any later changes in this edition of the Code are considered for incorporation by reference, CMS would publish appropriate notice in the **Federal Register**.

The 2024 edition of the LSC (NFPA 101) provides minimum requirements, with due regard to function, for the design, operation and maintenance of buildings and structures for safety to life from fire. Its provisions also aid life safety in similar emergencies.

The 2024 edition of the HCFC (NFPA 99), (including TIAs 24–1 and 24–2), with the exception of chapters 7 (Information Technology and Communications Systems), 8 (Plumbing), 12 (Emergency Management), and 13 (Security Management) provides minimum requirements for health care facilities for the installation, inspection, testing, maintenance, performance, and safe practices for facilities, material, equipment, and appliances, including secondary hazards associated with the primary hazards (see the discussion in paragraph (h) of this section); TIA 24–1 and TIA 24–2 include targeted revisions and clarifications to health care facility requirements.

The 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) is a guide that provides alternative methods to achieve compliance with LSC (NFPA 101). It is to be used in conjunction with the LSC (NFPA 101), not as a substitute.

c. Content Overview of the 2024 Edition of the LSC (NFPA 101)

The 2024 edition of the LSC (NFPA 101) includes new provisions that are vital to the health and safety of patients and staff. Our intention is to ensure that patients and staff continue to experience the highest possible degree of fire safety. As in previous sections of this proposed rule, the general term ''patient(s)'' refers to patient, clients, residents and all other terms used to describe the type of individuals receiving services in each facility type discussed in this section.

The following updated general requirements from the 2024 edition of the LSC (NFPA 101) apply to all occupancy chapters of the code unless otherwise stated, including what the LSC terms ''Health Care Occupancies (HCOs)'', ''Ambulatory Health Care Occupancies'' (AHCOs) and ''Residential Board and Care Occupancies'' (RBCOs). We propose to adopt the entirety of requirements of the 2024 edition of the LSC (NFPA 101) (with one exception, addressed in section II.F.1(e)). In this section we highlight some specific requirements that represent a significant change from the 2012 edition of the LSC or additions that constitute new requirements. Each of these changes and additions is discussed in detail in the following paragraphs. This section is not intended to represent a comprehensive list of requirements.

(1) Updated Requirements for Greater Alignment With Building/Fire Codes

NFPA revised the requirements in other NFPA documents (for example, NFPA 72, National Fire Alarm and Signaling Code) to better align with the requirements of the 2024 edition of the LSC (NFPA 101) which we believe will greatly reduce conflicts between design and construction standards and operational compliance requirements. By providing a clear and unified set of standards, jurisdictions could adopt the codes without modification, which in turn would reduce conflicts that might arise between the NFPA standards and State and local fire code requirements.

(2) New Integrated System Testing Requirements—Section 9.11.4

NFPA 4, Standard for Integrated Fire Protection and Life Safety System Testing, is currently referenced at section 9.11.4 of the LSC for high rise HCOs and AHCOs. Section 9.11.4 requires that the system test plans be set in place to test all integrated fire and life safety systems and how they work together. Currently, they are tested individually. Integrated testing will ensure systems are working end-to-end. For example, fire alarm systems must be able to control elevators. Fire alarm testing confirms that a signal is sent to the elevator controller, but it does not verify that the elevator responds and performs its required functions. In many buildings, the fire alarm system and the elevator controller are maintained by different vendors and tested under separate standards; however, NFPA 4 requires the facility to develop and implement a plan for integrated testing to verify that these systems function together as intended. This coordination is critical in health care settings where patients often cannot self-evacuate. By confirming that all interconnected systems work in sequence, NFPA 4 helps keep evacuation routes safe, maintain a safe environment, and support staff in moving or protecting patients during a fire or other emergencies. The new provision, Integrated Fire Protection and Life Safety System Testing for high-rise buildings at section 11.8.9, requires testing to be conducted in accordance with 9.11.4.2 and NFPA 4. Both new and existing high-rise buildings will be required to adhere to NFPA 4 for integrated testing. New high-rise buildings shall be required to conduct their integrated testing prior to issuance of a certificate of occupancy. Existing high-rise buildings shall conduct their integrated testing at intervals not exceeding 10 years unless otherwise specified in an integrated system test plan in accordance with NFPA 4.

(3) New Definition of Gross Floor Area (HCOs and AHCOs)—Sections 3.3.24.2.2 and 3.3.24.2.3

The new definition of ''gross floor area'' no longer requires the inclusion of stairs and shafts within the boundary of smoke compartments or suites to be included in the area calculation, thus changing the way in which the size of these areas are calculated. Revisions to suite size calculations relax requirements regarding the extent of smoke detection, the use of quick-response sprinklers, and direct supervision of occupants by trained staff. Gross floor area now takes into account outside walls and fire walls of a building and walls that bound an occupancy or incidental use area. Gross floor area excludes floor openings for atriums and communicating spaces. A specific definition for HCOs and AHCOs was added to clarify smoke compartment calculations. For HCOs and AHCOs, gross floor area does not deduct stairs, elevator shafts, or service shafts but still excludes atrium and communicating space openings. We believe the changes will continue to provide safe refuge for patients in health care structures who cannot self-evacuate during a fire or emergency.

(4) New Non-Required Fire Door/Frame Does Not Require Inspections—Section 4.6.12.4

Facilities have been required to perform annual fire door inspections even when they are located in barriers that are not required to have a fire-resistance rating, as the doors were interpreted to be a life safety feature ''obvious to the public.'' The 2024 edition of the LSC (NFPA 101), Section 4.6.12.4 states that doors and door frames located in barriers that are not required to have a fire-resistance rating under the life safety plans are also no longer required to comply with NFPA 80, *Standard for Fire Doors and Other Opening Protectives.* This change would alleviate the annual inspection and testing requirement of the door assembly and would remove the need to modify door labels to avoid the annual inspection and testing requirement. This change would reduce the burden on facilities by no longer requiring compliance with NFPA 80 for non-required fire doors and frames.

(5) New Security and Communications Systems Allowed in Stairs Requirements—Section 7.1.3.2.1(9)(c)

Section 7.1.3.2.1(9)(c), permits penetrations into an exit enclosure for security and communication systems, provided the pathways are installed in metal conduit. The new provision for means of egress at 7.1.3.2.1(9)(c) allows penetrations into *and* openings through an exit enclosure assembly for security and communication systems as long as they are installed in a metal conduit. This provision would enhance patient safety by ensuring that critical security and communication systems serving exit enclosures remain operational during an emergency.

d. New and Existing Health Care Occupancies—Chapter 18 and 19

The 2024 edition of the LSC (NFPA 101) introduces several important new provisions in Chapter 18, New Health Care Occupancies, and Chapter 19, Existing Health Care Occupancies, as discussed in the sections that follow immediately in this rule. We have provided the LSC citation and a description of the updated 2024 requirements at the beginning of each section discussed.

In the 2024 edition of the LSC (NFPA 101), a ''Health Care Occupancy'' is defined as any facility that provides inpatient care for four or more patients. However, CMS does not apply this LSC standard with respect to patient census numbers. Unless specifically noted, the requirements, conditions of participation, and conditions for coverage for all Medicare and Medicaid-participating health care providers and suppliers subject to these rules would apply on a facility basis, regardless of the size of the facility or the facility's patient census. These basic requirements are established to ensure a core level of safety and quality for all patients, regardless of where they receive health care services. We believe that patients in small facilities should be assured of the same level of fire safety as those in larger facilities. Therefore, we propose that this definition would be inapplicable to Medicare and Medicaid-certified facilities because all HCOs that provide care to one or more patients would be required to comply with the relevant requirements of the 2024 edition of the LSC (NFPA 101).

(1) New Alternate Care Sites (ACS) Requirements—Sections 18.1.1.1.10, 19.1.1.1.10

The 2024 edition of the LSC includes a new definition for ''alternate care site'' (ACS) (3.3.16). An ACS is defined as a building, structure, or portion thereof not currently being used for health care that is temporarily reoccupied, converted, constructed, or relocated for health care use during an urgent need in capacity to provide additional capability for an affected community. This provision permits the use of an ACS for health care during an urgent need to provide additional capability for communities. New and existing HCOs may allow an ACS to temporarily convert to an HCO with an approved fire emergency plan and comply with alternate construction, design, protection, operational, and occupancy classification requirements. The associated provisions are intended to address urgent surges in demand and ensure that affected communities have safe, code-compliant capacity during times of public health emergencies or other crises.

(2) New Clarity Around Suite Requirements—Sections 18/19.2.5.7.2.2 & 18/19.2.5.7.3.1and 18/19.2.5.7.2.4 & 18/19.2.5.7.3.3

Suite size and egress requirements have been clarified to make sure that requirements can be applied and enforced correctly. In both new and existing Health Care Occupancies, the requirements for means of egress from sleeping and non-sleeping suites (Sections 18/19.2.5.7.2.2 and 18/19.2.5.7.3.1) now allow additional options for providing a single exit access door in suites that would otherwise require two exit access doors. One of the exit access doors shall be permitted to be either an exit stair, exit passageway, exit door to the exterior or another suite (separated by corridor requirements in Chapters 18 and 19). The 2024 edition of the LSC (NFPA 101) also provides clarified guidance for HCOs on travel distance requirements within patient care sleeping and non-sleeping suites (Sections 18/19.2.5.7.2.4 and 18/19.2.5.7.3.3).

(3) New Requirements for Hazardous Areas—Sections 18.3.2.1.3 and 19.3.2.1.5

Requirements were added for new and existing HCOs regarding hazardous areas. Rooms used as sterile core areas supporting operating rooms and anesthetizing areas shall be considered hazardous areas and be protected by smoke partitions unless provided with automatic extinguishing systems; walls that limit the transfer of smoke; and doors with self-closing or automatic-closing devices. This is a patient safety requirement to ensure that hazardous areas are protected appropriately.

(4) New Carbon Monoxide (CO) Detector Requirements—Sections 18.3.2.5.3(15)/18.3.4.6

The 2024 edition of the LSC (NFPA 101) includes a new definition for CO alarms (3.3.14.1). CO alarms, whether single- or multiple-station, alert facility occupants to the presence of unsafe levels of CO within the facility. The 2024 edition of the LSC now requires facilities to have CO detection and warning equipment in accordance with NFPA 72, National Fire Alarm and Signaling Code, to enhance patient safety. Requirements for CO detection were added for cooking facilities open to the corridor, to ceilings of rooms containing fuel-burning appliances or fireplaces, and within 36 inches of the first air vent from fuel-burning heating, ventilation and air-conditioning (HVAC) systems in new HCOs. In addition, requirements for CO detection were also added where new residential board and care facilities that have communicating garages, fuel-burning appliances, or fuel burning fireplaces. Effective with the 2024 edition of the LSC (NFPA 101), new HCOs are required to have CO detection and warning equipment provided in accordance with NFPA 72 to increase patient safety. The new requirements apply to locations in facilities with fuel-burning appliances, fuel burning fireplaces, fuel burning HVAC systems, and attached garages.

(5) New Requirements for Coded Announcements Permitted for Fire Alarm Notification Appliances—Sections 18/19.3.4.3.1 & 20/21.3.4.3.1.2

Instead of fire alarm notification appliances (loud horns and strobe lights) that need to be activated, facilities are permitted to use coded announcements to staff. This should improve patient experience as the alarm notification appliances can startle patients and only signal something is wrong without providing context, while coded announcements support a patient-centered care environment. The fire alarm notification systems still need to be tested at intervals but not as frequently activated during fire drills. New and existing HCOs and new and existing AHCOs have revised the occupant notification requirements at sections 18/19.3.4.3.1 & 20/21.3.4.3.1.2 of the LSC (NFPA 101) to permit the omission of notification appliances in patient care spaces. The requirement is applicable where alarm notification would adversely affect patient care and the private operating mode (the mode in which only staff or key personnel responsible for initiating and directing emergency actions are notified) is utilized in accordance with NFPA 72, National Fire Alarm and Signaling Code.

(6) New Requirements for Subdivision of Building Spaces—Sections 18.3.7.1 and 19.3.7.1, 20.3.7.2 and 21.3.7.2

New and existing HCOs smoke compartment maximum size has increased to 40,000 square feet where the building is protected by quick-response or listed residential sprinklers, sleeping rooms are configured for only one patient or contain no sleeping rooms, and the maximum travel distance from any point to reach a door in the required smoke barrier does not exceed 200 feet. In existing hospitals, standard-response sprinkles are permitted to continue to be used in approved existing sprinkler systems where quick-response and residential sprinklers were not listed for use at the time of installation. This requirement allows for new and existing HCOs to have more flexibility with the designs of hospital smoke compartments.

(7) New Increased Maximum Allowable Sizes for Soiled Linen and Trash Receptacles Requirements—Sections 18/19.7.5.7.1/.2

The 2024 edition of the LSC (NFPA 101) states the maximum allowable size of soiled linen and trash receptacles not located in hazardous area enclosures increased from 32 gallons to 64 gallons. This modification made the requirement consistent with the threshold for a room storing soiled linen or trash to be considered a hazardous area. Additionally, the 2018 edition of the LSC (NFPA 101) removed the restriction limiting the capacity of containers within any 64-square-foot area, thus improving flexibility for environmental services staff. The container density criteria requirements from Sections 18/19.7.5.7.1/.2 were removed from new and existing HCOs and AHCOs. Also, the capacity for soiled linen or trash collection receptacles increased from 32 gallons to 64 gallons and they are required to be located in a hazardous area when not attended. Two exceptions apply to receptacles used solely for the purpose of recycling of clean waste or patient records awaiting destruction, which have a maximum capacity of 96 gallons and are required to be labeled and listed in accordance with FM Approvals 6920/6921. FM (Factory Mutual) Approval is a certification system that verifies the performance and safety of products and systems.

(8) Requirements for High-Rise Building Containing HCOs

The 2012 edition of the LSC (NFPA 101), which was adopted in the CMS final rule titled, *Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities,*[282] required existing HCOs in a high rise building to be fully sprinklered. The LSC allowed for a 12-year phase-in period for compliance., which began on the day of publication of the final rule. Considering the CMS adoption of the 2012 edition of the LSC (NFPA 101), became effective on July 5, 2016, high-rise buildings containing existing HCOs (for example, hospitals, LTC facilities, inpatient hospice) must be compliant by July 5, 2028. Requiring existing HCOs in high-rise buildings to be fully sprinklered improves patient safety by providing rapid, automatic fire suppression close to the source of ignition. In health care settings, many patients cannot self-evacuate, so

[282] 81 FR 26872.

delaying or containing to allow time for the relocation or protection of patients. This requirement would remain unchanged.

e. Roller Latches—Sections 18.3.6.3.9.1 and 19.3.6.3.5

As previously stated, on January 10, 2003, we published a final rule in the **Federal Register** (68 FR 1374) adopting the 2000 edition of the LSC. In that final rule, we required that all affected facilities meet the provisions of the 2000 edition of the LSC, with certain exceptions. One of the exceptions to the 2000 edition of the LSC is the code's use of roller latches on corridor doors in buildings that are fully protected by a sprinkler system. A roller latch is a type of door latching mechanism to keep a door closed. Through fire investigations, roller latches have proven to be an unreliable door latching mechanism requiring extensive maintenance to operate properly. Many roller latches in fire situations failed to provide adequate protection to residents in their rooms during an emergency. Roller latches that are not properly maintained may be a danger to the health and safety of patients and staff. In addition, we found through our online survey, certification, and reporting (OSCAR) system data report that doors that include roller latches are consistently one of our most cited deficiencies. In fact, in skilled nursing facilities roller latches in corridor doors are consistently the number one cited deficiency under the life safety requirements.

The 2024 edition of the LSC (NFPA 101) requires corridor doors to be provided with a means for keeping the door closed that is acceptable to the authority having jurisdiction. The LSC permits roller latches capable of keeping the door fully closed if a force of 5 pounds is applied at the latch edge or roller latches in fully sprinklered buildings.

Regardless of its permissibility in the LSC, it was and remains our position that roller latches on corridor doors are a safety hazard under all circumstances and CMS prohibits their use on corridor doors. Therefore, we propose to continue prohibiting the use of roller latches in existing and new HCOs for corridor doors, excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the LSC.

f. New and Existing Ambulatory Health Care Occupancies—Chapters 20 and 21 [283]

In this section we describe select new provisions in Chapter 20, ''New Ambulatory Health Care Occupancies'' and Chapter 21, ''Existing Ambulatory Health Care Occupancies,'' of the 2024 edition of the LSC (NFPA 101). This discussion is intended to provide a high -level overview of the changes and additions from the 2012 edition that we have determined to be the most impactful to patient safety and enhancing provider flexibility, and most relevant to provider compliance interests. We have provided the LSC citation and a description of each selected requirement at the beginning of each section discussed.

The 2024 edition of the LSC (NFPA 101) defines an ''Ambulatory Health Care Occupancy'' as a facility capable of treating 4 or more patients simultaneously on an outpatient basis. However, CMS does not apply any patient census standard to its enforcement of the LSC regulations. The CMS regulations, including the LSC as incorporated by reference, apply to a regulated facility regardless of its size. CMS regulations for ASCs at *https://www.ecfr.gov/current/title-42/section-416.4442* CFR 416.44 require that all ASCs meet the provisions applicable to AHCOs, regardless of the number of patients served. We believe that hospital outpatient surgical departments are comparable to ASCs and thus propose that they should also be required to meet the provisions applicable to AHCOs in chapters 20 and 21 of the LSC (NFPA 101), regardless of the number of patients served.

(1) New Coded Announcements Permitted for Fire Alarm Notification Appliances Requirements—Sections 20/21.3.4.3.1.2

Instead of needing to activate fire alarm notification appliances (loud horns and strobe lights), facilities are permitted to use coded announcements to staff. This should improve patient experience as the alarm notification appliances can startle patients and only signal something is wrong without providing context, while the coded announcements support a patient-centered care environment. The fire alarm notification system still needs to be tested at intervals but not as frequently activated during fire drills. New and existing HCOs and new and existing AHCOs have revised the occupant notification requirements at section 20/21.3.4.3.1.2 of the LSC (NFPA 101) to permit the omission of notification appliances in patient care spaces. The requirement is applicable where alarm notification would adversely affect patient care and the private operating mode (the mode in which only staff or key personnel responsible for initiating and directing emergency actions are notified) is utilized in accordance with NFPA 72, National Fire Alarm and Signaling Code.

(2) New Carbon Monoxide (CO) Detectors Requirements—Section 20.3.4.5

The 2024 edition of the LSC (NFPA 101) includes a new definition for CO alarms (3.3.14.1). CO alarms, whether single- or multiple-station, alert facility occupants to the presence of unsafe levels of CO within the facility. The 2024 edition of the LSC now requires facilities to have CO detection and warning equipment in accordance with NFPA 72, National Fire Alarm and Signaling Code, to enhance patient safety. Requirements for CO detection were added for cooking facilities open to the corridor, to ceilings of rooms containing fuel-burning appliances or fireplaces, and within 36 inches of the first air vent from fuel-burning HVAC systems in new HCOs. In addition, requirements for CO detection were also added where new residential board and care facilities that have communicating garages, fuel-burning appliances, or fuel burning fireplaces. Effective with the 2024 edition of the LSC (NFPA 101), new AHCOs are now required to have CO detection and warning equipment provided in accordance with NFPA 72 to increase patient safety. The new requirements apply to locations in facilities with fuel-burning appliances, fuel burning fireplaces, fuel burning HVAC systems, and attached garages.

(3) New Requirements for the Subdivision of Building Spaces—Sections 20.3.7.2 and 21.3.7.2

New and existing AHCOs smoke compartment maximum size has increased to 40,000 square feet (3720 square meters) where the building is protected throughout by an automatic sprinkler system. This requirement allows for design flexibility and reduces burden.

[283] Ambulatory Health Care Occupancies include ambulatory surgical centers (ASC), Hospital Outpatient Surgical Departments, end-stage renal disease (ESRD) Facilities, rural emergency hospitals (REHs). This could also include separated sections of buildings that meet the LSC definition of an Ambulatory Health Care Occupancy and are separated in accordance with the LSC (for example, Hospital Emergency Room).

(4) New Increased Maximum Allowable Sizes for Soiled Linen and Trash Receptacles Requirements—Sections 20/21.7.5.5.1/.2

The 2024 edition of the LSC (NFPA 101) states the maximum allowable size of soiled linen and trash receptacles not located in hazardous area enclosures increased from 32 gallons to 64 gallons. This modification made the requirement consistent with the threshold for a room storing soiled linen or trash to be considered a hazardous area. Additionally, the 2018 edition of the LSC (NFPA 101) removed the restriction limiting the capacity of containers within any 64-square-foot area, thus improving flexibility for environmental services staff. The container density criteria requirements from sections 18/19.7.5.7.1/.2 and 20/21.7.5.5.1/.2 were removed from new and existing HCOs and AHCOs. Also, the soiled linen or trash greater than 64 gallons (an increase from 32 gallons) are required to be located in a hazardous area when not attended. Two exceptions apply to receptables used solely for the purpose of recycling clean waste or patient records awaiting destruction, which may have a maximum capacity of 96 gallons and must be labeled and listed in accordance with FM Approvals 6920/6921. FM Approval is a certification system that verifies the performance and safety of products and systems.

(5) New Requirements for High-Rise Buildings—Section 21.4.3.1

The 2024 edition LSC includes a provision requiring existing high-rise buildings containing AHCOs to be protected throughout a complete, approved, supervised automatic sprinkler system within 12 years of the adoption of the Code. This requirement improves patient safety throughout an existing high rise building that contains an AHCO.

(6) Removal of Requirement: Doors to Hazardous Areas—Section 20.3.2.1/21.3.2.1

We propose to remove an obsolete requirement for ambulatory surgical centers (ASCs) at § 416.44(b)(6) regarding doors to hazardous areas. ASCs were required to be in compliance with this requirement by July 5, 2017. All existing and new ASCs must meet this requirement pursuant to the LSC; therefore, continuing to specify this requirement in our regulations is redundant and no longer necessary.

g. New and Existing Residential Board and Care Occupancies (RBCOs)—Chapters 32 and 33 [284]

The 2024 edition of the LSC (NFPA 101) classifies ''board and care'' as a facility ''used for lodging or boarding of 4 or more patients not related to the owners or operators by blood or marriage, for the purpose of providing personal care services.'' However, CMS does not apply any patient census standard to its enforcement of its regulations, including the regulation that incorporates the LSC by reference. As such, CMS will continue to enforce the LSC for residential board and care occupancies of all sizes. We note that the only CMS-regulated facilities that would be subject to these provisions would be intermediate care facilities for individuals with intellectual disabilities (ICFs/IID), whose health and safety standards are regulated under 42 CFR part 483, subpart I.

The following are new key provisions that appear in the 2024 edition of the LSC (NFPA 101) for Chapter 32, ''New Residential Board and Care Occupancies'' (RCBOs) and Chapter 33, ''Existing Residential Board and Care Occupancies.'' We are providing the LSC citation and a description of the requirement at the beginning of each section discussed.

(1) New Carbon Monoxide (CO) Detectors Requirements—Sections 32.2.3.4.4/32.3.3.4.9

A definition of CO alarm extracted from NFPA 72, National Fire Alarm and Signaling Code, was added to support new requirements. Requirements for CO detection were added for cooking facilities open to the corridor, to ceilings of rooms containing fuel-burning appliances or fireplaces, and within 36 inches of the first supply air register from fuel-burning HVAC systems in new health care occupancies. In addition, requirements for CO detection were also added where new residential board and care facilities that have communicating garages (garage space that directly connects with another portion of the building through a doorway, passage, or a common wall), fuel-burning appliances, or fuel burning fireplaces. Certain exceptions apply to New RBCOs for unattached garages, open parking structures, and mechanically ventilated attached garages. NFPA 101 extracted the definition (located in section 3.3.14.1) from NFPA 72 to align with the new requirements. New RBCOs are now required to have CO detection and warning equipment provided in accordance with NFPA 72 to increase patient safety.

(2) New Cooking Facilities Requirements—Sections 32.3.3.8 and 33.3.3.8

The 2024 edition of the LSC (NFPA 101) added exceptions for new *large* RBCOs—defined as facilities providing sleeping accommodations for more than 16 residents—that exempt certain cooking facilities from protection as commercial cooking equipment in accordance with NFPA 96, Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations. The changes provide greater flexibility for cooking facilities designed for residential use in RBCOs, removing the need for them to meet full commercial kitchen fire protection standards. In addition, these same requirements and exceptions now apply to existing large RBCOs, except where the cooking installations are approved existing installations. Those approved installations are permitted to remain in service in accordance with section 9.2.3. The exceptions added for RBCOs in the 2024 edition of the LSC (NFPA 101) will provide additional patient safety and reduce burden.

(3) New Requirements for Portable Fire Extinguishers—Section 33.3.3.5.7

The 2024 edition of the LSC (NFPA 101) has revised the portable fire extinguishers requirements in large (meaning sleeping accommodations for more than 16 residents) existing RBCOs to be provided throughout rather than only near hazardous areas. There was no change to the portable fire extinguisher requirements in new RBCOs. These revised requirements will provide additional patient safety.

(4) Removal of Obsolete Requirements

We are proposing to remove two obsolete requirements for ICFs/IID. At § 483.470 (j)(1)(iv) and § 483.470 (j)(5)(iv), ICFs/IID were required to be in compliance with the requirements regarding sprinklers and heat detection systems in attics on and after July 5, 2019. All existing and new ICFs/IID must meet this requirement pursuant to the LSC; therefore, continuing to specify this requirement in our regulation is redundant and no longer necessary.

h. 2024 Edition of the Health Care Facilities Code (NFPA 99)

The 2024 edition of the HCFC (NFPA 99) addresses requirements for both health care occupancies and ambulatory care occupancies and serves as a

[284] Facilities deemed to be ICFs/IID would fall under the Residential Board and Care Occupancies (RBCOs) per the NFPA.

resource for those who are responsible for protecting health care facilities from fire and associated hazards. The purpose of this Code is to provide minimum requirements for the installation, inspection, testing, maintenance, performance, and safe practices for health care facility materials, equipment and appliances. The HCFC is a compilation of documents that have been developed over a 40-year period by NFPA and is intended to be used by those persons involved in the design, construction, inspection, and operation of health care facilities, and in the design, manufacture, and testing of appliances and equipment used in patient care areas of health care facilities. It provides information on various subjects, such as medical gas and vacuum systems, electrical systems, electrical equipment, and gas equipment. The HCFC applies specific requirements in accordance with the results of a risk-based assessment methodology. A risk-based approach allows for the application of requirements based upon the types of treatment and services being provided to patients or residents rather than the type of facility in which they are being performed.

To ensure the minimum level of protection afforded by the HCFC is applicable to all patient and resident care areas within a health care facility, CMS is proposing to incorporate by reference the 2024 edition of the NFPA 99 with the exception of chapters 7 (Information Technology and Communications Systems for Health Care Facilities); 8 (Plumbing); 12 (Emergency Management); and 13 (Security Management). We are not proposing to incorporate these chapters as we believe they are not within the scope of the CoPs and CfCs. In the following section, we describe selected provisions from the 2024 edition of the NFPA 99 that we have determined as the most significant in terms of patient health and safety. We are providing the HCFC citation and a description of the requirement at the beginning of each section discussed. The first three chapters of NFPA 99 address the administration of the HCFC, the referenced publications, and definitions.

(1) New Auxiliary Connection Requirements—Section 5.1.3.5.14

This new section of the 2024 edition of the NFPA 99 provides requirements for medical gases and vacuum systems to have auxiliary connections which allow emergency supply through a temporary source such as a truck in instances where there is an issue with the primary supply or where system maintenance requires shutdown of the source. This requirement provides additional patient safety features for health care facilities.

(2) New Oxygen Central Supply Systems Using Concentrator(s) Requirements—Section 5.1.3.9

This new section allows oxygen central supply systems to use an oxygen concentrator as one of the supply sources. Oxygen concentrators are engineered assemblies that concentrate oxygen from air to provide medical grade oxygen. This is a new form of technology allowed for health care facilities and provides additional patient safety.

(3) New Medical Gas, Vacuum, and Waste Anesthetic Gas Disposal Systems Requirements—Sections 5.1.10.1.4 and 5.1.10.2.1

This change allows for new piping corrugated medical tubing (CMT) material and is now permitted for medical gas, vacuum, and waste anesthetic gas disposal systems. CMT is flexible copper tubing that is externally coated with non-metallic fire-retardant sheath. Previously, only rigid copper tubing was allowed. Copper tubing cannot be bent and is typically brazed together, which is a specialized and labor-intensive process. CMT is typically provided in longer lengths than rigid copper tubing, is flexible requiring less cutting and fittings, and does not need to be brazed, making it more efficient and economical to install. In particular, CMT is beneficial for facilities undergoing renovations in reducing costs and time when an old system is taken out of service. This change would reduce burden, provide a new form of technology, and provide additional patient safety. This provision would enhance patient safety by lowering the risk of gas leaks, ensuring more reliable delivery of oxygen and medical gases to patients, and minimizing interruptions to critical gas and vacuum services.

(4) New Electrical Maintenance Program—Section 6.9

A new section has been added to NFPA 99 that includes requirements and prescriptive intervals for electrical system components that must undergo routine inspection, maintenance, and testing. It also consolidates existing requirements and guidance that were previously located in several sections of the code so that facilities can find a comprehensive list of minimum requirements for such a program. These requirements will reduce burden and provide patient safety by preventing electrical system failures that could disrupt patient care.

(5) New Health Care Microgrids—Section 6.10

NFPA 99 now permits normal and emergency power to be supplied by sources other than a generator or battery system, including a health care microgrid system (HCMS). HCMSs are small-scale personalized electrical networks with intelligent controls that can operate independently, or in tandem with a large-scale electric grid. The power sources for an HCMS can be provided or supplemented by a combination of alternative technologies such as fuel cells, solar panels, wind turbines, and energy storage systems. Microgrids provide a small-scale electrical network option that is tailored to each facility's needs. They are able to operate independently or with a larger electric grid. CMS issued a categorical waiver memo in March 2023 (QSO–23–11–LSC) to waive requirements in the 2012 edition of NFPA 99 that essential electric systems must be supplied by a generator or battery system, thus allowing for health care facilities to choose microgrids as a supply for essential electric systems when a microgrid best meets the needs of the facility. In proposing to adopt the 2024 edition of the NFPA 99, QSO–23–11–LSC could be rescinded as it would no longer be necessary.

(6) New Heliports Requirements—Section 16.8

A new requirement was added that references NFPA 418, Standard for Heliports, which establishes minimum fire safety requirements for the design, construction, maintenance, and operation of heliports.

i. Fire Safety Evaluation System (FSES, NFPA 101A)

On May 4, 2016, we published a final rule titled ''Fire Safety Requirements for Certain Health Care Facilities,'' adopting the 2012 edition of the LSC (NFPA 101). One of the references in the LSC is NFPA 101A, Guide on Alternative Approaches to Life Safety, also known as the Fire Safety Evaluation System (FSES). NFPA 101A is based on the most current LSC (NFPA 101) edition; therefore, it is published after NFPA 101.

The FSES is a scoring system in which points are scored based on predetermined criteria related to a facility's zone location, containment, extinguishment, and people movement. A facility that achieves a passing score on the FSES would be considered to meet the fire safety requirements for

Medicare and Medicaid certification and recertification in lieu of compliance with the LSC exactly as it is written. The FSES allow for flexibilities in the application of LSC standards to ensure equivalent fire safety protection when alternate materials, designs, or construction techniques are used in a particular facility. In 2017, CMS adopted the 2013 edition of the NFPA 101A by issuing a memo (QSO–17–15–LSC) [285] to permit the FSES option as an alternative approach to meeting the requirements of the LSC (NFPA 101) for health care occupancies and board and care occupancies. However, some LTC facilities that utilized the 2013 edition of the NFPA 101A to determine compliance with the containment, extinguishment and people movement requirements of the LSC were no longer able to achieve a passing score on the FSES due to a change in scoring methodology. To address this issue, in the August 2022 final rule (87 FR 47502), we finalized changes to § 483.90(a)(1)(iii) to allow LTC facilities that were Medicare or Medicaid-certified before July 5, 2016, and that had previously used the FSES to determine equivalent fire protection levels, to use the mandatory values from the 2001 edition of the FSES to meet the applicable requirements. This allowed existing LTC facilities that previously met the FSES requirements to continue to do so without incurring substantial financial burden to modify their construction type, while preserving the health and safety of residents and staff.

As we propose to adopt the 2024 edition of the LSC (NFPA 101), we are also proposing to adopt the 2025 edition of NFPA 101A. We propose to offer hospitals, LTCs, CAHs, ICFs/IID, hospice inpatient care facilities, PACE centers, and RNHCIs the option to use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) as a method to demonstrate compliance with the provisions of the 2024 edition of the LSC (NFPA 101). Additionally, the 2024 edition of the LSC the NFPA revised the requirements in such a way that, when applying the FSES standards to achieve equivalent compliance with the LSC standards, affected LTC facilities would now achieve a passing FSES score and be considered compliant with the CMS requirements. Therefore, we propose to remove the obsolete requirements set forth at § 483.90(a)(1)(iii). We have determined that the updated mandatory point value scoring contained within the 2025 edition of the NFPA 101A would allow the appropriate degree of flexibility for LTC facilities while assuring resident and staff safety.

j. Adoption of the 2022 Edition of the Standard for Emergency and Standby Power System (NFPA 110), the 2022 Edition of the Standard for the Installation of Sprinkler Systems (NFPA 13), and the 2023 Edition of the Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems (NFPA 25)

(1) Incorporation by Reference

In this rule we are proposing to incorporate by reference the following supporting standards, which are referenced by the 2024 edition of the LSC and HCFC:

- The 2022 edition of the Standard for Emergency and Standby Power Systems, NFPA 110, issued April 8, 2021;
- The 2022 edition of the Standard for the Installation of Sprinkler Systems, NFPA 13, issued April 15, 2021; and
- The 2023 edition of the Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, NFPA 25, issued September 1, 2022.

The materials that we propose to incorporate by reference would be reasonably available to interested parties and can be inspected at CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169–7471, 1–800–344–3555. If any later changes in this edition of the Code are considered for incorporation by reference, CMS would publish appropriate notice in the **Federal Register**.

k. 2022 Edition of the Standard for Emergency Standby Power Systems (NFPA 110)

The 2022 edition of the Standard for Emergency Standby Power Systems (ESPS) (NFPA 110) addresses performance requirements for emergency and standby power systems. These systems provide an alternate source of electrical power in buildings when the normal electrical power source fails. Emergency power systems are made up of several components that need to work together to make sure electrical power is restored. These include power sources, transfer equipment, controls, supervisory equipment, and accessory equipment needed to supply electrical power to the selected circuits. In addition, the 2024 edition of the NFPA 101 and NFPA 99 identifies the 2022 edition of ESPS (NFPA 110) as a mandatory reference, which establishes requirements for the installation, maintenance, operation, and testing of emergency and standby power systems Therefore, CMS is proposing to replace references to the 2010 edition of the ESPS (NFPA 110), including TIAs to chapter 7, issued August 6, 2009, with an incorporation by reference of the 2022 edition of the ESPS (NFPA 110), issued April 8, 2021. In the following section, we describe selected provisions that represent a significant change from the 2010 edition of the ESPS (2010) or additions that constitute new requirements.

(1) Chapter 5 Emergency Power Supply (EPS): Energy Sources, Converters, and Accessories

This chapter establishes requirements for the selection, installation, and operating conditions of energy sources (such as generators), temperature maintenance, fuel storage, and associated accessories that together make up the EPS.

Section 5.6.9.9, Generators, Exciters, and Voltage Regulators, specifies that the generator instrument panels for Level 1 applications must provide a voltage-adjusting feature to allow ±5 percent voltage adjustment and an AC kW or kVA meter to show total generator load. This requirement ensures that operators have immediate access to critical generator performance data for safe and effective monitoring during emergency operations.

(2) Chapter 7 System Design and Environmental Considerations

This chapter introduces enhanced clarity and requirements regarding the installation environment and service accessibility for Emergency Power Supply Systems (EPSS).

Section 7.2.6.1 mandates that generator sets installed in outdoor enclosures must provide a minimum of 0.9 meters (36 inches) of working space from the outside edge of the enclosure for inspection, repair, maintenance, cleaning, or replacement, or enough space to fully open all hinged doors, whichever is greater. This codifies best practices in system accessibility and safety, ensuring that maintenance personnel have unobstructed access to critical equipment components for reliable EPSS operation.

Section 7.13.5 provides comprehensive requirements for the acceptance testing of fuel cell–based Emergency Power Supply Systems

[285] ''Use of Fire Safety Evaluation System (FSES), National Fire Protection Association (NFPA 101A)''. *CMS.gov,* 2023, *https://www.cms.gov/files/document/17-15-lsc-revised.pdf.* Accessed April 2026.

(EPSS). This section mandates on-site acceptance testing protocols tailored to the unique operational characteristics of fuel cell technologies. It specifies that the EPSS must perform within the standard's limits, with compliance determined through a sequence of tests that simulate actual load conditions and system transfer responses. Key provisions include testing all fuel cell units with building load, documenting start-up timings, unit response, and all transfer switch operations. The tests also require at least 1.5 hours of continuous operation with either building or simulated loads. All voltage, frequency, amperage, and timing data must be recorded, and safeties specified to be verified on-site per manufacturer recommendations.

l. 2022 Edition of the Standard for the Installation of Sprinkler Systems (NFPA 13)

The 2022 edition of the Standard for the Installation of Sprinkler Systems (NFPA 13) provides the minimum requirements for the design, installation, and testing of automatic sprinkler systems to achieve a reasonable degree of protection for life and property from fire. In addition, the 2024 edition of the NFPA 101 and NFPA 99 identifies the 2022 edition of NFPA 13 as a mandatory reference. Therefore, CMS is proposing to incorporate by reference the 2022 edition of the Edition of the Standard for the Installation of Sprinkler Systems (NFPA 13) issued April 15, 2021, to replace the currently required 1999 edition of the code.

In the following section, we describe selected provisions that represent a significant change from the 1999 edition of the NFPA 13 or additions that constitute new requirements.

(1) Chapter 19, Design Approaches

Chapter 19, Design Approaches, provides comprehensive requirements for determining water demand and design approaches for spray sprinklers, detailing both hydraulic calculation and pipe schedule methods to address occupancy hazard fire control.

Section 19.2.3, Water Demand Requirements—Hydraulic Calculation Methods, governs water demand requirements using hydraulic calculation methods for occupancy hazard fire control. This section clarified and streamlined approaches for hydraulic calculations, distinguishing it from the pipe schedule method. It now emphasizes clearer requirements and organization for determining water demand, enhancing consistency and usability for design professionals in applying the hydraulic calculation method to extra hazard occupancies and other scenarios where appropriate.

(2) Chapter 30 Existing System Modifications

Chapter 30, Existing System Modifications, consolidated all requirements related to modifications of existing sprinkler systems into a single chapter. The requirements of this chapter apply if a system is being modified, added to, or repaired. This chapter provides clear and unified guidance improving both compliance and usability for system modifications. Previously approved or existing systems shall be allowed to remain in use as installed.

m. 2023 Edition of the Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems (NFPA 25)

The 2023 edition of the Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems (NFPA 25) establishes the minimum requirements for the periodic inspection, testing, and maintenance of water-based fire protection systems to ensure their operational readiness and provide a reasonable degree of protection for life and property from fire. In addition, the 2024 edition of the NFPA 101 and NFPA 99 identifies the 2023 edition of the NFPA 25 as a mandatory reference. Therefore, CMS is proposing to incorporate by reference the 2023 Edition of the Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems (NFPA 25), issued September 1, 2022, to replace the currently required 1998 edition of the code.

In the following section, we describe selected provisions that represent a significant change from the 1998 edition of the NFPA 25 or additions that constitute new requirements.

(1) Section 8.1.1.2 Fire Pump Inspection, Testing and Maintenance

Section 8.1.1.2 requires that the minimum frequency of inspection, testing, and maintenance for fire pumps must follow both the manufacturer's recommendations and Table 8.1.1.2, which summarizes these required activities and their frequencies. Table 8.1.1.2 is more comprehensive, including new items and maintenance tasks, expanded references to specific section numbers, and consolidated maintenance tasks with clear frequencies, that is, weekly, monthly, quarterly, annually, etc. The table separates ''Inspection,'' ''Test,'' and ''Maintenance'' items, streamlining responsibilities and tracking requirements.

(2) Section 14.2.1 Assessment of Internal Condition of Piping

Section 14.2.1 addresses the requirements for assessing the internal condition of piping in water-based fire protection systems for the presence of foreign organic and inorganic material (for example, corrosion or obstruction). The assessment must be conducted at intervals specified in sections 14.2.1.1 (typically every 5 years) or per 14.2.1.2 (as conditions warrant). Various acceptable methods are described, including physically opening/inspecting main ends or branch lines at strategic locations most susceptible to corrosion or blockage; use of alternative non-invasive methods; assessing during major system work (for example, renovations, draining for repairs).

n. Removal of the Outside Window or Door Requirements

The 2000 edition of the LSC required that every health care occupancy patient sleeping room shall have an outside window or outside door, with new health care occupancies having an allowable sill height not to exceed 36 inches above the floor with certain exceptions. This requirement no longer existed in the 2012 edition of the LSC; however, CMS believed that outside doors and windows were necessary for the health and safety of patients and decided to retain the requirement.

On May 4, 2016, we published a final rule titled ''Fire Safety Requirements for Certain Health Care Facilities,'' which required hospitals, CAHs, and RNHCIs, LTCs facilities, and hospice inpatient care facilities to have outside windows and doors in every patient sleeping areas. Interested parties have expressed concerns about their ability to comply with this requirement. Additionally, the 2024 edition of the LSC does not include this requirement as an essential life safety feature; therefore, we propose to remove the outside window and door requirements for hospitals, CAHs, RNHCIs, LTC Facilities, and hospice inpatient care facilities.

We note that LTC facilities would continue to be required to provide at least one window to the outside in residents' bedrooms in accordance with the longstanding requirement at newly redesignated § 483.90(e)(1). While we are maintaining this outside window requirement, we believe it continues to impose a lower burden on providers than what was required in the outside window and door requirements at § 483.90(a)(7), which contained more

prescriptive specifications (for example, window sill height requirement).

Additionally, we propose to remove obsolete regulatory provisions regarding outside widows for ICFs/IID. The current requirements at § 483.470(b)(2) state that bedrooms below grade level (that is, below ground level) in an ICF/IID must have a window that can be used as a second means of escape. The window must be no more than 44 inches above the ground unless the facility is surveyed under the HCO chapter of the LSC, in which case the window must be no more than 36 inches above the floor. ICFs/IID must meet outside window requirements pursuant to the LSC; therefore, continuing to specify this requirement in our regulations is redundant and no longer necessary.

3. Provisions of the Proposed Regulations

This section details the specific regulatory changes for each applicable provider and supplier. Due to the similar content and structure of the regulations for the various providers and suppliers, most of the information presented repeats for each provider and supplier type.

a. Religious Nonmedical Health Care Institutions: Condition of Participation: Life Safety From Fire (§ 403.744) and Condition of Participation: Building Safety (§ 403.745)

We propose the following for Religious Nonmedical Health Care Institutions:

- We propose to revise § 403.744(a)(1)(i) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 with references to the 2024 edition of the LSC (NFPA 101) applying the requirements within the provisions detailed in section II.F.1. of this proposed rule.
- We propose a technical change to § 403.744(a)(1)(ii) to update the corridor latching requirements. We are clarifying that we continue to prohibit the use of roller latches for corridor doors excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the LSC and expand the prohibition on inadequate latching hardware to include any device—not just roller latches.
- We propose to add a new requirement at § 403.744(a)(1)(iii) to allow RCNHIs the option to use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) as a method to show compliance with the provisions of the 2024 edition of the LSC (NFPA 101).
- We also propose to remove the requirement at § 403.744(a)(6) related to having an outside window or door for all patient sleeping rooms and a 36-inch windowsill requirement for buildings constructed after July 5, 2016.
- We propose a technical change to § 403.744(b)(1) to update the regulatory language pertaining to the waiver process. We are clarifying that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency.
- We propose a technical change to § 403.744(b)(2) to update the regulatory language pertaining to the State fire and safety code exemption. We are clarifying that CMS, at the discretion of the Secretary, may accept a State's fire and safety code in lieu of the LSC if CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in RNHCIs.
- We propose adding a requirement at § 403.744(b)(3) to establish that if CMS determines that a specific updated provision of the LSC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (c)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We propose to revise § 403.744(c) by replacing references the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 with references to the 2024 edition of the LSC (NFPA 101) and adding reference to the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A).
- We also propose a technical change at § 403.744(c) to update CMS contact information.
- We propose to revise § 403.745(a) by replacing references to the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 24–1 and TIA 24–2.
- We propose to retain the requirement at § 403.745(b) that Chapters 7, 8, 12, and 13 of the HCFC do not apply to RNHCIs.
- We propose to revise § 403.745(c) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We also propose to add a new requirement § 403.745(d) to establish that if CMS determines that a specific updated provision of the HCFC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We propose to revise proposed § 403.745(e) by replacing references to the 2012 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the HCFC (NFPA 99).
- We also propose a technical change at § 403.745(e) to update CMS contact information.

b. Ambulatory Surgery Centers: Condition for Coverage: Environment (§ 416.44)

We propose the following for Ambulatory Surgery Centers:

- We propose to revise § 416.44(b)(1) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 with references to the 2024 edition of the LSC (NFPA 101).
- We propose a technical change to § 416.44(b)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We propose a technical change to § 416.44(b)(3) to update the regulatory language pertaining to the State fire and safety code exemption. We are clarifying that CMS, at the discretion of the Secretary, may accept a State's fire and safety code in lieu of the LSC if CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in ASCs.
- We propose to add a new requirement § 416.44(b)(4) to if CMS determines that a specific updated

provision of the LSC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (f)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

- We propose to remove an obsolete requirement at § 416.44(b)(6) regarding doors to hazardous areas, as ASCs are required to meet this requirement pursuant to the LSC, and therefore is redundant and no longer necessary.
- We propose to revise § 416.44(c) by replacing references to the 2012 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of HCFC (NFPA 99) including Tentative Interim Amendments TIA 24–1 and TIA 24–2.
- We propose to retain the requirement at § 416.44(c)(1) that Chapters 7, 8, 12, and 13 of the HCFC do not apply to ASCs.
- We propose to revise § 416.44(c)(2) to update the regulatory language pertaining to the waiver process. We are clarifying that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We propose to add a new requirement § 416.44(c)(3) to establish that if CMS determines that a specific updated provision of the HCFC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (f)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We propose to revise § 416.44(f) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and the 2012 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and HCFC (NFPA 99), respectively.
- We also propose a technical change at § 416.44(f) to update CMS contact information.

c. Hospice Care: Condition of Participation: Hospices That Provide Inpatient Care Directly (§ 418.110)

We propose the following for Hospices:

- We propose to revise § 418.110(d)(1)(i) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 with references to the 2024 edition of the LSC (NFPA 101).
- We propose a technical change to § 418.110(d)(1)(ii) to update the corridor latching requirements. We are clarifying that we continue to prohibit the use of roller latches for corridor doors excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code and expand the prohibition on inadequate latching hardware to include any device—not just roller latches.
- We propose to add a new requirement at § 418.110(d)(1)(iii) to allow inpatient hospice facilities the option to use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) as a method to show compliance with the provisions of the 2024 edition of the LSC (NFPA 101).
- We propose a technical change to § 418.110(d)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We propose a technical change to § 418.110(d)(3) to update the regulatory language pertaining to the State fire and safety code exemption. We are clarifying that CMS, at the discretion of the Secretary, may accept a State's fire and safety code in lieu of the LSC if CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in hospices.
- We propose adding a requirement at proposed § 418.110(d)(4) to establish that if CMS determines that a specific updated provision of the LSC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (q)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We also propose to remove the requirement at § 418.110(d)(6), which require an outside window or door for all patient sleeping rooms and a 36-inch window sill requirement for buildings constructed after July 5, 2016. Hospices would continue to be required to provide a ''home-like atmosphere'' in accordance with the longstanding requirements at § 418.110(f).
- We propose to revise § 418.110(e) by replacing references to the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 24–1 and TIA 24–2.
- We propose to retain the requirement at § 418.110(e)(1) that Chapters 7, 8, 12, and 13 of the HCFC do not apply to hospice inpatient care facilities.
- We propose to revise § 418.110(e)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We also propose to add a requirement § 418.110(e)(3) to establish that if CMS determines that a specific updated provision of the HCFC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (q)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We propose to revise § 418.110(q) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and HCFC (NFPA 99) and adding reference to the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A).
- We also propose a technical change at § 418.110(q) to update CMS contact information.

d. Programs of All-Inclusive Care for the Elderly (PACE): Condition of Participation: Physical Environment (§ 460.72)

We propose the following for PACE centers:

- We propose to revise § 460.72(b)(1)(i) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 with references to the 2024 edition of the LSC (NFPA 101).
- We propose a technical change to § 460.72(b)(1)(ii) to update the corridor latching requirements. We are clarifying that we continue to prohibit the use of roller latches for corridor doors excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code and expand the prohibition on inadequate latching hardware to include any device—not just roller latches.
- We propose to add a new requirement at § 460.72(b)(1)(iii) to allow PACE centers the option to use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) as a method to show compliance with the provisions of the 2024 edition of the LSC (NFPA 101).
- We propose a technical change to § 460.72(b)(2)(i) to update the regulatory language pertaining to the State fire and safety code exemption. We are clarifying that CMS, at the discretion of the Secretary, may accept a State's fire and safety code in lieu of the LSC if CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in PACE centers.
- We propose a technical change to § 460.72(b)(2)(ii) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We propose adding a requirement at proposed § 460.72(b)(2)(iii) to establish that if CMS determines that a specific updated provision of the LSC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We propose to revise § 460.72(d) by replacing references to the 2012 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the HCFC (NFPA 99) including TIA 24–1 and TIA 24–2.
- We propose to retain the requirement at § 460.72(d)(1) that Chapters 7, 8, 12, and 13 of the HCFC do not apply to PACE centers.
- We propose to revise § 460.72(d)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We also propose adding a requirement at § 460.72(d)(3) to establish that if CMS determines that a specific updated provision of the HCFC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We propose to revise § 460.72(e) by replacing references with the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99), respectively, and adding reference to the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A).
- We also propose a technical change at § 460.72(e) to update CMS contact information.

e. Hospitals: Condition of Participation: Emergency Preparedness (§ 482.15) and Physical Environment (§ 482.41)

We propose the following for Hospitals:

- We propose to revise § 482.15(e) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99), respectively, and replacing references to the 2010 edition of the ESPS (NFPA 110) with references to the 2022 edition of the ESPS (NFPA 110). We also propose a technical change at § 482.15(e) by adding the phrase ''install and maintain'' to clarify that hospitals must both establish and continuously upkeep their emergency and standby power systems on an ongoing basis. Additionally, we propose to replace the term ''emergency generator'' and ''emergency generators'' throughout paragraphs (e)(1), (e)(2), and (e)(3) with the term ''emergency power supply''.
- We propose to revise § 482.15(h) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99), respectively, and replacing references to the 2010 edition of the ESPS (NFPA 110) with references to the 2022 edition of the ESPS (NFPA 110).
- We also propose a technical change at § 482.15(h) to update CMS contact information.
- We propose to revise § 482.41(b)(1)(i) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 with references to the 2024 edition of the LSC (NFPA 101). There can be multiple occupancy classifications within a single hospital. Therefore, multiple chapters of the code may be applied to a single hospital in accordance with the Multiple Occupancies provisions in 18.1.3 and 19.1.3 of the LSC (NFPA 101).
- We also propose that hospital outpatient surgical departments are comparable to ASCs and thus should be required to meet the provisions applicable to AHCO chapters.
- We propose a technical change to § 482.41(b)(1)(ii) to update the corridor latching requirements. We are clarifying that we continue to prohibit the use of roller latches for corridor doors excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code and expand the prohibition on inadequate latching hardware to include any device—not just roller latches.
- We propose to add a new requirement at § 482.41(b)(1)(iii) to allow hospitals the option to use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) as a method to show compliance with

the provisions of the 2024 edition of the LSC (NFPA 101).

- We propose a technical change to § 482.41(b)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We propose a technical change to § 482.41(b)(3) to update the regulatory language pertaining to the State fire and safety code exemption. We are clarifying that CMS, at the discretion of the Secretary, may accept a State's fire and safety code in lieu of the LSC if CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in hospitals.
- We propose adding a requirement at proposed § 482.41(b)(4) to establish that if CMS determines that a specific updated provision of the LSC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We also propose to remove the requirement at § 482.41(b)(9), which requires an outside window or door for all patient sleeping rooms, a 36-inch window sill requirement for buildings constructed after July 5, 2016, and a 60-inch window sill requirement for special nursing care areas in new occupancies.
- We propose to revise § 482.41(c) by replacing references to the 2012 edition of the and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6 with references to the 2024 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 24–1, and TIA 24–2.
- We propose to retain the requirement at § 482.41(c)(1) that states Chapters 7, 8, 12, and 13 of the HCFC do not apply to hospitals.
- We propose to revise § 482.41(c)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We also propose adding a requirement at § 482.41(c)(3) to establish that if CMS determines that a specific updated provision of the HCFC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We propose to revise § 482.41(e) by replacing references to 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 2012 and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and HCFC (NFPA 99), respectively, and adding reference to the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A).
- We also propose a technical change at § 460.72(d) to update CMS contact information.

f. Long-Term Care Facilities: Condition of Participation: Emergency Preparedness (§ 483.73) and Physical Environment (§ 483.90)

We propose the following for Long-Term Care Facilities:

- We propose to revise § 483.73(e) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4) and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99), respectively, and replacing references to the 2010 edition of the ESPS (NFPA 110) with references to the 2022 edition of the ESPS (NFPA 110).
- We also propose a technical change at § 483.73(e) by adding the phrase ''install and maintain'' to clarify that LTC facilities must both establish and continuously upkeep their emergency and standby power systems on an ongoing basis. Additionally, we propose to replace the term ''emergency generator'' and ''emergency generators'' throughout paragraphs (e)(1), (e)(2), and (e)(3) with the term ''emergency power supply''.
- We propose to revise § 483.73(g) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99), respectively, and replacing references to the 2010 edition of the ESPS (NFPA 110) with references to the 2022 edition of the ESPS (NFPA 110).
- We also propose a technical change at § 483.73(g) to update CMS contact information. We propose to revise § 483.90(a)(1)(i) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 with references to the 2024 edition of the LSC (NFPA 101).
- We propose a technical change to § 483.90(a)(1)(ii) to update the corridor latching requirements. We are clarifying that we continue to prohibit the use of roller latches for corridor doors excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code and expand the prohibition on inadequate latching hardware to include any device—not just roller latches.
- With the adoption of the 2024 edition of the LSC (NFPA 101), LTC facilities no longer need to use the 2001 mandatory values chart that was published in the regulatory text, therefore we propose to replace the entirety of § 483.90(a)(1)(iii) and with a requirement that LTC facilities are allowed the option to use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) as a method to show compliance with the provisions of the 2024 edition of the LSC (NFPA 101).
- We also propose to add an exception to § 483.90(a)(1)(iv) that LTC facilities may not use the FSES as a method to address non-compliance with NFPA 13 and NPFA 25.
- We propose a technical change to § 483.90(a)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We propose to remove an obsolete requirement at § 483.90(a)(5). This provision addressed smoke alarm requirements and applied only to facilities without automatic sprinkler systems. In accordance with a previous CMS mandate to install automatic sprinkler systems (73 FR 47075) and subsequent revisions to the LSC (NFPA

101), all LTC facilities are now fully sprinklered, making this requirement obsolete.

- We propose a new requirement at § 483.90(a)(5) to establish that if CMS determines a specific updated provision of the LSC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (j)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance, provided that CMS has determined that the waiver does not adversely affect the health and safety of residents or personnel. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We propose to revise § 483.90(a)(6)(i) by replacing references to the 1999 edition of the Standard for the Installation of Sprinkler Systems (NFPA 13) with references to the 2022 edition of NFPA 13, removing the compliance date as it has passed, and removing the incorporation by reference language for the 1999 edition of NFPA 13.
- We propose to revise § 483.90(6)(ii) by replacing references to the 1998 edition of the Standard for Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems (NFPA 25) with references to the 2023 edition of the NFPA 25 and removing the incorporation by reference language for the 1998 edition of NFPA 25.
- We also propose to remove an obsolete requirement at § 483.90(a)(6)(iii). The provision allowed CMS to grant extensions of up to 2 years to the sprinkler installation deadline for LTC facilities. All LTC facilities were required to be fully sprinklered by and after August 13, 2013. Since the initial effective date and all extension dates have passed, the deadlines no longer apply, and the extension provision is obsolete.
- We propose to remove the requirement at § 483.90(a)(7), which require an outside window or door for all patient sleeping rooms and a 36-inch windowsill requirement for buildings constructed after July 5, 2016. LTC facilities would continue to be required to provide at least one window to the outside in residents' bedrooms in accordance with the longstanding requirement at § 483.90(e)(1).
- We propose to revise § 483.90(b) by replacing references to the 2012 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 24–1 and TIA 24–2.
- We propose to retain the requirement at § 483.90(b)(1) that states Chapters 7, 8, 12, and 13 of the HCFC do not apply to LTC facilities.
- We propose to revise § 483.90(b)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We propose a new requirement at § 483.90(b)(3) to establish that if CMS determines that a specific updated provision of the HCFC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (j)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance, provided that CMS has determined that the waiver does not adversely affect the health and safety of residents or personnel. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We also propose to remove § 483.90(c) requirements, since LTC facilities would be required to meet these requirements pursuant to the LSC. This provision therefore is redundant and no longer necessary.
- We propose to revise § 483.90(j) by replacing references to 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 2012 and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and HCFC (NFPA 99), respectively, and adding reference to the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A).
- We also propose a technical change at § 483.90(j) to update CMS contact information.

g. Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs/IID): Condition of Participation: Physical Environment (§ 483.470)

We propose the following for ICFs/IID:

- We propose to remove an obsolete requirement at § 483.470(b)(2) regarding outside windows for bedrooms below grade level and window sill height requirement, as ICFs/IID are required to meet an outside window requirement pursuant to the LSC, and therefore is redundant and no longer necessary.
- We propose to revise § 483.470(j)((i)1)(i) by replacing references to the 2012 edition of the LSC (NFPA 101) with references to the 2024 edition of the LSC (NFPA 101). ICFs/IID would continue to be permitted to meet either the RBCOs chapter or the Health Care Occupancy chapter of the 2024 edition of the LSC (NFPA 101).
- We propose a technical change to § 483.470(j)(1)(ii) to update the corridor latching requirements. We are clarifying that we continue to prohibit the use of roller latches corridor doors excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code and expand the prohibition on inadequate latching hardware to include any device—not just roller latches.
- We propose a technical change at proposed § 483.470(j)(1)(iii) by replacing references to the 2012 edition of the LSC (NFPA 101) with the 2024 edition of the LSC (NFPA 101).
- We propose to remove an obsolete requirement at § 483.470(j)(1)(iv) regarding sprinklers and health detection systems in the attics, as ICFs/IID are required to meet this requirement pursuant to the LSC, and therefore redundant and no longer necessary.
- We propose to add a new requirement at § 483.470(j)(1)(iv) to allow ICFs/IID the option to use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) as a method to show compliance with the provisions of the 2024 edition of the LSC (NFPA 101).
- We propose to remove an obsolete requirement at § 483.470(j)(1)(iv) regarding sprinklers and health detection systems in the attics, as ICFs/IID are required to meet this requirement pursuant to the LSC, and therefore redundant and no longer necessary.
- We propose a technical change at proposed § 483.470(j)(1)(iv) by replacing references to the 2012 edition of the LSC (NFPA 101) with the 2024 edition of the LSC (NFPA 101).
- We propose a technical change to § 483.470(j)(4) to update the regulatory language pertaining to the State fire and safety code exemption. We are clarifying that CMS, at the discretion of the Secretary, may accept a State's fire and safety code in lieu of the LSC if CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in ICFs/IID.

• We propose a technical change to § 483.470(j)(5)(i) to update the regulatory language pertaining to the waiver process. We are clarifying that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.

• We propose to remove an obsolete requirement at § 483.470(j)(5)(iv) regarding sprinklers and health detection systems in the attics, as ICFs/IID are required to meet this requirement pursuant to the LSC, and therefore redundant and no longer necessary.

• We propose to § 483.470(j)(5)(v) by replacing references to the 2012 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to 2024 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 24–1 and TIA 24–2. ICFs/IID would continue to be permitted to meet either the RBCOs chapter or the Health Care Occupancy chapter of the 2024 edition of the HCFC (NFPA 99).

• We propose to retain the requirement at § 483.470(j)(5)(v)(A) that states Chapters 7, 8, 12, and 13 of the HCFC do not apply to ICFs/IID.

• We propose to revise § 483.470(j)(5)(v)(B) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.

• We also propose to add a requirement at § 483.470(j)(5)(v)(C) to establish that if CMS determines that a specific updated provision of the HCFC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (m)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

• We propose to add a requirement at § 483.470(j)(6) to establish that if CMS determines that a specific updated provision of the LSC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (m)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

• We propose to revise § 483.470(m) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99), respectively, and adding reference to the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A).

• We also propose a technical change at § 483.470(m) to update CMS contact information.

h. Conditions of Participation: Rural Emergency Hospitals (REHs): Emergency Preparedness (§ 485.542) and Physical Environment (§ 485.544)

We propose the following for REHs:

• We propose to revise § 485.542(e) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99), respectively, and by replacing references to the 2010 edition of the ESPS (NFPA 110) with references to the 2022 edition of the ESPS (NFPA 110). We also propose a technical change at § 485.542(e) by adding the phrase ''install and maintain'' to clarify that REHs must both establish and continuously upkeep their emergency and standby power systems on an ongoing basis. Additionally, we propose to replace the term ''emergency generator'' and ''emergency generators'' throughout paragraphs (e)(1), (e)(2), and (e)(3) with the term ''emergency power supply''.

• We propose to revise § 485.542 (g) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99), respectively, and replacing references to the 2010 edition of the ESPS (NFPA 110) with references to the 2022 edition of the ESPS (NFPA 110).

• We also propose a technical change at § 485.542(g) to update CMS contact information.

• We propose to revise § 485.544(c)(1) by replacing references to the 2012 edition of the LSC (NFPA 101)including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 with the 2024 edition of the LSC (NFPA 101). REHs must meet the provisions applicable to Ambulatory Health Care Occupancies.

• We propose a technical change to § 485.544(c)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.

• We propose a technical change to § 485.544(c)(3) to update the regulatory language pertaining to the State fire and safety code exemption. We are clarifying that CMS, at the discretion of the Secretary, may accept a State's fire and safety code in lieu of the LSC if CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in REHs.

• We also propose to add a requirement at § 485.544(c)(4) to establish that if CMS determines that a specific updated provision of the LSC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

• We propose to revise § 485.544(d) by replacing the references to the 2012 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to 2024 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 24–1 and TIA 24–2. REHs must meet the provisions applicable to Ambulatory Health Care Occupancies.

• We propose to retain the requirement at § 485.544(d)(1) that states Chapters 7, 8, 12, and 13 of the HCFC do not apply to REHs.

• We propose to revise § 485.544(d)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a

recommendation from the State survey agency or an approved accrediting organization.

- We also propose to add a requirement at § 485.544(d)(3) to establish that if CMS determines that a specific updated provision of the HCFC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We propose to revise § 485.544(e) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99) respectively.
- We also propose to remove the outdated CMS contact information from § 485.544(e), as the listed contact is no longer current.

i. Critical Access Hospitals: Condition of Participation: Physical Plant and Environment (§ 485.623) and Emergency Preparedness (§ 485.625)

We propose the following for Critical Access Hospitals:

- We propose to revise § 485.623(c)(1)(i) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 to the 2024 edition of the LSC (NFPA 101).
- We propose to revise the corridor door latching requirements at § 485.623(c)(1)(ii) to exclude auxiliary spaces not classified as hazardous areas under the LSC, remove the separate reference to rooms containing flammable or combustible materials, and expand the prohibition on inadequate latching hardware to include any device—not just roller latches.
- We propose to add a new requirement at § 485.623(c)(1)(iii) to allow CAHs the option to use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) as a method to show compliance with the provisions of the 2024 edition of the LSC (NFPA 101).
- We propose a technical change at § 485.623(c)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We propose to add a requirement at § 485.623(c)(3) to establish that CMS, at the discretion of the Secretary, may accept a State's fire and safety code in lieu of the LSC if CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in CAHs.
- We propose to add a requirement at proposed § 485.623(c)(4) to establish that if CMS determines that a specific updated provision of the LSC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We also propose to remove the requirement at § 485.623(c)(7) which requires an outside window or door for all patient sleeping rooms, a 36-inch windowsill requirement for buildings constructed after July 5, 2016, and a 60-inch windowsill requirement for special nursing care areas in new occupancies.
- We propose to revise § 485.623(d) by replacing the 2012 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to 2024 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 24–1 and TIA 24–2
- We propose to retain the requirement at § 485.623(d)(1) that states Chapters 7, 8, 12, and 13 of the HCFC do not apply to CAHs.
- We propose to revise § 485.623(d)(2) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We also propose to add a requirement at § 485.623(d)(3) to establish that if CMS determines that a specific updated provision of the HCFC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We propose to revise § 485.623(e), by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99) including Tentative Interim Amendments TIA–24–1 and TIA 24–2, respectively, and adding reference to the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A).
- We also propose a technical change at § 494.60(e)(1) to update CMS contact information.
- We propose to revise § 485.625(e) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4, and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99), respectively, and by replacing references to the 2010 edition of the ESPS (NFPA 110) with references to the 2022 edition of the ESPS (NFPA 110).
- We also propose a technical change at § 485.625(e) by adding the phrase ''install and maintain'' to clarify that CAHs must both establish and continuously upkeep their emergency and standby power systems on an ongoing basis. Additionally, we propose to replace the term ''emergency generator'' and ''emergency generators'' throughout paragraphs (e)(1), (e)(2), and (e)(3) with the term ''emergency power supply''.
- We propose to revise § 485.625(g) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and the HCFC (NFPA 99), respectively, and replacing references to the 2010 edition of the ESPS (NFPA 110) with references to the 2022 edition of the ESPS (NFPA 110).
- We also propose a technical change at § 485.625(g) to update CMS contact information.

j. Conditions for Coverage: End Stage Renal Disease (ESRD) Facilities: Physical Environment (§ 494.60)

We propose the following for ESRD facilities:

- We propose to revise § 494.60 (d)(1) by replacing references to the 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 to the 2024 edition of the LSC (NFPA 101).
- We propose a technical change to § 494.60(d)(3) to update the regulatory language pertaining to the State fire and safety code exemption. We are clarifying that CMS, at the discretion of the Secretary, may accept a State's fire and safety code in lieu of the LSC if CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in dialysis facilities.
- We propose a technical change at § 494.60(d)(4) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We also propose a technical change at § 494.60(d)(5) to replace the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6 with references to the HCFC (NFPA 99) including Tentative Interim Amendments TIA 24–1 and TIA 24–2.
- We propose to add a new requirement at § 494.60(d)(6) to establish that if CMS determines that a specific updated provision of the LSC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (f)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We propose to revise § 494.60(e)(1) by replacing the 2012 edition of the HCFC (NFPA 99) with references to the 2024 edition of the HCFC (NFPA 99) including Tentative Interim Amendments TIA 24–1 and TIA 24–2. Dialysis facilities meet the provisions applicable to AHCOs.
- We propose to retain the requirement at § 494.60(e)(2) that Chapters 7, 8, 12, and 13 of the HCFC do not apply to dialysis facilities.
- We propose a technical change at § 494.60(e)(3) to update the regulatory language pertaining to the waiver process. We would clarify that CMS, at the discretion of the Secretary, may grant such waivers following a recommendation from the State survey agency or an approved accrediting organization.
- We propose to add a requirement at § 494.60(e)(4) to establish that if CMS determines that a specific updated provision of the HCFC provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (f)(1), CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.
- We also propose to revise § 494.60(f) by replacing references to 2012 edition of the LSC (NFPA 101) including Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 and the HCFC (NFPA 99) including Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6 with references to the 2024 edition of the LSC (NFPA 101) and HCFC (NFPA 99) respectively.
- We also propose a technical change at § 494.60(f) to update CMS contact information.

G. Transplant Programs—Request for Information (RFI)

CMS is seeking public comments related to requirements for initial approval for solid organ transplant programs, specifically the requirements concerning clinical experience (or volume) and outcome requirements for the initial approval of transplant programs, as well as the exceptions for specific type of organ(s) programs.

1. Initial Approval and Re-Approval of Transplant Programs: Background

Transplant programs, located within a hospital that has a Medicare provider agreement, provide transplant services for one or more specific organs. Transplant programs must comply with the Medicare transplant program CoPs regulations at 42 CFR 482.68 through 482.104, and with the hospital CoPs at §§ 482.1 through 482.58. There are several types of CMS-approved transplant programs, including heart, heart-lung, lung, liver, kidney, intestine, and pancreas..

In 2005, CMS proposed CoPs for transplant programs that we believed would be necessary to: (1) protect other potential Medicare beneficiaries who are waiting for organs for transplantation; (2) establish sufficient quality and procedural standards to ensure that transplants are performed in a safe and efficient manner; and (3) reduce Medicare expenses by decreasing the likelihood that a transplant would fail (70 FR 6140). The regulations were intended to assess an organ transplant center's ability to perform successful transplants and deliver quality patient care as evidenced by good outcomes and sound policies and procedures. They were finalized in 2007 and set forth clear expectations for safe, high-quality transplant service delivery in Medicare-participating facilities (72 FR 15198).

In the 2007 final rule, CMS finalized two requirements related to the approval of transplant programs: (1) § 482.80 Data submission, clinical experience, and outcome requirements for initial approval of transplant programs and (2) § 482.82 Data submission, clinical experience, and outcome requirements for re-approval of transplant programs. After publication of the 2007 Final Rule, we continued to review how effective the transplant program requirements were, as well as the effectiveness of the sub-regulatory guidance and the data derived from the transplant program surveys.

On September 20, 2018, we published the Omnibus Burden Reduction Proposed Rule Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (83 FR 47686) that, among other things, proposed removing all the requirements set forth in § 482.82 for the re-approval of transplant programs. We discussed various articles that suggested that the requirements for re-approval of transplant programs had resulted in unintended negative consequences for patients on the transplant waiting lists. We were especially concerned with the findings that suggested that transplant programs that were low performing might be removing sicker patients from their transplant lists due to the outcome measures set forth in § 482.82.[286] Subsequently, on September 30, 2019, we published a final rule titled Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and CAH Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (84 FR 51732) that, among other things, finalized the removal of § 482.82. We stated that the removal of these requirements would lead to improved

[286] 83 FR 47686, 47704–47706.

patient outcomes, increased transplantation opportunities for patients on the waitlist, improved organ procurement for transplantation, greater organ utilization, and reduced burden on transplant programs. Most of the commenters supported the removal of the requirements in § 482.82. However, there were also commenters that were concerned about how CMS would continue to monitor transplant programs and ensure patient safety and outcomes. We indicated that the requirements set forth in § 482.80 Data submission, clinical experience, and outcome requirements for initial approval of transplant programs and § 482.96 QAPI, as well as survey processes, both routine and complaint-based, would provide the oversight needed to ensure safety and quality of care for patients and transplant recipients.

On December 3, 2021, we published, Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organization, and End-Stage Renal Disease Facilities (CMS 3409–NC, 86 FR 68594). Among the issues we solicited comments on was whether the initial approval requirements in § 482.80 created barriers to the establishment of new transplant programs (86 FR 68594, 68596). We also asked about alternative requirements that could be used to ensure that new transplant programs would provide quality care for transplant recipients. Many commenters stated that the requirements in § 482.80 were a barrier due to the volume requirements and timeframe to obtain outcome requirements. However, other commenters indicated that they did not believe the initial requirements were excessive. They indicated that organ transplantation was very expensive and required complex procedures so that facilities must be ready to invest the required resources to achieve strong performance. However, since the publication of this RFI, CMS has continued to receive feedback from prospective transplant programs regarding the timeframe to obtain the 1-year outcomes data.

Initiatives Related to Kidney Health:

In 2019, the Trump Administration released Executive Order (E.O.) 13879 dedicated to advancing American kidney health citing too many at-risk patients progress to late-stage kidney failure, high mortality rates, the high cost of current treatment options, the inability of current treatment options to produce an acceptable quality of life for patients, and the lack of sufficient kidneys donated to meet the current demand for transplants.[287]

In response to this E.O., CMS published a proposed rule in 2019 that was finalized in 2020, revising the outcome measures utilized to assess performance of organ procurement organizations (OPOs). The rule was specifically designed to drive OPO performance and increase the number of organs available for transplantation. There has been significant progress since the rule was finalized. Between 2019 and 2024, there was a nearly 37 percent increase in the number of organ donors and 30 percent increase in the number of organ transplants. During this same period there was a more than 26 percent increase in the number of kidneys transplanted.

In addition to this action, in 2024 the CMS Innovation Center finalized the Increasing Organ Transplant Access (IOTA) Model, which is a 6-year mandatory model for approximately half of the transplant hospitals around the country. The IOTA Model holds transplant centers accountable for the volume, efficiency, and outcomes for their patients and offers the opportunity for upside or downside payments based on performance. CMS will evaluate the results from that model as it considers future regulatory efforts and how to best increase the number of patients successfully transplanted.

Despite ongoing government initiatives, kidney disease remains a leading cause of death in the United States.[288] In 2024, approximately 35.5 million Americans were suffering from chronic kidney disease and 808,000 were living with ESRD. More than 100,000 Americans begin dialysis each year to treat ESRD with twenty percent dying within a year and 50 percent dying within 5 years.[289] Currently, nearly 90,000 Americans are on the waiting list to receive a kidney transplant, making up the vast majority of Americans waiting for organ transplantation.[290]

The 2019 E.O. provided the policy framework to prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care; increasing patient choice through affordable alternative treatments for ESRD (by encouraging higher value care and educating patients on treatment alternatives); and increasing access to kidney transplants by modernizing the organ recovery and transplantation systems. We seek to continue our efforts to improve the system and are therefore requesting information that may lead to improvements in certification of new transplant programs.[291]

2. Solicitation of Public Comments

CMS continues to strongly believe that having requirements for clinical experience and outcomes for initial approval of transplant programs is necessary to protect the health and safety of patients. While we acknowledge the advances in transplant medicine and science since publication of the 2007 final rule, establishing a newly formed transplant program remains a considerable undertaking given the complexity of the procedures and scope of services that are necessary for a successful outcome. Approval of a new transplant program currently requires evaluation of both short and long-term outcomes. This requires evaluation of both the surgical skill of the transplant surgeon and surgical team, as well as the longer-term medical management of the transplant recipient by the transplant interdisciplinary team. The transplant community has long considered the post-transplant outcomes, such as graft and patient survival, to be important metrics for evaluating a transplant center's performance. At the time of our 2007 final rule, the outcome measures available to assess performance in these aspects were the 1-month, 1-year, and 3-year survival outcomes. We finalized the requirements utilizing a 1-year graft and patient survival outcome measures. The 1-year outcome utilizes a 2.5-year cohort necessary to produce a statistically valid outcome resulting in a significant time delay for new program approvals. We considered using a shorter timeframe (for example 1-month) of outcome measures for initial

[287] *Advancing American Kidney Health,* Executive Order 13879. Published July 10, 2019. Accessed at *https://www.federalregister.gov/documents/2019/07/15/2019-15159/advancing-american-kidney-health.* Accessed on June 11, 2026.

[288] CDC. Chronic Kidney Disease: Common, Serious, and Costly. May 15, 2024. Accessed at *https://www.cdc.gov/kidney-disease/ckd-facts/index.html.* Accessed on June 11, 2026.

[289] Advancing American Kidney Health, Executive Order 13879. Published July 10, 2019. Accessed at *https://www.federalregister.gov/documents/2019/07/15/2019-15159/advancing-american-kidney-health.* Accessed on June 11, 2026.

[290] United Network for Organ Sharing, 2026. U.S. surpasses 49,000 organ transplants while deceased organ donations dip. January 28, 2026. Accessed at *https://unos.org/media-resources/releases/u-s-surpasses-49000-organ-transplants-while-deceased-organ-donations-dip/.* Accessed on June 11, 2026.

[291] *Advancing American Kidney Health,* Executive Order 13879. Published July 10, 2019. Accessed at *https://www.federalregister.gov/documents/2019/07/15/2019-15159/advancing-american-kidney-health.* Accessed on June 11, 2026.

approval of transplant programs. We concluded that approving new transplant centers based on a review of only the 1-month post-transplant outcomes data was not of sufficient duration and could pose the risk for potential harm to patients (72 FR 15198, 15221 through15222). We continue to believe this timeframe is too short for this purpose, however, we are sensitive to feedback regarding the timeframe to obtain 1-year outcomes and the challenges this poses to new programs seeking Medicare approval. Under the current requirement for outcome measures at § 482.80, it takes approximately 18 to 24 months from the time the program has their first transplant for initial Medicare approval.

Considering this information, we are soliciting public comments on whether the clinical experience and outcome requirements for initial approval of transplant programs for Medicare participation could be revised to lessen the timeframe to initial certification for a transplant hospital while maintaining patient safety and ensuring the transplant program provides quality and safe care to transplant recipients.

We are specifically soliciting comments on the following areas:

Clinical experience: At § 482.80(b), to be considered for initial approval, transplant programs must generally perform 10 transplants over a 12-month period with certain organ-specific exceptions (see § 482.80(d) below).

- Are the current clinical experience requirements, specifically, performing 10 transplants over a 12-month period, still appropriate for demonstrating a new transplant program's readiness for Medicare approval?
- Should the 12-month timeframe for meeting the clinical experience requirement be modified (*e.g.,* shortened or extended)? If so, what alternative timeframe would be appropriate, and what evidence supports that change?
- Is the current volume threshold of 10 transplants for most organs sufficient to assess a new program's competency, or should CMS consider alternative indicators of clinical readiness?

Outcome requirements: The current standard at § 482.80(c) sets forth several requirements that a transplant program must meet to be granted initial approval by CMS. CMS compares each transplant program's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent Scientific Registry of Transplant Recipients (SRTR) program-specific report. The transplant program's patient and graft survival rates will not be acceptable if (1) the observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and (2) all three of the following thresholds are crossed over: (A) the one-sided p-value is less than 0.05, (B) the number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and (C) the number of observed events divided by the number of expected events is greater than 1.85.

- Are the current outcome measures still appropriate for demonstrating a new transplant program's readiness for Medicare approval?
- What is the timeframe during which patients should be followed post-transplant that would enable an adequate assessment of a program's performance?
- What alternative metric, or combination of metrics, could be used to assess a program's performance in ensuring high-quality care and protecting patient health and safety?
- How would these metrics work independently or in tandem to assess a program's short and longer-term outcomes and performance of the interdisciplinary team in managing transplant patients?
- Should pre-transplant outcome measures be considered in this initial approval evaluation process? If so, please identify the measures and provide any data or other information that supports your position.
- What timeframe would be required for any alternative metrics to become available for CMS to consider for initial program approval?

Exceptions to Clinical Experience: In addition to the previous requirements, § 482.80(d) contains certain exceptions to the clinical experience requirements. These exceptions include:

1. A heart-lung transplant program is not required to comply with the clinical experience requirements or the outcome requirements for heart-lung transplants performed at the program.
2. An intestine transplant program is not required to comply with the outcome performance requirements for intestine, combined liver-intestine or multivisceral transplants performed at the program.
3. A pancreas transplant program is not required to comply with the clinical experience requirements or the outcome requirements for pancreas transplants performed at the program.
4. A program that is requesting initial Medicare approval to perform pediatric transplants is not required to comply with the clinical experience requirements prior to its request for approval as a pediatric transplant program.
5. A kidney transplant program that is not Medicare-approved is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval.

For the earlier exceptions:

- Should any of these exceptions be removed or revised? If yes, please indicate the exception, provide a rationale, and indicate whether it should be removed or how it should be revised. Please be as specific as possible and provide any data or other information that supports your position.

Living Donation: CMS does not currently include specific outcome or clinical experience requirements related to living donation when considering a program for initial Medicare approval. However, CMS has requirements specific to living donation related to patient rights, living donor selection, and organ recovery & receipt, and living donor management.

- Should CMS consider specific outcome or clinical experience requirements for living donors in the initial program certification process? What outcome and/or clinical experience requirements would be appropriate for program approval?

We thank commenters in advance for considering this RFI and taking time to provide information on this important topic related to initial Medicare certification of transplant programs.

H. Supervision of Anesthesia Services RFI

CMS is seeking public comments related to requirements for Medicare supervision of anesthesia services provided in hospitals, critical access hospitals (CAHs), rural emergency hospitals (REHs), and ambulatory surgical centers (ASCs).

The regulations that address the health and safety provisions for anesthesia services are in Title 42 of the Code of Federal Regulations. The specific requirements for each facility type are located at § 416.42 for ASCs, § 482.52 for hospitals, § 485.524 for REHs, and § 485.639 for CAHs. The regulations vary slightly in structure across the settings but generally include requirements for items such as organization and staffing, the pre-operative anesthesia risk evaluation, anesthesia administration, service delivery, supervision, and a post-operative anesthesia evaluation. The regulations also include the requirements for the process to request a State exemption from the requirement for physician supervision of CRNAs.

CMS' longstanding policy is that anesthesia must be administered only by certain qualified practitioners and the requirements vary slightly by setting in which the services are provided. CMS requires that when anesthesia services are administered by a certified registered nurse anesthetist (CRNA), the services must be under the supervision of a physician, such as the operating practitioner or an anesthesiologist who is immediately available. In 2001, CMS amended this policy to permit the Governor of a State to request an exemption from the CRNA supervision requirement if the Governor determined that it is in the best interests of the State's citizens to exercise this exemption. The exemption would permit CRNAs to practice independently if consistent with State law. Since that time, Governors from 26 states and one U.S. territory have exercised the provision to opt out of the Medicare physician supervision requirement. CMS is soliciting comments on this policy, including whether it should be retained, revised, or otherwise modified.

1. Regulatory History

Section 1861(bb) of the Act provides definitions for certified registered nurse anesthetists (CRNAs) and their services. The initial Medicare requirements for anesthesia services were published for the hospital Conditions of Participation (CoPs) on June 17, 1986 (51 FR 22010). The CoPs required that when anesthesia services are administered by a CRNA, those services must be under the supervision of the operating room practitioner or an anesthesiologist who is immediately available, if needed. CMS published similar requirements for other facilities that provide anesthesia services including ASCs in 1992 (57 FR 33899), CAHs in 1995 (60 FR 45851), and REHs in 2022 (87 FR 722293).

On December 19, 1997, we published a proposed rule entitled, ''Hospital Conditions of Participation, Provider Agreements and Supplier Approval,'' (62 FR 66726) in the **Federal Register**. We proposed, among other things, to let State law determine which professionals would be permitted to administer anesthetics, and the level of supervision required for practitioners in each category, recognizing States' traditional domain in establishing professional licensure and scope-of-practice laws. Policy surrounding the proposal was based on the principle that States traditionally regulate practitioner scope-of-practice and the lack of evidence to support maintaining a special Federal requirement for physician supervision of CRNAs that would have the effect of superseding State requirements. We also stated that a fundamental principle was to facilitate flexibility in how a hospital would meet our performance expectations, and to eliminate structure and process requirements unless there was evidence that they improved desired outcomes for patients. This proposal received significant public interest with over 20,000 public comments provided on the topic.

The final rule was published on January 18, 2001 (66 FR 4674) and was to have been effective March 19, 2001. In accordance with the proposed rule, the January 2001 final rule changed the physician supervision requirement for CRNAs furnishing anesthesia services in hospitals, ASCs, and CAHs. Under that rule, State laws would control which professionals would be permitted to administer anesthesia and the level of supervision required for CRNAs. The rule did not prohibit, limit, or restrict in any way the practice of medicine by a physician or anesthesiologist. Hospitals retained the ability to exercise stricter standards than those required by State law.

On March 19, 2001, the effective date of the final rule was delayed 60 days and published in the **Federal Register** (see 66 FR 15352). On May 18, the rule was further delayed for 180 days, until November 14, 2001, to explore alternatives for implementation (see 66 FR 27598). We published a new proposed rule on July 5, 2001 (66 FR 35395), which proposed an alternative method for implementing the independent practice proposal in lieu of proposing removal of the requirement. Our alternative proposal established an exemption from the physician supervision requirement by recognizing a Governor's written request to CMS attesting that after consultation with the State's Boards of Medicine and Nursing on issues related to access to and the quality of anesthesia services, and consistent with State law, he or she is aware of the State's right to an exemption from the requirement and has determined that it is in the best interests of the State's citizens to exercise this exemption. This proposed rule again received significant interest with over 28,500 public comments. The final rule was published on November 13, 2001 (66 FR 56762). Under the final rule, the previous physician supervision requirement was maintained, unless the governor of a State, in consultation with the State's Boards of Medicine and Nursing, exercises the option of exemption from this requirement, consistent with State law. In publishing the final rule, CMS stated that we believe these changes would improve the quality of care furnished through Federal programs, while recognizing the States' traditional domain in establishing professional licensure and scope-of-practice laws.

During the COVID–19 PHE, the HHS Secretary utilized authority under Section 1135 of the Act to waive the requirement that CRNAs practice under the supervision of a physician. This waiver authority permits the Secretary to waive requirements to ensure that sufficient health care items and services are available to meet the needs of the public in an area affected by a federally declared PHE. This waiver was one of many requirements that was waived during the PHE.[292] During this period, CRNA supervision was delegated to the discretion of the facility (hospital, CAH, or ASC) and state law provided that it was not inconsistent with a state's emergency preparedness or pandemic plan. This waiver expired at the end of the declared PHE on May 11, 2023.

2. Current Status of Anesthesia Supervision

Since the 2001 final rule, Governors from 26 states and one U.S. territory have requested and been approved for the Medicare exemption to physician supervision of anesthesia services. These include Iowa, Nebraska, Idaho, Minnesota, New Hampshire, New Mexico, Kansas, North Dakota, Washington, Alaska, Oregon, Montana, South Dakota, Wisconsin, California, Colorado, Kentucky, Arizona, Oklahoma, Michigan, Arkansas, Wyoming, Delaware, Massachusetts, Vermont, Ohio, and Guam. Governors may request an exemption by submitting a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law. CMS only approves the opt-out provision for the entire state and does not selectively apply the provision to certain areas or institutions within the state. Any restrictions to the supervision requirement at the state level must be approved by the State in accordance with state laws and requirements. The

[292] *https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf.*

request for exemption and recognition of State laws, or the withdrawal of the request may be submitted at any time, and are effective upon submission. Exemption requests should be emailed to: *HealthandSafetyInquiries@cms.hhs.gov.*

In implementing this requirement, CMS established a shared commitment to quality care with States and Medicare providers. The shared commitment with States enables each State's Governor to assess the currently available evidence and consider data relevant to their own situation for items such as physician access, hospital and patient characteristics, and the needs of rural areas when considering the best way to deliver anesthesia care. Additionally, hospitals can, and frequently do, exercise stricter standards than required by State law. For instance, many hospitals continue to require physician supervision of CRNA services in states where governors have requested exemption from this requirement.

While licensing of health professions and scope of practice are aspects that are generally deferred to States, there is a lack of definitive evidence related to health and safety to support a singular policy position related to the supervision of CRNA services. This was a consideration at the time of the 2001 final rule and has continued to be a factor that has supported continuation of the current policy. A 2014 Cochrane review assessed studies evaluating the safety and effectiveness of different anesthesia providers.[293] The authors concluded that no definitive statement could be made regarding the superiority of one type of anesthesia care citing the complexity of perioperative care, the low intrinsic rate of complications relating directly to anesthesia services, and the potential confounding effects within the studies reviewed. Additionally, they noted that none of the data were of sufficiently high quality, frequently presented inconsistent findings, and were at risk for bias in interpreting results. Therefore, the shared commitment with states and providers has provided flexibility in enabling states to consider currently available evidence against the unique needs in each state when determining CRNA scope of practice and supervision requirements.

[293] Lewis, Sharon R., et al. ''Physician Anaesthetists versus Non-physician Providers of Anaesthesia for Surgical Patients.'' Cochrane Database of Systematic Reviews [Chichester, UK], vol. 2014, no. 7, no. CD010357, July 2014, *https://doi.org/10.1002/14651858.CD010357.pub2.*

3. Request for Information

Given this information, CMS invites public comment on the current anesthesia supervision and exemption policy as part of its ongoing review of these requirements. Specifically, CMS is seeking information, detailed sources of data, and peer-reviewed research related to the following questions:

- To what extent has the current policy changed practice patterns in States that have opted out of the supervision requirement? Have facilities utilized this flexibility across all geographic areas in these states? What impact has there been on access to anesthesia services?
- What benefits or unintended consequences have emerged from the exemption to the Medicare supervision requirements?
- Are there recent sufficient objective studies assessing the safety of anesthesia services to support a policy change related to the current supervision requirements?
- Do available studies provide the level of precision necessary to make a determination related to outcomes from anesthesia services? What changes in documentation, coding, or other methods would better support assessing outcomes related to anesthesia services?
- What benefits or unintended consequences could arise if the current supervision and exemption policy is retained or eliminated.
- Does the current supervision and exemption policy provide sufficient flexibility to States to opt out of the federal supervision requirements or is the policy excessively burdensome? What changes could be made to the current policy to reduce burden while balancing patient health and safety concerns?

We thank commenters in advance for considering this RFI and taking time to provide information on this important topic related to Medicare requirements for supervision of anesthesia services.

I. Reducing Reporting Burden for Hospital and CAH Respiratory Illness and Infectious Disease Data—RFI

We are seeking public comment on ways to reduce the reporting burden associated with respiratory illness and infectious disease data reporting requirements for hospitals, including CAHs (collectively referred to as ''hospitals'' for purposes of this subsection of the preamble), under this proposed rule. During and following the COVID–19 response, the health care community identified the need for standardized data elements and digital data collection approaches to ease reporting burden. We recognize that overlapping or duplicative reporting requirements across agencies can place a significant administrative burden on hospitals, particularly smaller or resource-constrained facilities. In response to this, CMS, in partnership with CDC, have continued to work to reduce reporting burden particularly for respiratory illness and infectious diseases through the development of data standards, adoption of interoperability modernization activities, and offering a single system, the NHSN, for data collection and reporting. The NHSN Hospital Respiratory Data Reporting (*https://www.cdc.gov/nhsn/psc/hospital-respiratory-reporting.html*) currently offers hospitals flexible reporting options (for example, CSV import, use of APIs, Fast Healthcare Interoperability Resources (FHIR) based approaches, etc.) to ease burden given the variation in adoption of data modernization capabilities across hospital systems. Building on these efforts, CMS is seeking information on how to better support adoption of data and interoperability capabilities to reduce burden through automation and digital collection of data.

Specifically, we request public comments on the following:

- How can CMS, in collaboration with CDC, support expanded adoption of HL7 and Fast Healthcare Interoperability Resources (FHIR) standards to reduce reporting burden in hospitals, particularly during a PHE. We invite comments on approaches, resources (*e.g.,* training, technical guidance) and assistance, such as pilots, that could support continued adoption and automation of reporting to reduce burden. What specific needs do rural hospitals have that would enable their adoption of this automated approach?
- NHSN currently serves as the point of submission that hospitals use to comply with respiratory illness and infectious disease reporting requirements when there is a PHE. We invite comments on how this approach is supporting streamlined reporting, and if additional informational resources or assistance could be offered to reduce burden during ongoing reporting of acute respiratory illnesses, including influenza, SARS–CoV–2/COVID–19, and RSV, and PHE reporting of acute infectious illnesses.
- During a PHE, reporting requirements may need to be revised. What approaches and informational resources could support hospital adoption and ease reporting burden and adjustment to the updated requirements?

• Are there specific variables collected by CDC that are particularly difficult to collect or easy to integrate into existing clinical work flows and electronic health records? How could CMS revise its regulations or information collection to better integrate into clinical work flows and to be more policy relevant for facilities while still maintain monitoring federal capabilities to prevent, identify, and mitigate a PHE?

J. Medicaid Institutional Payment Transparency Reporting Provision (§§ 438.72 and 442.43)

1. Background and Scope

Children and adults of all ages need long-term services and supports (LTSS) because of disabling conditions, chronic illness, and other factors. Medicaid allows for the coverage of these services through several authorities and in a variety of settings, ranging from institutional facilities to home and community-based settings. Medicaid programs are required to provide a nursing facility benefit for eligible individuals aged 21 or older. They are also required to provide medically necessary nursing facility services to children under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit and have obligations under Preadmission Screening and Resident Review requirements to provide nursing facility services to Medicaid beneficiaries of any age who need LTSS and for whom a nursing facility is the most appropriate setting to meet their needs. In addition, Medicaid programs may provide other institutional LTSS as optional services, including nursing facility services for persons under age 21 and services in Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID). Medicaid is the largest payer nationally of LTSS. In 2023, 1.29 million Medicaid beneficiaries received nursing facility services, and approximately 86,000 Medicaid beneficiaries received ICF/IID services.[294] These services accounted for over $79.4 billion in Medicaid expenditures ($68.8 billion for nursing facility services; $10.6 billion for ICF/IID services),[295] roughly 9 percent of the $871.7 billion in total Medicaid expenditures during that year.[296] Demand for LTSS, whether delivered in an institutional setting or in the home or community, is expected to continue rising due to the growing needs of the aging population.[297] [298]

As we discussed in the *Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting* proposed rule (88 FR 61352) (''2023 Minimum Staffing proposed rule''),[299] State Medicaid agencies (SMAs), provider groups, and beneficiary advocates have routinely expressed concern that chronic understaffing and high rates of turnover of direct care workers in Medicaid-participating nursing facilities and ICFs/IID make it difficult to ensure access to high-quality institutional services for people with disabilities and older adults. Additionally, direct care workers play a critical role in helping some residents develop the daily living skills needed to transition out of facilities and back to the community, as well as with assessing individuals' readiness for discharge and assisting with discharge planning. In addition to direct care nursing staff, other types of direct care workers, such as physical therapists and feeding assistants, provide LTSS (including, if applicable, components of active treatment as defined at § 483.440) to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Also important to residents' quality of life and quality of care are support staff who maintain the physical environment of the care facility or provide other supports to residents, such as housekeeping, environmental services, food services, or transportation.

Insufficient staffing in nursing facilities and ICFs/IID can reduce the efficiency of Medicaid payment for services, most clearly when the payment methodology is based on the actual cost of delivering services and such costs are increased due to reliance on overtime and temporary staff, which can have higher hourly costs than non-overtime wages paid to permanent staff. Further, understaffing can reduce quality of care, which can lead to poorer outcomes for people in institutional settings [300] and result in costly emergency department visits and hospitalizations.[301] [302] [303] As a result, understaffing is one of many factors that can reduce the cost-effectiveness of Medicaid institutional services.

In response to these concerns about the institutional workforce, we finalized Federal requirements through the ''Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care (LTC) Facilities and Medicaid Institutional Payment Transparency Reporting'' final rule (89 FR 40876) (''2024 Minimum Staffing final rule'').[304] These requirements were intended to promote public transparency around States' statutory obligation under section 1902(a)(30)(A) of the Act and around the quality requirements in section 1932(c) of the Act for services furnished through managed care organizations (MCOs) and prepaid inpatient health plans (PIHPs) [305] under our authority under section 1902(a)(4) of the Act. Specifically, we added new Federal requirements to promote better understanding and transparency related to the percentages of Medicaid payments for nursing facility and ICF/IID services that are spent on

[294] Carpenter, Alexandra, Cara Stepanczuk, and Andrea Wysocki. ''Medicaid Long-Term Services and Supports Users and Expenditures by Service Category, 2023.'' Mathematica, October 17, 2025. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-users-expenditures-category-brief-2023.pdf.*

[295] Carpenter, Alexandra, Cara Stepanczuk, and Andrea Wysocki. ''Medicaid Long-Term Services and Supports Users and Expenditures by Service Category, 2023.'' Mathematica, October 17, 2025. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-users-expenditures-category-brief-2023.pdf.*

[296] Medicaid and CHIP Payment and Access Commission (MACPAC). February 2026. MACStats: Medicaid and CHIP Data Book, accessed May 22, 2026.

[297] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

[298] Centers for Medicare & Medicaid Services. November 2020. Long-Term Services and Supports Rebalancing Toolkit. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-toolkit.pdf.*

[299] *https://www.federalregister.gov/documents/2023/09/06/2023-18781/medicare-and-medicaid-programs-minimum-staffing-standards-for-long-term-care-facilities-and-medicaid#page-61382.*

[300] We note that the requirements we finalized in the 2024 Minimum Staffing final rule and the proposals in this proposed rule are specific to nursing facility and ICF/IID services, which we at times may refer to collectively in this preamble as ''institutional services.'' We also note that unlike in other sections of this proposed rule, we will not be referring to LTC facilities, as the term typically is not used to describe ICFs/IID.

[301] Zheng, Q., Williams, C.S., Shulman, E.T., White, A.J. Association between staff turnover and nursing home quality—evidence from payroll-based journal data. J. Am. Geriatr. Soc. 2022;70(9):2508–2516. DOI: 10.1111/jgs.17843.

[302] Loomer, L., Grabowski, DC, Yu, H., Gandhi, A. Association between nursing home staff turnover and infection control citations. Health Serv. Res. 2022;57(2):322–332. DOI: 10.1111/1475–6773.13877.

[303] Lerner, N.B., Johantgen, M., Trinkoff, A.M., Storr, C.L., Han, K. Are nursing home survey deficiencies higher in facilities with greater staff turnover. J. Am. Med. Dir. Assoc. 2014;15(2):102–7. DOI: 10.1016/j.jamda.2013.09.003.

[304] *https://www.federalregister.gov/documents/2024/05/10/2024-08273/medicare-and-medicaid-programs-minimum-staffing-standards-for-long-term-care-facilities-and-medicaid#h-32.*

[305] Throughout this section, the use of the term ''managed care plan'' means MCOs and PIHPs.

compensation to direct care workers and support staff.

To support the implementation of the Medicaid institutional payment transparency reporting requirements finalized in the 2024 Minimum Staffing final rule, we engaged with States, providers, and other interested parties to provide training and technical assistance and address questions. We also began drafting technical specifications and guidance to support States with implementing the requirements and to explore options for collecting the required data from States. Through the public input received through this engagement and our internal deliberations related to the implementation of the requirements, we have developed a better understanding of the complexity and challenges of implementing certain Medicaid institutional payment transparency reporting requirements that we finalized in the 2024 Minimum Staffing final rule. As we discuss in more detail in section I.3. of this proposed rule, we also now believe we may be able to approximate the percentage of Medicaid payments spent on direct care worker compensation for nursing facilities using a combination of existing data, such as payroll-based journal data, the Minimum Data Set, Bureau of Labor Statistics data, Medicare Cost Reports, and/or Medicaid claims and encounter data. Based on this new understanding, we are proposing regulatory changes at §§ 438.72 and 442.43 to rescind requirements for States to report annually, at the facility level, on the percentage of payments for nursing facility services that is spent on compensation for direct care workers, the percentage of payments for nursing facility services that is spent on compensation for support staff, and the percentage of payments for ICF/IID services that is spent on compensation for support staff. In addition, we are soliciting public comment on approaches to address direct care worker shortages and strengthen the direct care workforce in nursing facilities and ICFs/IID.

2. Purpose and Statutory Basis

Title XIX of the Act established the Medicaid program as a joint Federal and State program to provide medical assistance to eligible individuals. Under the Medicaid program, each State that chooses to participate in the program and receive Federal financial participation (FFP) for program expenditures establishes eligibility standards, benefits packages, and payment rates, and undertakes program administration in accordance with Federal statutory and regulatory requirements. The provisions of each State's Medicaid program are described in the Medicaid ''State plan'' and, as applicable, in documents related to a State's use of other authorities, such as demonstration projects and waivers of State plan requirements. CMS reviews and approves State plans, State plan amendments, demonstration projects authorized under section 1115 of the Act, and waivers authorized under section 1915 of the Act. CMS also reviews expenditures for compliance with Federal Medicaid law, including the requirements of section 1902(a)(30)(A) of the Act relating to efficiency, economy, quality of care, and access, to ensure that all applicable Federal requirements are met.

Section 1902(a)(30)(A) of the Act requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports.

Institutional services include care delivered by direct care workers including nursing services, assistance with activities of daily living (such as mobility, personal hygiene, and eating), therapies (such as physical, speech or occupational), and recreation. Institutional services also require support staff who maintain the physical environment of the care facility or provide other services for residents (such as housekeeping, janitorial and environmental services, food preparation, and transportation).

Through the 2024 Minimum Staffing final rule, under our authority at section 1902(a)(6) of the Act, and consistent with section 1902(a)(30)(A) of the Act, we required that SMAs report annually, at the facility level, on the percentage of Medicaid payments (not including excluded costs, which are discussed later in this section) for nursing facility and ICF/IID services that is spent on compensation for the direct care and support staff workforce.[306] This requirement was intended to promote transparency around compensation for direct care workers and support staff.

To support the implementation of the Medicaid institutional payment transparency reporting requirements we finalized in the 2024 Minimum Staffing final rule, we engaged with States, providers, and other interested parties to provide training and technical assistance and address questions. This included participating in CMS Open Door Forums on April 25, 2024,[307] May 7, 2024,[308] and July 30, 2024,[309] to discuss the institutional payment transparency reporting requirements. We also participated in external meetings with SMAs, State operating agencies (such as State developmental disability agencies responsible for operating programs for people with intellectual and developmental disabilities), State associations, advocacy organizations, and others during summer and fall 2024 to disseminate information on the regulations and address questions. In addition, we began drafting technical specifications and guidance to support States with implementing the requirements and to explore options for collecting the required data from States.

Through these public engagements and our internal deliberations related to the implementation of the requirements, we have developed a better understanding of the complexity and challenges of implementing certain Medicaid institutional payment transparency reporting requirements we finalized in the 2024 Minimum Staffing final rule. Based on this understanding, we are proposing several changes to the regulatory text at §§ 438.72 and 442.43, to rescind the requirements for States to report annually, at the facility level, on the percentage of payments for nursing facility services that is spent on compensation for direct care workers, the percentage of payments for nursing facility services that is spent on compensation for support staff, and the percentage of payments for ICF/IID services that is spent on compensation for support staff. However, we are soliciting public comment on approaches to address worker shortages and strengthen the workforce in nursing facilities and ICFs/IID.

We note that while aspects of this proposal are intended to complement the goals expressed in other sections of this preamble, the following proposals

[306] Throughout this discussion, we use the term ''States'' to include all States, Washington, DC, and the territories that include nursing facility services or ICF/IID services in their State plans.

[307] See *https://www.cms.gov/files/zip/ltssodf07302024.zip* for more information.

[308] See *https://www.cms.gov/files/zip/ltssodf05072024.zip* for more information.

[309] See *https://www.cms.gov/files/zip/ruralhealthodf04252024.zip* for more information.

presented later in this section of the preamble would be, if finalized, distinct provisions. To the extent a court may enjoin any part of a final rule, the Department intends that other provisions or parts of provisions should remain in effect. Should they be finalized, we intend that any provision of the proposals described in this section or in another section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, would be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding is one of utter invalidity or unenforceability, in which event we intend that the provision would be severable from the other finalized provisions described in this section and in other sections and would not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

3. Proposed Provisions

In the 2024 Minimum Staffing final rule, we noted that a few commenters on the 2023 Minimum Staffing proposed rule did not believe that the reporting requirement as proposed would yield consistent or fully transparent data, given the differences among facilities, their payment models, current reporting practices, case mixes, size, geographical location, staffing requirements, and staff roles.[310] At the time, we did not understand in particular how diversity in payments could impact the accuracy of the reporting. Through our engagement since the rule was finalized and our internal deliberations related to the implementation of the requirements, we now understand that this diversity in payment sources for nursing facilities would create operational challenges related to the institutional payment transparency reporting requirements that would be difficult for States to address and could result in inaccurate reporting. For instance, nursing facilities typically receive payments from multiple payers, including Medicare, Medicaid, commercial insurance, Veterans Affairs, and self-pay. To comply with the institutional payment transparency reporting requirements, States would need to determine the share of direct care worker and support staff compensation that is for the care specifically of Medicaid beneficiaries, even though the residents that nursing facilities provide services to on a daily basis likely have a mix of payers. To accurately report on the percentage of Medicaid payments spent on compensation for direct care workers, we believe that States would need to require nursing facilities to do extensive daily time tracking of each of their direct care workers (including the amount of time each day that each direct care worker spent specifically caring for each Medicaid resident). We believe that such tracking would extend beyond any such tracking that is necessary to meet other Federal reporting requirements, even though nursing facilities have extensive Federal reporting requirements in addition to the Medicaid institutional payment transparency reporting requirements. Further, we believe that such tracking would detract from the amount of time that direct care workers spend caring for residents, thereby potentially exacerbating concerns related to understaffing in nursing facilities, quality of care, and poor outcomes that we cited in establishing the requirements.[311]

To avoid onerous time tracking of direct care workers in nursing facilities, we could potentially advise States that they could approximate the time that direct care workers spend caring for Medicaid residents in calculating the percentage of Medicaid payments spent on compensation for direct care workers.

However, we believe that we could make such an approximation using existing data sources, thereby reducing burden on nursing facilities without necessarily impacting the accuracy of the reporting. These existing data sources may include (but are not necessarily limited to): payroll-based journal data,[312] which includes data on direct care worker staff hours at the individual staff level for all Medicare- and Medicaid-certified nursing facilities; resident census data from the Minimum Data Set,[313] which provide information on how many residents there are overall and how many residents are Medicaid beneficiaries in each facility; Bureau of Labor Statistics data on average wages by occupation and county; [314] Medicare Cost Reports,[315] which contain financial information for Medicare-certified [316] skilled nursing facilities, including the proportion of resident days paid for by Medicaid, facility revenue, and facility expenditures on nursing staff; and/or Medicaid claims and encounter data which provide information on Medicaid fee-for-service and managed care payments to facilities.

a. Rescinding References to Nursing Facility Services and Nursing Facilities (§§ 438.72(a) and 442.43(a)(3), (b)(1), (d), (f))

CMS is proposing several changes to the regulatory text at §§ 438.72 and 442.43. Specifically, we are proposing to revise §§ 438.72(a) and 442.43(a)(3), (b)(1), (d), (f) to remove references to nursing facility services and nursing facility. If finalized, this proposal would remove the Medicaid Institutional Payment Transparency Reporting requirement for states to report on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers and support staff.

As we discussed in the 2024 Minimum Staffing final rule, we received comments on the 2023 Minimum Staffing proposed rule that supported using existing data sources to approximate the information required under the Medicaid institutional payment transparency reporting requirement for nursing facilities. For instance, one commenter stated that we already collect multiple data sets [317] that could be used to approximate the information that would be subject to the direct care worker reporting requirement, including: direct care salary, benefits, and hours for freestanding nursing facilities using the Medicare Cost Report; Medicaid fee-for-service per diems in upper payment limit reporting; and quarterly supplemental payment information through the Medicaid Budget and Expenditure System (MBES) [318] and in

[310] *https://www.federalregister.gov/d/2024-08273/p-477.*

[311] Min A., Hong HC. Effect of nurse staffing on rehospitalizations and emergency department visits among short-stay nursing home residents: A Cross-sectional study using the US Nursing Home Compare database. Geriatr Nurs. 2019 Mar-Apr;40(2):160–165. doi: 10.1016/j.gerinurse.2018.09.010. Epub 2018 Oct 4. PMID: 3029252.8.

[312] *https://www.cms.gov/medicare/quality/nursing-home-improvement/staffing-data-submission.*

[313] *https://www.cms.gov/medicare/quality/nursing-home-improvement/resident-assessment-instrument-manual.*

[314] *https://www.bls.gov/bls/blswage.htm.*

[315] *https://data.cms.gov/provider-compliance/cost-reports/skilled-nursing-facility-cost-report.*

[316] We recognize that nursing facilities that are not Medicare-certified are not required to submit cost reports to CMS. However, these facilities make up a very small percentage of all nursing facilities nationally. In 2020, only 2 percent of nursing facilities were Medicaid-certified only, according to the Congressional Research Service (*https://www.congress.gov/crs-product/IF11545*).

[317] *https://www.federalregister.gov/d/2024-08273/p-472.*

[318] *https://www.medicaid.gov/medicaid/data-systems/medicaid-and-chip-business-information-solution/macbis-financial/medicaid-budget-and-expenditure-system-mbes.*

Form CMS–64 reports.[319] This commenter stated that we should use existing Federal data to approximate the proposed metrics, which the commenter believed would reduce administrative burden and ensure consistent calculations across Medicaid programs.[320] A few commenters noted that facilities already complete cost reports and suggested that researchers and regulators interested in Medicaid expenditures could obtain spending information from these cost reports.[321] At the time, we disagreed that data on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers are readily available from existing data sources currently collected by CMS, and the data sources that the commenter listed would not provide information about Medicaid revenues at the facility level.

While we continue to agree that existing nursing facility data have limitations for the purpose of reporting on the percentage of Medicaid payments that is spent on compensation, we are no longer convinced, given the challenges discussed earlier with nursing facility reporting on the percentage of Medicaid payment that is spent on compensation, that existing data would necessarily result in a less accurate calculation than the regulatory requirement would. We believe it is important to further explore the feasibility of using existing data sources to report on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers before imposing additional and potentially unnecessary reporting requirements. As a result, we are proposing to rescind the requirement that States report on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers. See section II.H.3.(c) of this proposed rule for an articulation of each proposed recission.

b. Revising the Medicaid Institutional Payment Transparency Reporting Provision for Intermediate Care Facilities (§ 442.43(a)(3), (a)(3)(i) and (ii), (b), and (c)(1))

CMS is proposing to revise § 442.43(a)(3), (a)(3)(i) and (ii), (b), and (c)(1) by removing references to support staff. If finalized, this proposal would: 1) remove the Medicaid Institutional Payment Transparency Reporting requirement for states to report on the percentage of Medicaid payments for ICFs/IID that is spent on compensation for support staff, and 2) retain the requirement for states to report on the percentage of Medicaid payments for ICFs/IID that is spent on compensation for direct care workers.

Compared to nursing facilities, there is substantially less data available nationally on ICFs/IID. We do not believe that existing data on ICFs/IID can be used to approximate the percentage of Medicaid payments spent on compensation for direct care workers. Further, ICF/IID services are generally covered by Medicaid, but not Medicare or most private health insurance plans, reducing the complexity of the institutional payment reporting requirements for these providers compared to nursing facilities.[322] [323] As a result, we are not proposing to rescind the requirement that States report on the percentage of Medicaid payments for ICF/IID services spent on compensation for direct care workers. We continue to believe, as we did when we finalized the 2024 Minimum Staffing final rule, that promoting transparency around the percentage of Medicaid payments spent on compensation for direct care workers in ICFs/IID can improve understanding of policies that can support the direct care workforce and improve access to high quality care for Medicaid beneficiaries.[324] Further, they can help CMS, States, and the public assess whether Medicaid payments are being appropriately used to provide direct care to residents. Although we are not proposing any changes to this provision, we invite comment to inform future rulemaking on the merits of retaining this reporting requirement. See section II.H3(c) of this proposed rule for an articulation of each proposed revision.

c. Rationale for Proposed Recissions and Revisions (§§ 438.72 and 442.43)

As we discussed in the 2024 Minimum Staffing final rule, high-quality institutional services include support staff who maintain the physical environment of the care facility or provide other services for residents (such as housekeeping, janitorial and environmental services, food preparation, and transportation).[325] However, based on our engagement since the rule was finalized, we have learned that the amount of support staff needed to maintain the physical environment of the care facility or provide other services for residents is impacted by a variety of factors such as the age, condition, infrastructure, and physical layout of the facility; and whether the facility employs support staff or contracts for such services. Further, as a few commenters on the 2023 Minimum Staffing proposed rule indicated, facilities use Medicaid payments for a variety of expenses such as providing residents with private rooms, improving facility ventilation, evaluating and testing emergency preparedness plans, and other non-compensation activities that improve residents' care and safety.[326] We recognize that such costs can also have important impacts on the health and safety of residents but would not be accounted for in the Medicaid institutional payment transparency reporting requirements. We continue to believe that adequate support staffing is important to the health and safety of residents, but we are no longer convinced that data on the percentage of Medicaid payments spent on compensation for support staff is a useful metric for understanding whether payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent that such care and services are available to the general population in the same geographic area, consistent with section 1902(a)(30)(A) of the Act. As such, we do not believe that the current record supports maintaining the requirement, and we are proposing to rescind the requirements that States report on the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff and the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff.

We propose to rescind the three reporting requirements discussed in this section. We are proposing several changes to the regulatory text at §§ 438.72 and 442.43. Specifically, we are proposing to revise § 438.72(a) to remove references to nursing facility

[319] *https://www.medicaid.gov/medicaid/financial-management/state-budget-expenditure-reporting-for-medicaid-and-chip.*

[320] *https://www.federalregister.gov/d/2024-08273/p-472.*

[321] *https://www.federalregister.gov/d/2024-08273/p-472.*

[322] *https://www.cms.gov/medicare/health-safety-standards/certification-compliance/intermediate-care-facilities.*

[323] Medicaid and CHIP Payment and Access Commission (MACPAC ''MACStats: *Medicaid and CHIP Data Book.*'' December 2023. *https://www.macpac.gov/wp-content/uploads/2023/12/MACSTATS_Dec2023_WEB-508.pdf.*

[324] Sharma, H. and Liu, X. Association between wages and nursing staff turnover in Iowa. Innov Aging. 2022; 6(4): igac004. Published online 2022 Feb 5. doi: *10.1093/geroni/igac004.*

[325] *https://www.federalregister.gov/d/2023-18781/p-437.*

[326] *https://www.federalregister.gov/d/2024-08273/p-479.*

services and nursing facility. We are also proposing the following changes to the regulatory text at § 442.43:

- Revise the definition of *Compensation* in paragraph (a)(1) to remove ''and support staff'';
- Remove paragraph (a)(3), which defines *Support Staff;*
- Redesignate paragraph (a)(4), which defines *Excluded Costs,* as paragraph (a)(3);
- Revise newly redesignated paragraph (a)(3) to remove ''nursing facility or'' and ''and support staff'';
- Revise newly redesignated paragraphs (a)(3)(i) and (ii) to remove ''and support staff'';
- Revise paragraph (b), which establishes the reporting requirements, to remove ''and on compensation for support staff'' and ''pass-through payments'' as defined in § 438.6(a) for nursing facilities,'';
- Revise paragraph (b)(1), which describes the services subject to the reporting requirements, to remove ''nursing facility and'' and '', with the exception of services provided in swing bed hospitals as defined in § 440.40(a)(1)(ii)(B);
- Revise paragraph (c)(1) to read, ''*Contents.* Reporting must provide information necessary to identify, at the facility level, the percentage of Medicaid payments spent on compensation to direct care workers at each ICF/IID.'' and remove paragraphs (c)(1)(i) through (iv), which separately lists each of the reporting requirements; and
- Revise paragraph (d), which describes the website availability and accessibility requirements, to remove ''nursing facility and/or''; and
- Revise paragraph (f), which establishes the applicability date for the requirements, to remove ''nursing facility services or''.

We invite comment on these proposals.

We recognize that States and certain facilities may have begun planning for or implementing operational or systems changes to comply with the institutional payment transparency reporting requirements. We have considered such reliance costs in proposing to rescind the requirements that States report on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff, and the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff. Given the June 21, 2028, applicability date for the requirements, we believe that the costs that they may have incurred to date are minimal. We believe that any costs they have incurred to comply with the requirements are substantially less than any remaining initial implementation and ongoing costs they would incur if required to comply with the requirements as finalized. We also considered whether Medicaid beneficiaries, direct care workers, and support staff have relied on the institutional payment transparency reporting requirements. Since the applicability date for the requirements has not yet occurred, beneficiaries, direct care workers, and support staff have not experienced any benefits from the requirements. As such, we do not believe that they have relied on the institutional payment transparency reporting requirements.

As we discussed in the 2024 Minimum Staffing final rule, we intend to release subregulatory guidance and technical specifications to assist States with implementation of the requirements at § 442.43. We will make a reporting methodology and reporting template available for public comment through the Paperwork Reduction Act notice and comment process, which will give the public the opportunity to provide specific feedback and help us align the methodology and reporting process with existing State practices to the greatest extent possible. We also acknowledge that because State processes, timelines, and definitions vary, it may not be possible to align all details of the reporting process with existing practices in multiple States. We therefore plan to provide technical assistance, as needed, to facilitate further alignment with States' current reporting practices, to the greatest extent possible. As part of these materials, we intend to clearly indicate that States can use existing infrastructure or tools, such as provider surveys, to collect the necessary data to comply with the reporting requirements. Additionally, given the variety of contracting models, we will provide subregulatory guidance to States on how to approach reporting on compensation to contracted and subcontracted staff. We invite comment on other approaches or strategies that States could use to efficiently and effectively implement the requirements.

If the provisions discussed earlier in this section are finalized, States and CMS will be required to publicly report, at the facility level, on the percentage of Medicaid payments for ICF/IID services that are spent on compensation to direct care workers, but not on the percentage of Medicaid payments for nursing facility services that is spent on compensation to direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation to support staff, or the percentage of Medicaid payments for ICF/IID services that is spent on compensation to support staff. We also plan to explore the feasibility of using existing data sources to report on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, as we believe that promoting transparency around the percentage of Medicaid payments spent on compensation for direct care workers can improve understanding of how to enact policies that support the direct care workforce and advance access to high quality care for Medicaid beneficiaries. We request comment on other approaches we should consider for future rulemaking or policy guidance to address institutional workforce shortages and strengthen the institutional workforce. In particular, we invite comment on: if specific Federal policies, regulations, or processes hinder States', managed care plans', and providers' ability to recruit and retain direct care workers and support staff; effective reimbursement or other strategies for reducing turnover among direct care workers and support staff and addressing the shortage of institutional workers in rural areas; and promising approaches to building direct care worker career pathways.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This proposed rule would impose new information collection requirements for some hospitals and CAHs that offer OB services. At the same time, however, it would create savings by eliminating information

collection requirements and recordkeeping or third-party disclosure requirements. As discussed later in this section of the preamble, we provide details on the expected costs and savings, if any, for each of the information collection requirements that we are proposing to create and eliminate.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Ongoing Respiratory Illness Report in Long-term Care (LTC) Facilities (§ 483.80(g))

We are proposing to repeal the requirement at § 483.80(g) that LTC facilities engage in ongoing respiratory illness reporting when there is not a PHE. Currently, this reporting occurs on a weekly basis. This ongoing reporting requirement specifies that LTC facilities must submit data on the number of residents occupying a bed in the facility for at least 24 hours during the week, as well as residents' vaccination status, the number of confirmed resident cases and hospitalizations due to respiratory illnesses that include but are not limited to influenza, SARS–CoV–2/COVID–19, and RSV. We also propose to retain the following data elements currently in the ongoing reporting requirement for use during periods of Secretary-declared public health emergencies (PHEs): (1) facility census (currently § 483.80(g)(1)(ii)(A)); (2) confirmed, resident cases (currently § 483.80(g)(1)(ii)(C)); (3) hospitalized residents with confirmed cases (currently § 483.80(g)(1)(ii)(D)); (4) confirmed infections for staff (currently § 483.80 (g)(2)(i)); (5) supply inventory shortages (currently § 483.80 (g)(2)(ii)); (6) staffing shortages (currently § 483.80 (g)(2)(iii)); and (7) medical countermeasures and therapeutic inventories (currently § 483.80 (g)(2)(iv)).

To estimate the savings from eliminating the ongoing data reporting requirement, we followed the methodology used to estimate its cost in the CY 2025 Home Health PPS final rule (89 FR 88354).[327] We first assumed that since the infection preventionist (IP) oversees the facility's infection prevention and control program (IPCP), they would have retained responsibility for continuing to ensure that the facility met this requirement. We also assumed that the IP would be a registered nurse (RN). We calculated the hourly rate for the IP by doubling the national mean salary for RNs (occupation code 29–1141) using the BLS' May 2025 National Occupational Employment and Wage Estimates,[328] leading to an hourly cost of $97.52 ($48.76 × 2). We doubled the mean salary since the BLS data do not include overhead costs and fringe benefits. The HHS-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for including these overhead and fringe benefit costs.

We do not estimate savings from reviewing and updating the facility's policies and procedures since we expect that most facilities will continue to review their policies and procedures to ensure that they are up to date. We also do not estimate new costs for moving the elements listed in the ongoing reporting requirements to the PHE reporting requirements since LTC facilities are already required to report these data elements during a PHE. We do, however, estimate the change in burden due to the elimination of the ongoing (weekly) reporting requirement.

Reviewing data from the Administration for Strategic Preparedness and Response (ASPR) on public health emergencies between 2005 and 2025, we identified four public health emergencies (H1N1, Zika, Mpox, and COVID–19), or approximately 1 every 5 years, where PHE reporting could occur. Two of these illnesses (H1N1 and COVID–19) are respiratory illnesses with the COVID–19 PHE lasting nearly 3.5 years and the H1N1 PHE lasting approximately 12 months. Given the extraordinary nature of COVID–19, we estimate that on average, there would be a 1-year respiratory illness PHE every 10 years where facilities would not incur savings from the proposed requirements. In addition, with the PHEs for Zika and Mpox lasting 9 months (0.75 years) and 6 months (0.5 years), respectively, we estimate that there would be approximately 7.5 months, or approximately 32 weeks every 10 years where facilities would report on other acute infectious illnesses.

According to CMS, there are 14,732 LTC facilities as of February 2026.[329] We expect that LTC facilities, on average, spend one hour weekly collecting the data and reporting the required information. Utilizing these data, we estimate in Table 1 that removing the ongoing reporting requirements would save LTC facilities 766,064 hours (52 hours × 14,732 facilities) and $74,706,561 (766,064 hours × $97.52) annually when there is no PHE. In Table 2, we estimate the savings when there is a PHE for an acute infectious illness that lasts 7.5 months (32 weeks). In that year, removing the ongoing reporting requirement would result in savings for the 20 weeks when there is not a PHE that requires reporting, leading to expected savings of 294,640 hours (20 hours × 14,732 facilities) and $28,733,293 (294,640 hours × $97.52).

TABLE 1: 1 Year Burden Reduction from Removing non-PHE Reporting in LTC Facilities When There is no PHE

Facilities (a)	Hourly Salary (b)	Hourly Burden per Facility (c)	Per facility Cost Savings (d = b × c)	Total Financial Savings (e = d × a)	Total Hourly Savings (f = a × c)
14,732	$97.52	52	$5,071	$74,706,561	766,064

[327] ''Medicare Program; Calendar Year (CY) 2025 Home Health Prospective Payment System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies Final Rule''.

[328] Available at *https://www.bls.gov/oes/current/oes291141.htm.*

[329] *https://qcor.cms.gov/active_nh.jsp?which=0&report=active_nh.jsp,* report ran 2/06/2026.

TABLE 2: 1 Year Burden Reduction from Removing non-PHE Reporting in LTC Facilities When there is a Partial Year PHE

Facilities (a)	Hourly Salary (b)	Hourly Burden per Facility (c)	Per facility Cost (d = b × c)	Total Financial Savings (e = d × a)	Total Hourly Savings (f = a × c)
14,732	$97.52	20	$1,950	$28,733,293	294,640

In Table 3, we combine this information to estimate total savings over 10 years. For the 10-year estimate, we assume $0 in savings in year 5 based on our assumption of one year of acute respiratory illness reporting every 10 years, as well as an acute infectious illness occurring in year 10 that lasts 32 weeks (7.5 months). Over 10 years we estimate total savings would be $626,385,783 and 6,423,132 staff hours.

TABLE 3: 10-Year Burden Reduction for Removing LTC Facilities' Non-PHE Reporting Requirements

Year	Financial Savings	Hourly Savings
1	$74,706,561	766,064
2	$74,706,561	766,064
3	$74,706,561	766,064
4	$74,706,561	766,064
5	$0	0
6	$74,706,561	766,064
7	$74,706,561	766,064
8	$74,706,561	766,064
9	$74,706,561	766,064
10	$28,733,293	294,620
Total 10-Year Savings	$626,385,783	6,423,132

The information collection currently approved under OMB Control No. 0938–1363 (Long-Term Care Facilities) will be revised and submitted to OMB for review and approval.

B. ICRs Regarding Proposal To Amend Transfer Notice to Ombudsman (§ 483.15(c))

We are proposing to remove the requirement for LTC facilities to provide Ombudsman notice of resident transfers related to emergent care. To estimate the savings from removing this requirement, we followed the same methodology used to estimate its cost in the final rule establishing this requirement.[330] Specifically, we estimate that it costs $0.10 per notice to make a copy and $0.95 for a pre-stamped first-class envelope (USPS) retail. An OIG report estimates that 25 percent of nursing home residents are transferred to hospitals each year.[331] As of January 2026, there were 1,231,691 residents in Medicare/Medicaid-certified nursing homes.[332] While recognizing that some nursing homes send bulk notices to ombudsmen on a regular basis, such as once a month, we also recognize that some nursing home residents may have more than one transfer for emergent care. As such, we assume that LTC facilities are currently sending 307,923 notices (1,231,691 residents × 25 percent) annually. We assume that it takes a secretary or administrative assistant 5 minutes to print and address each notice, for a total time burden of 25,660 hours (307,923 residents × .083 hours). We calculated the employee's hourly rate by doubling the national mean salary for secretaries and administrative assistants (occupation code 43–6010) using the BLS' May 2025 National Occupational Employment and Wage Estimates,[333] leading to an hourly cost of $51.26 ($25.63 × 2). We doubled the mean salary since the BLS data do not include overhead costs and fringe benefits. This leads to an average cost of $5.30 per notice ($1.05 for printing and envelope + $4.25 staff time).

As indicated in Table 4, we estimate that the proposed change in notices would lead to a $1,631,991 annual reduction in burden with 25,660 hours saved. Table 5 provides the total savings

[330] 81 FR 68688.

[331] Office of Inspector General. Medicare Nursing Home Resident Hospitalization Rates Merit Additional Monitoring (OEI–06–11–00040; 11/13). Published online November 2013:28.

[332] Centers for Medicare and Medicaid Services. Provider Information. *https://data.cms.gov/provider-data/dataset/4pq5-n9py* (January 27, 2026).

[333] Available at *https://www.bls.gov/oes/current/oes291141.htm.*

over 10 years that we estimate would be $16,319,906 and 256,600 hours.

TABLE 4: Annual Burden Reduction from Removing Ombudsmen Notices of Transfer for Emergent Care

Number of Residents (a)	% of Resident Needing Transfer (b)	Envelope and Printing Cost Savings (c)	Staff Cost Savings per Patient Notice (d)	Savings per Patient Transfer (e = c + d)	Total Cost Savings (f = a × b × e)	Total Hourly Savings (g = a × b × 5 minutes/notice)
1,231,691	0.25	$1.05	$4.25	$5.30	$1,631,991	25,660

TABLE 5: 10-Year Burden Reduction from Removing Ombudsmen Notices of Transfer for Emergent Care

Year	Financial Savings	Hourly Savings
1	$1,631,991	25,660
2	$1,631,991	25,660
3	$1,631,991	25,660
4	$1,631,991	25,660
5	$1,631,991	25,660
6	$1,631,991	25,660
7	$1,631,991	25,660
8	$1,631,991	25,660
9	$1,631,991	25,660
10	$1,631,991	25,660
Total 10-Year Savings	$16,319,906	256,600

The information collection currently approved under OMB Control No. 0938–1363 will be revised and submitted to OMB for review and approval.

C. ICRs Regarding Proposal To Amend Facility Assessment by Removing Active Involvement of Direct Care Staff Representatives (Union Representatives) (§ 483.71)

We are proposing to modify the LTC facility assessment requirement (§ 483.71) by removing the requirement that LTC facilities include the active involvement of representatives of direct care staff when conducting the LTC facility assessment. The Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting final rule (89 FR 40876) that established the requirement that representatives of direct care staff be included in the assessment process, estimated no burden for including them in the assessment process. As such, we estimate no financial savings from their removal from the process. We do expect, however, that ending their inclusion will streamline the process and ensure that the focus remains on the residents.

D. ICRs Regarding Staff COVID–19 Vaccine Educate, Offer, and Documentation Requirements in LTC Facilities (§ 483.80(d))

We are proposing to remove the requirement (§ 483.80(d)) that LTC care facilities educate staff members on the benefits and risks of COVID–19 vaccines, offer the COVID–19 vaccine to staff members, and maintain documentation related to staff COVID–19 vaccination. To estimate the savings from removing these requirements, we utilized the same methodology that we used to estimate the collection of information costs in the Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff IFC (86 FR 26306).

Specifically, we assume that a registered nurse (RN) oversees LTC facilities' updates to the facility's policies and procedures. We calculated the RN's hourly rate by doubling the national mean salary for RNs (occupation code 29–1141) using the BLS' May 2025 National Occupational

Employment and Wage Estimates,[334] leading to an hourly cost of $97.52 ($48.76 × 2). We originally estimated that it would take 12 hours annually for each facility to update its policies and procedures related to staff and resident COVID–19 education and vaccination efforts. Since we are proposing to remove the requirements related to staff education, we estimate that the time needed to update policies and procedures will decline by 6 hours annually. As of February 2026, there were 14,732 Medicare/Medicaid-certified nursing homes.[335] As indicated in Tables 6, facilities would save 88,392 hours (14,732 facilities × 6 hours) and $8,619,988 (88,392 hours × $97.52) annually from not needing to update their policies and procedures related to staff COVID–19 vaccine education. Table 7 provides the 10-year savings that we estimate would be $86,199,878 and 883,920 hours.

TABLE 6: Annual Burden Reduction from Removing Updates to Facility Policies Regarding Staff COVID-19 Education

Total Facilities (a)	Loaded Hourly Wage (b)	Hours per Facility (c)	Total Financial Savings (d = a × b × c)	Total Hourly Savings (e = a × c)
14,732	$97.52	6	$8,619,988	88,392

TABLE 7: 10-Year Burden Reduction from Removing Updates to Facility Policies Regarding Staff COVID-19 Education

Year	Financial Savings	Hourly Savings
1	$8,619,988	88,392
2	$8,619,988	88,392
3	$8,619,988	88,392
4	$8,619,988	88,392
5	$8,619,988	88,392
6	$8,619,988	88,392
7	$8,619,988	88,392
8	$8,619,988	88,392
9	$8,619,988	88,392
10	$8,619,988	88,392
Total 10-Year Savings	$86,199,878	883,920

In addition to updating their policies and procedures, facilities must also document their education efforts surrounding staff COVID–19 vaccination. We estimate that documentation in employee records takes each facility 6 hours annually for a total annual burden of 88,392 hours (14,732 facilities × 6 hours) across all facilities. This documentation would be completed by a financial clerk (occupation code 43–3099) using the BLS' May 2025 National Occupational Employment and Wage Estimates, at an hourly cost of $54.28 ($27.14 × 2). As indicated in Tables 8 and 9, removing this documentation requirement would save facilities 88,392 hours and $4,797,918 annually (88,392 hours × $54.28) with total 10-year savings of $47,979,178 and 883,920 hours.

[334] *https://qcor.cms.gov/active_nh.jsp?which=0&report=active_nh.jsp,* report ran 02/06/2026.

[335] iQIES (02/03/2026). Available at *qcor.cms.gov* (accessed February 6, 2026).

TABLE 8: Annual Burden Reduction from Removing Staff Documentation of COVID-19 Education

Total Facilities (a)	Loaded Hourly Wage (b)	Hours per Facility (c)	Total Cost Savings (d = a × b × c)	Total Hourly Savings (e = a × c)
14,732	$54.28	6	$4,797,918	88,392

TABLE 9: 10-Year Burden Reduction from Removing Staff Documentation of COVID-19 Education

Year	Financial Savings	Hourly Savings
1	$4,797,918	88,392
2	$4,797,918	88,392
3	$4,797,918	88,392
4	$4,797,918	88,392
5	$4,797,918	88,392
6	$4,797,918	88,392
7	$4,797,918	88,392
8	$4,797,918	88,392
9	$4,797,918	88,392
10	$4,797,918	88,392
Total 10-Year Savings	$47,979,178	883,920

The information collection currently approved under OMB Control No. 0938–1363 will be revised and submitted to OMB for review and approval.

E. ICRs Regarding Staff COVID–19 Vaccine Educate, Offer, and Documentation Requirements in ICFs-IID (§ 483.460(a)(4))

We are proposing to remove the requirements *(§ 483.460(a)(4))* that ICFs-IID educate staff members on COVID–19 vaccines and offer the COVID–19 vaccine to staff members and modifying the policies and procedures surrounding the procedures for COVID–19 vaccination education and offer for clients. To estimate the savings from removing these requirements for staff members, we utilized the same methodology that we used to estimate the collection of information costs in the Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for LTC Facilities and ICFs-IID Residents, Clients, and Staff IFC (86 FR 26306).

Specifically, we assume that an RN oversees ICFs-IID's updates to the facility's policies and procedures. We calculated the RN's hourly rate by doubling the national mean salary for RNs (occupation code 29–1141) using the BLS' May 2025 National Occupational Employment and Wage Estimates, leading to an hourly cost of $97.52 ($48.76 × 2). We originally estimated that it would take 6 hours annually for each facility to update its policies and procedures related to staff and resident COVID–19 education and vaccination efforts. Since we are proposing to remove the requirements related to staff education, we estimate that the time needed to update policies and procedures would decline by 3 hours annually. As of February 2026, there were 5,332 Medicare/Medicaid-certified ICFs-IID.[336] As indicated in Table 10, facilities would save 15,996 hours (5,332 facilities × 3 hours) and $1,559,930 (15,996 hours × $97.52) annually from not needing to update their policies and procedures related to staff COVID–19 vaccine education. Table 11 contains the total 10-year savings that we estimate would be $15,599,299 and 159,960 hours.

[336] iQIES (02/03/2026). Available at *qcor.cms.gov* (accessed February 6, 2026).

TABLE 10: Annual Burden Reduction from Removing Updates to Facility Policies Regarding Staff COVID-19 Education in ICFs-IID

Total Facilities (a)	Loaded Hourly Wage (b)	Hours per Facility (c)	Total Financial Savings (d = a × b × c)	Total Hourly Savings (e = a × c)
5,332	$97.52	3	$1,559,930	15,996

TABLE 11: 10-Year Burden Reduction from Removing Updates to Facility Policies Regarding Staff COVID-19 Education in ICFs-IID

Year	Financial Savings	Hourly Savings
1	$1,559,930	15,996
2	$1,559,930	15,996
3	$1,559,930	15,996
4	$1,559,930	15,996
5	$1,559,930	15,996
6	$1,559,930	15,996
7	$1,559,930	15,996
8	$1,559,930	15,996
9	$1,559,930	15,996
10	$1,559,930	15,996
Total 10-Year Savings	$15,599,299	159,960

For the modification to the policies and procedures surrounding the COVID–19 vaccination for clients, we do not expect these changes will modify the collection of information costs.

The information collection under OMB Control No. 0938–1402 will be revised and sent to OMB for approval.

F. ICRs Regarding COVID–19 Sunset Requirements for REHs (§ 485.526(e) and (g))

We are proposing to repeal the requirement (§ 485.526(e)) that REHs electronically report information about COVID–19 and seasonal influenza in a standardized format specified by the Secretary. We are also proposing to remove the requirement (§ 485.526(g)) that REHs must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. The COVID–19 and seasonal influenza reporting requirement ended on April 30, 2024, while the requirement that REHs must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19 ended on November 4, 2024. As such, we do not expect that REHs will see a reduction in information collection costs from removing these requirements.

G. ICRs Regarding Proposals To Remove Data Reporting Requirements for REHs During a PHE (§ 485.526(f))

We propose to remove the requirement for REHs to report data related to viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential when the Secretary has declared a PHE. Currently, the elements that REHs are required to report during a PHE exceed those required for hospitals and CAHs. Eliminating this requirement would alleviate burden on REHs, which typically operate with a limited number of staff members. Additionally, we are retaining the requirements for hospitals and CAHs to report data on infectious illness during a PHE. As a result, relevant data on patients that are stabilized in REHs and transferred to other hospitals would be accounted for in this reporting. We anticipate that removing this data reporting requirement would likely reduce burden for REH providers. Given the timing of the implementation of the REH program and the limited mandated PHE data reporting period, we are seeking comments on potential savings for REHs that would occur under the proposed removal of the PHE reporting requirements.

H. ICRs Regarding Revisions to Physical Environment and Emergency Preparedness Incorporation by Reference (§§ 485.542(g) & 485.544(e)) for REHs

We are proposing to modify the REH physical environment and emergency preparedness incorporation by reference requirements that outline procedures for enforcing updated editions and provide contact information for accessing the incorporated materials through CMS and the National Archives and Records Administration (NARA) by removing the outdated CMS contact information and updating the NARA contact information for access to the incorporated materials. We expect no financial savings from updating this requirement although we expect that it will reduce confusion when interested parties are seeking to access this information from CMS.

I. ICRs Regarding Obstetrical Services (OB) Training Policies and Procedures for Hospitals (§ 482.59(c)) and CAHs (§ 485.649(c))

We are proposing to repeal the requirement that hospitals (§ 482.59(c)) and CAHs (§ 485.649(c)) that offer obstetrical services develop policies and procedures to ensure that relevant staff are trained on select topics for improving the delivery of maternal care. In addition to developing these policies and procedures, facilities must provide relevant new staff with initial training and subsequent biennial training, document that the training was completed, and be able to demonstrate staff knowledge on the training topics. Finally, they must review and assess the training's efficacy on an ongoing basis based on the results of data, measures, and quality indicators from the facility's QAPI program.

In the final rule [337] that established the requirement for developing these policies and procedures, the expectation was that facilities would incur the burden for doing so during the first year after the effective date of January 1, 2025, or between January and December 2025. As such, we expect that most facilities have already completed their policies and procedures for this requirement and do not expect that removing it would reduce hospital or CAHs burden. We do not estimate anticipated savings for not needing to document that training was completed as updating employee records is a customary business practice. We also do not estimate savings for hospitals and CAHs not needing to review and assess the efficacy of their training since we expect that even with the elimination of the training requirement, hospitals and CAHs will still spend time assessing the efficacy of their maternal health efforts to meet requirements for their QAPI programs as outlined for hospitals (§ 482.21(e)) and CAHs (§ 485.641(e)). In the section titled ''OB Services Staff Training for Hospitals (§ 482.59(c)) and CAHs (§ 485.649(c))'', we estimate the savings hospitals and CAHs would obtain by not needing to train employees and review and assess the efficacy of these efforts.

J. ICRs Regarding Emergency Services Readiness Staff Training for Hospitals (§ 482.55(c)(3)) and CAHs (§ 485.618(e)(2))

We are proposing to repeal the requirement that staff in hospitals (§ 482.55(c)(3)) and CAHs (§ 485.618(e)(2)) that offer emergency services receive annual training on provisions and protocols to meet the emergency needs of patients. This requirement includes identifying and documenting which staff must receive the training, documenting that the staff received the training, demonstrating staff knowledge on the topics, and using findings from its QAPI program to inform staffing training needs and any additions, revisions, or updates to training topics on an ongoing basis.

We do not estimate savings for not needing to add, revise or update training topics since reviewing and updating policies and procedures is a customary business practice. We also do not estimate savings for documenting which staff received the training since this is also a customary business practice. In the regulatory impact analysis, below, in the section titled ''Emergency Services Readiness Staff Training for Hospitals (§ 482.55(c)(3)) and CAHs (§ 485.618(e)(2))'', we estimate hospital and CAH savings from not needing to train employees and test their knowledge on the training topics

K. ICRs Regarding OB QAPI Requirements for Hospitals (§ 482.21(b) and (e)) and CAHs (§ 485.641(d) and (e))

We are proposing to repeal OB QAPI requirements for hospitals (§ 482.21(b)(4) and (e)(1) and (2)) and CAHs (§ 485.641(d)(4)(i) and (ii) and (e)(2)) that offer obstetrical services. These requirements include utilizing their QAPI programs to assess and improve health outcomes and disparities among OB patients on an ongoing basis. They also require OB leadership to participate in a facility's QAPI program and where a State, local, or tribal MMRC exists, the facility must establish a process for incorporating publicly available MMRC data and recommendations into its QAPI activities.

To estimate the savings from these proposed changes, we use the same methodology that we used to estimate information collection costs in the CY 2025 OPPS/ASC final rule (89 FR 93912). First, we expect that hospitals would spend 4 hours annually modifying their information technology infrastructure to ensure that they capture the relevant features for the diverse subpopulations that facilities identify for their QAPI project. Specifically, we expect that these modifications would be undertaken by a mixture of staff from computer and mathematical occupations (occupation code 15–0000) at an average hourly cost of $115.46 ($57.73 × 2). We doubled the mean salary from the BLS' May 2025 National Occupational Employment and Wage Estimates,[338] since the BLS data do not include overhead costs and fringe benefits.

As indicated in Table 12, we expect that hospitals and CAHs would save 12,516 hours (3,129 facilities × 4 hours) and $1,445,097 (12,516 hours × $115.46) annually for not needing to update information technology infrastructure. In Table 13, we combine this information to estimate total savings over 10 years of $14,450,974 and 125,160 staff hours.

TABLE 12: 1Year Burden Reduction Due to End of QAPI Information Technology Infrastructure Updates in Hospitals and CAHs

Provider Type	Number of Providers (a)	Annualized Hourly Burden (b)	Hourly Wage Cost (c)	Total Hourly Savings (d = a × b)	Total Financial Savings (e = c × d)
Hospital	2,645	4	$115.46	10,580	$1,221,567
CAH	484	4	$115.46	1,936	$223,531
Total	3,129			12,516	$1,445,097

[337] 89 FR 93912.

[338] Available at *https://www.bls.gov/oes/current/oes291141.htm.*

TABLE 13: 10-Year Burden Reduction Due to End of QAPI Information Technology Infrastructure Updates in Hospitals and CAHs

Year	Hospital Financial Savings	Hospital Hourly Savings	CAH Financial Savings	CAHs Hours Savings	Combined Hospital and CAH Financial Savings	Combined Hospital and CAH Hourly Savings
1	$1,221,567	10,580	$223,531	1,936	$1,445,097	12,516
2	$1,221,567	10,580	$223,531	1,936	$1,445,097	12,516
3	$1,221,567	10,580	$223,531	1,936	$1,445,097	12,516
4	$1,221,567	10,580	$223,531	1,936	$1,445,097	12,516
5	$1,221,567	10,580	$223,531	1,936	$1,445,097	12,516
6	$1,221,567	10,580	$223,531	1,936	$1,445,097	12,516
7	$1,221,567	10,580	$223,531	1,936	$1,445,097	12,516
8	$1,221,567	10,580	$223,531	1,936	$1,445,097	12,516
9	$1,221,567	10,580	$223,531	1,936	$1,445,097	12,516
10	$1,221,567	10,580	$223,531	1,936	$1,445,097	12,516
Total 10-Year Savings	$12,215,668	105,800	$2,235,306	19,360	$14,450,974	125,160
Average Annual Savings	$1,221,567	10,580	$223,531	1,936	$1,445,097	12,516

Second, based on our experience working with healthcare data, we expect that it takes each facility 8 hours annually to stratify data and quality indicators and monitor results after actions are taken to address any identified disparities. We anticipate that data scientists are overseeing these efforts at an average hourly cost of $121.92 ($60.96 × 2). As indicated in Table 14, we expect that hospitals and CAHs would save 25,032 burden hours (3,129 facilities × 8 hours) with a cost savings of $3,051,901 annually (25,032 hours × $121.92) for not needing to update information technology infrastructure. In Table 15, we combine this information to estimate total savings over 10 years of $30,519,010 and 250,320 staff hours.

TABLE 14: 1 Year Burden Reduction Due to End of QAPI Data Stratification and Monitoring

Provider Type	Number of Providers (a)	Annualized Hourly Burden (b)	Hourly Wage Cost (c)	Total Hourly Savings (d = a × b)	Total Financial Savings (e = c × d)
Hospital	2,645	8	$121.92	21,160	$2,579,827
CAH	484	8	$121.92	3,872	$472,074
Total	3,129			25,032	$3,051,901

TABLE 15: 10-Year Burden Reduction Due to End of QAPI Data Stratification and Monitoring

Year	Hospital Financial Savings	Hospital Hourly Savings	CAH Financial Savings	CAH Hourly Savings	Combined Hospital and CAH Financial Savings	Combined Hospital and CAH Hourly Savings
1	$2,579,827	21,160	$472,074	3,872	$3,051,901	25,032
2	$2,579,827	21,160	$472,074	3,872	$3,051,901	25,032
3	$2,579,827	21,160	$472,074	3,872	$3,051,901	25,032
4	$2,579,827	21,160	$472,074	3,872	$3,051,901	25,032
5	$2,579,827	21,160	$472,074	3,872	$3,051,901	25,032
6	$2,579,827	21,160	$472,074	3,872	$3,051,901	25,032
7	$2,579,827	21,160	$472,074	3,872	$3,051,901	25,032
8	$2,579,827	21,160	$472,074	3,872	$3,051,901	25,032
9	$2,579,827	21,160	$472,074	3,872	$3,051,901	25,032
10	$2,579,827	21,160	$472,074	3,872	$3,051,901	25,032
Total 10-Year Savings	$25,798,270	211,600	$4,720,740	38,720	$30,519,010	250,320
Annual Savings	$2,579,827	21,160	$472,074	3,872	$3,051,901	25,032

The information collections currently approved under OMB Control No. 0938–0328 and OMB Control No. 0938–1043 will be revised and submitted to OMB for review and approval.

L. ICRs Regarding Birth Tissue Collection for Hospitals (§ 482.59(c)) and CAHs (§ 485.649(c)) That Offer OB Services

We are proposing to require that hospitals (§ 482.59(c)(1)) and CAHs (§ 485.649(c)(1)) that offer OB services and participate in the collection, storage, donation, banking, transfer, or release to patients of birth tissues must ensure that informed consent is obtained prior to the collection, storage, donation, transfer, banking, or release to patients of birth tissues. They must document this consent in the patient's medical records. Hospitals (§ 482.59(c)(2)) and CAHs (§ 485.649(c)(2)) must also have written policies and procedures that permit patients to request retention or release of birth tissue and provide these patients with instructions for safe handling, transport, storage, and disposition of the tissues.

To estimate the cost for this policy, we first assumed that all hospitals and CAHs that offer OB services are also participating in the collection, storage, donation, banking transfer, or release to patients of birth tissue and would need to develop policies and procedures to request retention or release of birth tissue for cultural, religious, or personal reasons. As outlined in 84 FR 51732, writing new policies related to patient care is estimated to take eight hours for each member of the staff involved in the care policy. We have included the involvement of an obstetrician or gynecologist at $2,102.24 (8 × $262.78), a lawyer at $1,734.08 (8 × $216.76), a registered nurse at $777.76 (8 × $97.22), a medical secretary at $365.60 (8 × $45.70), and a health services manager at $1,148.80 (8 × $143.60) for a total estimated cost of $6,128 per policy. This estimate leads to an average hourly cost of $153.20 ($6,128 ÷ 40) per staff member involved in developing this standard. As shown in Table 16, we estimate a total financial cost of $19,174,512 and a total hourly cost of 125,160 in Year 1 across all hospitals and CAHs. We expect no information collection costs in subsequent years.

TABLE 16: Birth Tissue Policies and Procedures Development

Provider Type	Number of Providers (a)	Hourly Burden (b)	Cost per Facility (c)	Total Hourly Cost (d = a × b)	Total Financial Cost (e = a × c)
Hospital	2,645	40	$6,128	105,800	$16,208,560
CAH	484	40	$6,128	19,360	$2,965,952
Total	3,129		$6,128	125,160	$19,174,512

The information collections currently approved under OMB Control No. 0938–0328 and OMB Control No. 0938–1043 will be revised and submitted to OMB for review and approval.

M. ICRs Regarding Transfer Protocols for Hospitals (§ 482.43(c))

There are no collection of information savings associated with the proposed change to hospital transfer protocols. In the section titled ''Staff Transfer Protocols Training for Hospitals (§ 482.43(c))'' in the regulatory impact analysis section, below, we estimate the savings hospitals would obtain by not needing to train employees on transfer protocols.

N. ICRs Regarding Proposal To Amend Status and Location Requirements (§ 485.610(c) and (e))

We are proposing to revise §§ 485.610(c)(1) and (e)(2) to make permanent existing policy clarifying how the CAH distance requirement is applied. There are no collection of information requirements associated with these proposals.

O. Adoption of the 2024 Edition of the Life Safety Code (National Fire Protection Association (NFPA) 101) and the 2024 Edition of the Health Care Facilities Code (National Fire Protection Association (NFPA) 99)

We do not anticipate a reduction in collection of information costs related to the adoption *of the 2024 Edition of the Life Safety Code (NFPA 101), the 2024 Edition of the Health Care Facilities Code (NFPA 99), the 2022 edition of the Standard for Emergency and Standby Power Systems (NFPA 110), the 2022 edition of the Standard for the Installation of Sprinkler Systems (NFPA 13), and the 2023 edition of the Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems (NFPA 25)* since changes in the edition in the codes that CMS requires focus primarily on the physical requirements for the facility rather than record-keeping requirements. We also do not anticipate any collection of information costs for the proposal that CMS may issue categorical waivers to provide hospitals, CAHs, REHs, ASCs, ICFs/IID, hospice inpatient care facilities, PACE centers, RNHCIs, and ESRD facilities with flexibility in complying with specific provisions of newer editions of the LSC or HCFC.

P. ICRs Regarding Medicaid Institutional Payment Transparency Reporting Provision (§§ 438.72 and 442.43)

The following proposed changes will be submitted to OMB for their approval when our survey instrument has been developed; we are using feedback received during public comment on the proposed rule to inform the development of the survey instrument. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden reduction figures (see below) as a means of estimating the impact of this proposed rule. The availability of the survey instrument and more definitive burden reduction estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10851 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new information collection request. Note that we intend that the following finalized changes associated with § 442.43(b), (c), and (d), discussed later in this section, will be submitted to OMB for review as a single PRA package under control number 0938–TBD (CMS–#####).

1. Wage Estimates

To derive average costs, we used data from the U.S. BLS May 2025 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). Table 17 presents BLS's mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 17: National Occupational Employment and Wage Estimates

OCCUPATION TITLE	OCCUPATION CODE	MEAN HOURLY WAGE ($/HR)	FRINGE BENEFITS AND OVERHEAD ($/HR)	ADJUSTED HOURLY WAGE ($/HR)
Administrative Services Manager	11-3012	62.44	62.44	124.88
Chief Executive	11-1011	129.63	129.63	259.26
Compensation, Benefits, and Job Analyst	13-1141	40.54	40.54	81.08
Computer Programmers	15-1251	50.56	50.56	101.12
General and Operations Manager	11-1021	64.87	64.87	129.74
Management Analyst	13-1111	54.71	54.71	109.42
Training and Development Specialist	13-1151	36.32	36.32	72.64

For States and the private sector, our employee hourly wage estimates are adjusted by a factor of 100 percent. Both fringe benefits and other indirect costs vary significantly across employers, and because methods of estimating these costs vary widely across studies, these are conservative estimates. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

a. One-Time Burden Reduction for Implementation (§ 442.43(b)): States

To estimate the reduction in the financial burden on States related to the proposed changes to the Medicaid Institutional Payment Transparency Reporting provisions (discussed below), it was important to consider the Federal government's contribution to the cost of administering the Medicaid program. The Federal government provides funding based on a Federal medical assistance percentage (FMAP) that is established for each State, based on the per capita income in the State as compared to the national average. FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83 percent in States with lower per capita incomes. For Medicaid, all States receive a 50 percent FMAP for administration. States also receive higher Federal matching rates for certain systems improvements, redesign, or operations. Taking into account the Federal contribution to the costs of administering the Medicaid programs for purposes of estimating State burden reduction with respect to collection of information, we elected to use the higher end estimate that the States would contribute 50 percent of the costs, even though the burden reduction would likely be smaller given that some States contributions will be less than 50 percent.

The burden reduction associated with rescinding the three reporting requirements in this proposed rule would affect all 51 States (including Washington DC). While States are not required to cover ICF/IID services (because it is an optional Medicaid benefit), the majority do. All States must offer Medicaid nursing facility services (because it is a mandatory Medicaid benefit). Thus, we anticipate that all 51 States (including Washington, DC) would experience reduced burden from rescinding the nursing facility and one of the ICFs/IID reporting requirements proposed at § 442.43(b). Additionally, three Territories (Guam, Puerto Rico, and the U.S. Virgin Islands) are required to include nursing facility services in their State plans and are therefore included in these calculations.[339] While we include these Territories in our saving estimates, we continue to refer to the affected entities collectively as ''States''. We estimate the ongoing and annual burden reductions to implement and administer these requirements at the State and provider levels. Under § 442.43(b), we anticipate a one-time implementation burden reduction for States, through their designated State Medicaid agency. The State Medicaid agencies would have to: (1) draft new policy describing the State-specific reporting process (one-time); (2) update any related provider manuals and other policy guidance, including guidance on excluded costs (one-time); (3) build, design, and operationalize an electronic system for data collection and aggregation (one-time); and (4) develop and conduct an initial training for providers on the reporting requirement and State-developed reporting system (one-time). Because we are proposing to rescind three of the four Medicaid institutional payment transparency requirements, we estimate the burden reduction attributable to the three requirements that we are proposing to rescind. The remaining reporting requirement on ICFs/IID is retained and would still require State implementation; therefore, its associated burden is excluded from the burden reduction estimates. These estimates are calculated by applying a 75 percent reduction to the time-per-response figures (expressed in hours) established in the 2024 Minimum Staffing final rule.[340] We note that we are not requiring that States update their Medicaid State plans as part of this reporting requirement, and thus we did not estimate a burden reduction associated with State plan amendments.

With regard to this one-time burden reduction for States, we estimate it would have taken: 30 hours at $124.88/hr. for an administrative services manager to draft new policy describing the State-specific reporting process; 30 hours at $109.42/hr. for a management analyst to update any related provider manuals and other policy guidance; 30 hours at $101.12/hr. for a computer programmer to build, design, and operationalize an electronic system for data collection on the percent of Medicaid payments going to compensation; 22.5 hours at $72.64/hr.

[339] Note that due to waiver under section 1902(j) of the Social Security Act, American Samoa and the Commonwealth of the Northern Marianas Islands are not required to include nursing facility services in their State plans and are therefore not included in these estimates. Additionally, no territory currently includes the optional ICF/IID benefit in their State plan.

[340] *https://www.federalregister.gov/d/2024-08273/p-777.*

for a training and development specialist to develop and conduct training for providers on the reporting requirement and system; 2.25 hours at $129.74/hr. for a general and operations manager to review and approve policy updates, provider agreement updates, and training materials; and 0.25 hour at $259.26/hr. for a chief executive to review and approve all operations associated with this requirement.

In addition to the activities outlined above, States may also have to update managed care contracts to reflect the new reporting requirement and provide managed care-specific guidance on the reporting requirement. Recent data indicates that 24 States provide at least some long-term services through a managed care delivery system. For the managed care-specific burden, we estimate 7.5 hours at $124.88/hr. for an administrative services manager to draft updates to managed care plan (that is, MCO and/or PIHP) contracts. (We anticipate that all other State activities associated with managed care plans would be reflected in the activities described previously in this section.)

In aggregate, we estimate a one-time burden of 6,320 hours [(122.5 hours × 54 States) + (10 × 24 States)]. We estimate a cost of $650,901 (54 States × [(30 hr. × $124.88) + (30 hr. × $109.42) + (30 hr. × $101.12) + (22.5 hr. × $72.64) + (2.25 hr. × $129.74) + (0.25 hr. × $259.26)]), with an additional $22,478 for managed care-related costs (24 States × [10 hr. × $124.88]). As shown in Table 18, the total cost is estimated at $673,380 ($650,901 + $22,478). Considering the Federal contribution to Medicaid administration, the estimated State share of the cost would be $336,690 ($673,380 × 0.50).

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TABLE 18: One-Time Implementation Burden Reduction for States from Rescinding Certain Medicaid Institutional Payment Transparency Reporting Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)
Draft new policy describing the State-specific reporting process	54	54	Once	30	1620	124.88	-202,306	-101,153
Update any related provider manuals and other policy guidance, including guidance on excluded costs	54	54	Once	30	1620	109.42	-177,260	-88,630
Build, design, and operationalize an electronic system for data collection and aggregate, and stratify reporting	54	54	Once	30	1620	101.12	-163,814	-81,907
Develop and conduct an initial training for providers on the reporting requirement and State-developed reporting system	54	54	Once	22.5	1215	72.64	-88,258	-44,129
Review and approve policy updates and training materials	54	54	Once	2.25	121.5	129.74	-15,763	-7,882
Review and approve all operations associated with this requirement	54	54	Once	0.25	13.5	259.26	-3,500	-1,750
Draft contract modifications for managed care plans	24	24	Once	7.5	180	124.88	-22,478	-11,239
Total	Varies	348	Once	122.5	6,390	$921.94	-673,380	-336,690

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b. One-Time Burden Reduction for Implementation (§ 442.43(b)): Nursing Facilities and ICFs/IID

The burden reduction associated with this proposed rule would affect nursing facility and ICF/IID providers in both FFS and managed care systems. We estimate a one-time implementation burden reduction to rescind three of the four measures of the reporting requirement proposed at § 442.43(b) (that is, the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff, and the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff). We present two separate one-time burden reduction estimates for providers, that is, nursing facilities and ICFs/IID, to reflect the distinct scope of the rescissions being proposed. For nursing facilities, CMS is proposing to rescind the Medicaid institutional payment transparency reporting requirement in its entirety. For ICFs/IID, CMS is proposing to rescind only one of the two applicable reporting requirements; we are proposing to retain the remaining reporting requirement.

To estimate the number of nursing facility and ICF/IID providers that would have been subject to these requirements, we used data from the CMS Quality Certification and Oversight Reports (QCOR) system (*qcor.cms.gov*) to identify the total number of Medicaid-certified nursing facilities and ICFs/IID in all States (including Washington DC) and the three Territories that are required to include nursing facility services in their State plan. Data from QCOR indicates that in FY 2026, there were 13,605 freestanding Medicaid-certified nursing facilities (including facilities dually certified for both Medicare and Medicaid, and Medicaid-only facilities) and 5,262 ICFs/IID. In total, we estimate 18,867 Medicaid-certified nursing facilities and ICFs/IID would be impacted by this proposal and would benefit from rescinding certain parts of this requirement to provide data to the State.

We estimate this proposal to rescind the requirement for States to report the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff would have taken nursing facilities 10 hours at $81.08/hr. for a compensation, benefits, and job analysis specialist to learn the State-specific reporting policy and calculate compensation for each direct care worker and support staff; 10 hours at $101.12/hr. for a computer programmer to build, design, and operationalize an internal system for developing the report for the State; and 1 hour at $129.74/hr. for a general and operations manager to review and approve the reporting system. In aggregate, we estimate a one-time implementation burden of 418,047 hours (18,867 nursing facilities × 21 hours) at a cost of $36,560,002 (18,867 nursing facilities × [(10 hr. × $81.08) + (10 hr. × $101.12) + (1 hr. × $129.74)] for nursing facilities. To estimate the time-per-response for nursing facilities, we adopted the time-per-response figures established for providers in the 2024 Minimum Staffing final rule without adjustment, as the Medicaid institutional payment transparency reporting requirement is being rescinded in its entirety for this facility type.[341]

TABLE 19: One-Time Implementation Burden Reduction from Rescinding the Medicaid Institutional Payment Transparency Reporting Requirements for Nursing Facilities

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)
Learn State-specific reporting policy; calculate compensation for each direct care worker and support staff	18,867	18,867	Once	10	188,670	81.08	-15,297,364	n/a
Build, design, and operationalize an internal system for developing the report for the State	18,867	18,867	Once	10	188,670	101.12	-19,078,310	n/a
Review and approve reporting system	18,867	18,867	Once	1	18,867	129.74	-2,447,805	n/a
Total	18,867	56,601	Once	Varies	396,207	varies	-36,823,479	n/a

[341] *https://www.federalregister.gov/d/2024-08273/p-787.*

We estimate rescinding the requirement for ICFs/IID to report the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff would reduce burden by 5 hours at $81.08/hr. for a compensation, benefits, and job analysis specialist to learn the State-specific reporting policy and calculate compensation for each direct care worker and support staff; 5 hours at $101.12/hr. for a computer programmer to build, design, and operationalize an internal system for developing the report for the State; and 0.5 hour at $129.74/hr. for a general and operations manager to review and approve the reporting system. As shown in Table 20, in aggregate, we estimate a one-time implementation burden of 55,251 hours (5,262 ICF/IIDs facilities × 21 hours) at a cost of $5,135,028 (5,262 ICF/IIDs × [(5 hr. × $81.08) + (5 hr. × $101.12) + (0.5 hr. × $129.74)] for ICFs/IID. To estimate the time-per-response for ICFs/IID, we applied a 50 percent reduction to the time-per-response figures established for providers in the 2024 Minimum Staffing final rule.[342] This adjustment reflects that only one of the two ICF/IID reporting requirements is being proposed to be rescinded, while the remaining requirement is being proposed to be retained and would continue to require facility implementation.

TABLE 20: One-Time Implementation Burden Reduction from Rescinding the Medicaid Institutional Payment Transparency Support Staff Reporting Requirements for ICFs/IID

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)
Learn State-specific reporting policy; calculate compensation for each support staff	5,262	5,262	Once	5	26,310	81.08	-2,133,215	n/a
Build, design, and operationalize an internal system for developing the report for the State	5,262	5,262	Once	5	26,310	101.12	-2,660,467	n/a
Review and approve reporting system	5,262	5,262	Once	1	2,631	129.74	-341,346	n/a
Total	5,262	15,786	Once	Varies	55,251	varies	-5,135,028	n/a

c. Annual Reporting Requirements and Burden Reduction (§ 442.43(b)): States

Under § 442.43(b), we estimate an annual burden reduction for States that would have required: 6 hours at $72.64/hr. for a training and development specialist to notify and train providers about the annual reporting requirements on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff, and the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff; 1.5 hours at $109.42 for a management analyst to review and make any needed updates to guidance for nursing facility; 4.5 hours at $101.12/hr. for a computer programmer to collect information from providers, aggregate data as needed, derive percentages for compensation, and develop a report for the State; 1.5 hours at $129.74/hr. by a general and operations manager to review, verify, and submit the report to CMS; and 0.75 hour at $259.26/hr. for a chief executive to review and approve all operations associated with this requirement.

In aggregate, we estimate a burden reduction of 256.5 hours (4.75 hours. × 54 States) at a savings of $25,993 (54 States × [(6 hr. × $72.64) + (1.5 hr. × $109.42) + (4.5 hr. × $101.12) + (1.5 hr. × $129.74) + (0.75 hr. × $259.26)]. Considering the Federal contribution to Medicaid administration, the estimated State savings would be $38,990 ($77,980 × 0.50) annually as shown in Table 21.

[342] *https://www.federalregister.gov/d/2024-08273/p-787.*

TABLE 21: Annual Burden Reduction for States from Rescinding Certain Medicaid Institutional Payment Transparency Reporting Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)
Notify and train providers about annual reporting requirement	54	54	Annually	6	324	72.64	-23,535	-11,768
Review and make any needed updates to nursing facility provider guidance and manuals	54	54	Annually	1.5	81	109.42	-8,863	-4,432
Collect information from providers; aggregate data as required; derive an overall percentage for compensation; and develop report for State	54	54	Annually	4.5	243	101.12	-24,572	-12,286
Review, verify, and submit report to CMS	54	54	Annually	1.5	81	129.74	-10,509	-5,254
Review and approve all operations associated with this requirement	54	54	Annually	0.75	40.5	259.26	-10,500	-5,250
Total	54	54	Annually	Varies	769.5	Varies	-77,980	-38,990

d. Annual Reporting Requirements and Burden Reduction (§ 442.43(b)): Nursing Facilities and ICFs/IID

The burden reduction associated with this proposed rule would affect nursing facility and ICF/IID providers in both FFS and managed care systems. We estimate an annual burden reduction to rescind three of the four measures of the reporting requirement proposed at § 442.43(b) (that is, the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff, and the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff).

To estimate the number of nursing facility and ICF/IID providers that would have reported these requirements, we used data from the CMS Quality Certification and Oversight Reports (QCOR) system (*qcor.cms.gov*) to identify the total number of Medicaid-certified nursing facilities and ICFs/IID in all States (including Washington, DC) and the three Territories that are required to include nursing facility services in their State plan. Data from QCOR indicates that in FY 2026, there were 13,605 freestanding Medicaid-certified nursing facilities (including facilities dually certified for both Medicare and Medicaid, and Medicaid-only facilities) and 5,262 ICFs/IID. In total, we estimate 18,867 Medicaid-certified nursing facilities and ICFs/IID are impacted by this finalized reporting requirement and will benefit from rescinding certain parts of this requirement to provide data to the State.

We estimate this proposal to rescind the requirement for States to report the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff would have taken nursing facilities 8 hours at $81.08/hr. for a compensation, benefits, and job analysis specialist to update compensation calculations to

account for staffing changes; 2 hours at $101.12/hr. for a computer programmer to calculate compensation, aggregate data, and report to the State as required; and 1 hour at $129.74/hr. for a general and operations manager to review, approve, and submit the report to the State. As shown in Table 22, we estimate an annual burden reduction of 285,705 hours (13,605 providers × 21 hours) at a savings of $26,553,423 (13,605 facilities × [(8 hr. × $81.08) + (2 hr. × $101.12) + (1 hr. × $129.74)] for nursing facilities.

TABLE 22: Annual Burden Reduction from Rescinding the Medicaid Institutional Payment Transparency Reporting Requirements for Nursing Facilities

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)
Account for staffing changes among employees and contracted employees	13,605	13,605	Annually	10	136,050	81.08	-11,030,934	n/a
Calculate compensation, aggregate data, and report to the State	13,605	13,605	Annually	10	136,050	101.12	-13,757,376	n/a
Review, approve, submit report to the State	13,605	13,605	Annually	1	13,605	129.74	-1,765,113	n/a
Total	13,605	40,815	Annually	Varies	285,705	varies	-26,553,423	n/a

We estimate rescinding the requirement for ICFs/IID to report the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff would reduce burden by 10 hours at $81.08/hr. for a compensation, benefits, and job analysis specialist to update compensation calculations to account for staffing changes; 1 hours at $101.12/hr. for a computer programmer to calculate compensation, aggregate data, and report to the State as required; and 0.5 hour at $129.74/hr. for a general and operations manager to review, approve, and submit the report to the State. As shown in Table 23, for ICFs/IID, we estimate an annual burden reduction of 28,941 hours (5,262 providers × 5.5 hours) at a savings of $2,580,011 (5,262 facilities × [(4 hr. × $81.08) + (1 hr. × $101.12) + (0.5 hr. × $129.74)].

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TABLE 23: Annual Burden Reduction from Rescinding the Medicaid Institutional Payment Transparency Support Staff Reporting Requirements for ICFs/IID

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)
Account for staffing changes among employees and contracted employees	5,262	5,262	Annually	4	21,048	81.08	-1,706,572	n/a
Calculate compensation, aggregate data, and report to the State	5,262	5,262	Annually	1	5,262	101.12	-532,093	n/a
Review, approve, submit report to the State	5,262	5,262	Annually	0.5	2,631	129.74	-341,346	n/a
Total	5,262	15,786	Annually	Varies	28,941	varies	-2,580,011	n/a

TABLE 24: 10-Year Burden Reduction from Rescinding Certain Reporting Measures in the Medicaid Institutional Payment Transparency Reporting Requirement for States and Providers

Year	Federal Savings	State Savings	Nursing Facility Savings	ICFs/IID Savings	Total Savings	Total Hourly Savings
1	$336,690	$336,690	$36,823,479	$5,135,028	$42,631,887	457,848
2	$38,990	$38,990	$26,553,423	$2,580,011	$29,211,414	315,416
3	$38,990	$38,990	$26,553,423	$2,580,011	$29,211,414	315,416
4	$38,990	$38,990	$26,553,423	$2,580,011	$29,211,414	315,416
5	$38,990	$38,990	$26,553,423	$2,580,011	$29,211,414	315,416
6	$38,990	$38,990	$26,553,423	$2,580,011	$29,211,414	315,416
7	$38,990	$38,990	$26,553,423	$2,580,011	$29,211,414	315,416
8	$38,990	$38,990	$26,553,423	$2,580,011	$29,211,414	315,416
9	$38,990	$38,990	$26,553,423	$2,580,011	$29,211,414	315,416
10	$38,990	$38,990	$26,553,423	$2,580,011	$29,211,414	315,416
Total 10-Year Savings	$687,600	$687,600	$275,804,286	$28,355,127	$305,534,613	3,296,588

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Q. Summary of Information Collection Savings

Table 25 and Table 26 provides a summary of the total financial and hourly impact from the proposed removal for (1) ongoing respiratory illness reporting for LTC care facilities when there is not a PHE as outlined in Table 3; (2) the amendment of transfer notice to ombudsman when there is emergent care as outlined in Table 5; (3) the removal of staff COVID–19 vaccine, educate, offer, and documentation requirements for LTC facilities as outlined in Table 7 and Table 9; (4) the removal of staff COVID–19 vaccine, educate, offer requirements for ICFs-IID as outlined in Table 11; (5) the removal of information technology updates and data stratification QAPI requirements

for hospitals and CAHs as outlined in Table 13 and Table 15; and (6) new requirements for hospitals and CAHs that offer obstetrical services and participate in the collection, storage, donation, banking, transfer, or release to patients of birth tissues as outlined in Table 16. Overall, we expect that these changes would result in average annual savings of $81,827,951 with total savings over 10 years estimated at $818,279,516 ($776,884,745 + $41,394,771). In addition, as indicated in Table 24 above, we also expect rescinding certain reporting measures in the Medicaid institutional payment transparency reporting requirement for states and providers would result in average annual savings of $30,553,461 with total savings over 10 years estimated at $305,534,613. Combined, all the proposed requirements would result in approximately $112 million in annual savings.

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TABLE 25: Total Reduction in Collection of Information Costs for LTC Facilities, Part I

Year	Ongoing Respiratory Illness Reporting		Ombudsmen Notice of Transfer for Emergent Care		Staff Covid-19 Vaccine Educate, Offer, and Documentation - Facility Policy Updates		Staff Covid-19 Vaccine Educate, Offer, and Documentation - Staff Education Documentation		Total Hourly Savings	Total Financial Savings ($ Million)
	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings		
1	$74.71	766,064	$1.63	25,660	$8.62	88,392	$4.80	88,392	968,508	$89.76
2	$74.71	766,064	$1.63	25,660	$8.62	88,392	$4.80	88,392	968,508	$89.76
3	$74.71	766,064	$1.63	25,660	$8.62	88,392	$4.80	88,392	968,508	$89.76
4	$74.71	766,064	$1.63	25,660	$8.62	88,392	$4.80	88,392	968,508	$89.76
5	$0.00	0	$1.63	25,660	$8.62	88,392	$4.80	88,392	202,444	$15.05
6	$74.71	766,064	$1.63	25,660	$8.62	88,392	$4.80	88,392	968,508	$89.76
7	$74.71	766,064	$1.63	25,660	$8.62	88,392	$4.80	88,392	968,508	$89.76
8	$74.71	766,064	$1.63	25,660	$8.62	88,392	$4.80	88,392	968,508	$89.76
9	$74.71	766,064	$1.63	25,660	$8.62	88,392	$4.80	88,392	968,508	$89.76
10	$28.73	294,620	$1.63	25,660	$8.62	88,392	$4.80	88,392	497,064	$43.78
Total 10-Year Savings	$626.39	6,423,132	$16.32	256,600	$86.20	883,920	$47.98	883,920	8,447,572	$776.88

TABLE 26: Total Reduction in Collection of Information Costs for Hospitals, CAHs, and ICFs-IID, Part II

Year	QAPI Data System Modifications in Hospitals and CAHs		QAPI Data Stratification in Hospitals and CAHs		Birth Tissue Policies and Procedures in Hospitals and CAHs		Staff Covid-19 Vaccine Educate, Offer, and Documentation - Facility Policy Updates in ICFs-IID		Total Hourly Savings	Total Financial Savings ($ Million)
	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings		
1	$1.45	12,516	$3.05	25,032	-$19.17	-125,160	$1.56	15,996	(71,616)	($13.12)
2	$1.45	12,516	$3.05	25,032	$0.00	0	$1.56	15,996	53,544	$6.06
3	$1.45	12,516	$3.05	25,032	$0.00	0	$1.56	15,996	53,544	$6.06
4	$1.45	12,516	$3.05	25,032	$0.00	0	$1.56	15,996	53,544	$6.06
5	$1.45	12,516	$3.05	25,032	$0.00	0	$1.56	15,996	53,544	$6.06
6	$1.45	12,516	$3.05	25,032	$0.00	0	$1.56	15,996	53,544	$6.06
7	$1.45	12,516	$3.05	25,032	$0.00	0	$1.56	15,996	53,544	$6.06
8	$1.45	12,516	$3.05	25,032	$0.00	0	$1.56	15,996	53,544	$6.06
9	$1.45	12,516	$3.05	25,032	$0.00	0	$1.56	15,996	53,544	$6.06
10	$1.45	12,516	$3.05	25,032	$0.00	0	$1.56	15,996	53,544	$6.06
Total 10-Year Savings	$14.45	125,160	$30.52	250,320	-$19.17	-125,160	$15.60	159,960	410,280	$41.39

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If you comment on these proposed information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received by the date and time specified in the **DATES** section of this proposed rule.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

Medicare-certified healthcare providers, including hospitals, CAHs, REHs, LTC facilities, and ICFs/IID, must comply with regulatory requirements that protect resident and patient health and safety. Some regulatory requirements, however, may become duplicative, unnecessary, or have unintended consequences that negatively affect the health and safety of those needing care. Providers may need to hire administrative staff for these tasks, diverting resources that could otherwise be used to hire clinicians to provide direct resident and patient care. Alternatively, time that clinicians could spend on ensuring that residents and patients receive the highest level of care, may instead be spent on filling out forms, completing trainings, or gathering information to meet these requirements.

The diversion of clinician time from patient care to fulfilling regulatory requirements comes at a time when healthcare providers are grappling with a growing workforce shortage that is expected to worsen in many areas in coming years.[343] The National Center for Health Workforce Analysis at the Health Resource and Services Administration (HRSA) projects that by 2037, the national demand for RNs will exceed supply by more than 300 thousand, while the supply of emergency medicine physicians in non-metropolitan areas will only meet 52 percent of projected demand.[344] Regulatory requirements may also increase administrative costs to such an extent that providers will close or stop offering needed optional services, negatively affecting access to care and

[343] Shanafelt T, Kuriakose C. Widespread Clinician Shortages Create a Crisis that Will Take Years to Resolve. NEJM Catalyst 2023;4(3). DOI: doi:10.1056/CAT.23.0044.

[344] Health Resources & Services Administration. ''Workforce Projections.'' *https://data.hrsa.gov/topics/health-workforce/workforce-projections* (Accessed March 25, 2025).

undermining the health and safety of those needing care. This problem may be even more dire in rural areas where individuals may not be able to easily access alternative sources of care when a provider closes or stops offering needed services. As directed in E.O. 14192, the executive branch's policy is to remove unnecessary regulatory burden and to be financially responsible with the expenditure of both private and public sector funds.

To protect resident and patient health and safety and access to care, we are proposing to remove a variety of requirements across providers and add several new requirements, including one for hospitals and CAHs that offer obstetrical services and services and participate in the collection, storage, donation, banking, transfer, or release to patients of birth tissues. First, we are proposing to remove the requirement that LTC facilities provide ongoing (weekly) data on acute respiratory illnesses when there is not a PHE. Second, we are proposing to remove hospital and CAH staff training requirements related to obstetrical care and emergency services, the OB QAPI requirements for hospitals and CAHs that offer obstetrical services, and the transfer protocol training requirement for hospitals. Third, we are proposing to remove the requirements that LTC facilities and ICFs/IID educate staff about and offer COVID–19 vaccines and that LTC facilities provide Ombudsman notice of resident transfers related to emergent care. Fourth, we are proposing to adopt more recent editions of the Life Safety Code, the Health Care Facilities Code, and other NFPA codes related to building sprinkler systems and emergency power systems. Fifth, we are proposing to codify existing CMS policy into statute and clarify that CAHs would need to be located more than a 35-mile drive on primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from an acute care hospital or another CAH. Sixth, we are also proposing to modify the distance requirement related to CAHs to indicate that a CAH described in section 241 of CAA 2026 is not subject to the distance requirements.

Seventh, we are proposing to require that hospitals *and* CAHs that offer OB services and participate in the collection, storage, donation, banking, transfer, or release to patients of birth tissues obtain informed consent, document this consent in the patient's medical record, have policies and procedures to permit the retention or release of birth tissue, and provide education to patients' on safe handling of these tissues. Finally, we are proposing to rescind requirements for States to report annually, at the facility level, on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff, and the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff. In addition, we are soliciting public comment on approaches to address direct care worker shortages and strengthen the direct care workforce in nursing facilities and ICFs/IID.

Below, we discuss the impact of each of these proposals.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

Based on our estimates, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f)(1). In accordance with the provisions of E.O. 12866, this proposed rule was reviewed by the Office of Management and Budget.

As indicated in previous Tables J24, J25, and J26, we estimate annual savings of approximately $112 million due to a reduction in collection of information costs across the proposed requirements. As discussed later in this section of the preamble, we estimate additional impacts from the proposed requirements.

C. Detailed Economic Analysis

1. Repeal of Ongoing Respiratory Illness Report in LTC Facilities (§ 483.80(g))

In the collection of information requirements section, we have already estimated the reduction in information collection burden from the proposal to eliminate the ongoing reporting of respiratory illnesses for LTC facilities when there is not a PHE. Specifically, as indicated in Table 1, we estimate annual savings of approximately $62.64 million and 10-year savings of $626.38 million. While repealing this requirement would reduce information collection costs, it could hinder identification of respiratory illness outbreaks in their initial stages when Federal, State, and local authorities could deploy resources to prevent it from spreading. In addition to the pain and suffering that LTC facility residents would incur from contracting these illnesses that could have otherwise been avoided, Medicare, Medicaid, and private payors could incur expenses to treat these individuals. Many States, however, already have legal requirements that medical facilities report suspected and/or confirmed cases of respiratory illness to local or State health officials. In addition, these States also provide up-to-date information about respiratory illnesses, such as influenza. As such, we expect that current surveillance efforts, separate from the CoPs, would avoid the unnecessary spread of these illnesses, and we do not expect that payors or patients would incur any additional costs from repealing this requirement beyond what we have estimated in section III. of this proposed rule.

2. Proposal To Amend Transfer Notice to Ombudsman (§ 483.15(c))

In section III. of this proposed rule, we have already estimated the savings for LTC facilities not needing to provide notice of resident transfer for emergent care to the Ombudsman office. Specifically, as indicated in Table 5, we estimate annual savings of approximately $1.63 million and 10-

year savings of $16.32 million. We also expect that there will be savings for Ombudsman offices for the time they do not need to spend reading notices related to resident transfer for emergent care purposes. We expect that Ombudsman offices spend 2 minutes reading each notice of resident transfer [345] and for the purposes of this analysis assume that the Ombudsman official is a registered nurse at $48.76 per hour based on the BLS' May 2025 National Occupational Employment and Wage Estimates for RNs (occupation code 29–1141). We doubled the mean salary since the BLS data do not include overhead costs and fringe benefits. The HHS-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for including these overhead and fringe benefit costs. This leads to an average cost of $3.25 ($97.52/hr × 2 minutes/notice) for each notice. Utilizing the same data sources discussed in section III. of this proposed rule, we estimate that, on average, there are 307,923 resident transfers for emergent care each year. As such, in Table 27 and Table 28, we estimate the proposed removal of notice for emergent care would result in $1,000,954 in annual savings due to time Ombudsman offices would not need to spend reading these notices, with total 10 years savings of $10,009,540.

TABLE 27: 1-Year Burden Reduction for Not Reading Transfer Notices for Emergent Care

Number of Residents	% of Resident Needing Transfer	Minutes per Patient Transfer	Cost per Hour	Cost per Notice Read	Cost Savings	Hourly Savings
(a)	(b)	(c)	(d)	(e = c + d)	(f = a × b × e)	(g = (a × b × c) ÷ 60)
1,231,691	0.25	2	$97.52	$3.25	$1,000,954	10,264

TABLE 28: 10-Year Burden Reduction for Not Reading Transfer Notices for Emergent Care

Year	Financial Savings	Hourly Savings
1	$1,000,954	10,264
2	$1,000,954	10,264
3	$1,000,954	10,264
4	$1,000,954	10,264
5	$1,000,954	10,264
6	$1,000,954	10,264
7	$1,000,954	10,264
8	$1,000,954	10,264
9	$1,000,954	10,264
10	$1,000,954	10,264
Total 10-Year Savings	$10,009,540	102,640

3. Repeal of Staff COVID–19 Vaccine Educate, Offer, and Documentation Requirements in LTC Facilities (§ 483.80(d))

In section III. of this proposed rule, we have already estimated the savings for LTC facilities not needing to update their policies and procedures related to staff COVID–19 education and document in employees' records that staff were offered the education. Specifically, as noted in Table 7 and 9, respectively, we estimate annual savings of approximately $8.62 million for not needing to update facilities policies and $4.8 million for not needing to document that staff received education on the COVID–19 vaccines. As part of the staff COVID–19 education requirement, LTC facilities are required

[345] Available at *https://www.bls.gov/oes/current/oes291141.htm.*

to offer the COVID–19 vaccine to staff members. To estimate the savings from repealing this requirement, we use the same methodology used to estimate its cost in the Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for LTC Facilities and ICFs-IID Residents, Clients, and Staff IFC (86 FR 26306). First, based on data from that rule, we estimate that including turnover and new employees, each year there are approximately 1,900,000 employees who fall under the educate and offer requirements. According to data from the CDC's NHSN, approximately 6.7 percent of staff members were vaccinated as of the week ending February 1, 2026.[346] If this percentage remains stable for subsequent years, nursing homes would need to provide education on COVID–19 and offer the vaccine to approximately 1,772,700 (1.9 million staff members × 93.3 percent) staff members annually. Since nearly 5 years have passed since the first COVID–19 vaccines were made available to the public and there is widespread information available on COVID–19 vaccines, we expect that the amount of time that facilities spend to educate each staff members has declined from 30 minutes to 15 minutes.

We assume that an RN would provide this education at $97.52 per hour. In addition, we estimate the cost for staff time at $39.24 per hour based on the mean rate for healthcare support occupations (occupation code 31–0000) doubled to account for overhead and fringe benefits. As indicated in Table 29 and Table 30, using these data, we expect that repealing the staff education requirement would result in annual savings of $60,608,613 and $606,086,130 over 10 years.

TABLE 29: 1-Year Burden Reduction from Removal of Staff COVID-19 Education Requirement in LTC Facilities

Staff Needing Education	RN Educator Hourly Rate	Staff Hourly Rate	Hours per Staff	RN Educator Savings	Staff Education Savings	Total Financial Savings	RN Educator Hours Saved	Staff Education Hours Saved	Total Hourly Savings
(a)	(b)	(c)	(d)	(e = a × b × d)	(f = a × c × d)	(g = e + f)	(h = a × d)	(i = a × d)	(j = h + i)
1,772,700	$97.52	$39.24	0.25	$43,218,426	$17,390,187	$60,608,613	443,175	443,175	886,350

TABLE 30: 10-Year Burden Reduction from Removal of Staff COVID-19 Education Requirements in LTC Facilities

Year	Financial Savings	Hourly Savings
1	$60,608,613	886,350
2	$60,608,613	886,350
3	$60,608,613	886,350
4	$60,608,613	886,350
5	$60,608,613	886,350
6	$60,608,613	886,350
7	$60,608,613	886,350
8	$60,608,613	886,350
9	$60,608,613	886,350
10	$60,608,613	886,350
Total 10-Year Savings	$606,086,130	8,863,500

In developing the estimated savings, we acknowledge that the COVID–19 vaccination rate for nursing home staff could be higher than what we have estimated. For example, one study used survey data from a convenience sample and estimated that 44.5 percent of healthcare professionals working in LTC facilities were vaccinated during the 2024–2025 respiratory virus season.[347] While we believe that the NHSN provides the most accurate information

[346] Source: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP). *https://www.cdc.gov/nhsn/ltc/ltc-report-overview.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fnhsn%2Fcovid19%2Fltc-report-overview.html#anchor_1594393304* last reviewed May 28, 2026.

on staff vaccination rates, we seek comments on other sources of data we should consider when estimating the savings from removing this requirement.

The final component is offering the COVID–19 vaccine to staff members. We estimate that the average cost of the vaccine is the $45 that the government pays under Medicare for a single dose COVID–19 vaccine.[348] In addition, we continue with the assumption in the rule establishing this requirement that education will result in a 5-percentage point increase in staff vaccination. As indicated in Table 31 and Table 32, we estimate that repealing this part of the requirement would result in annual savings of $4,275,000 and 10-year savings of $42,750,000.

TABLE 31: 1-Year Burden Reduction from Removal of Staff COVID-19 Vaccination Offering in LTC Facilities

Staff Members (a)	% Point Increase in Vaccination (b)	Total Vaccines (c = a × b)	Cost per Vaccine (d)	Total Savings (c × d)
1,900,000	0.05	95,000	$45	$4,275,000

TABLE 32: 10 - Year Burden Reduction from Removal of Staff COVID-19 Vaccination Offering in LTC Facilities

Year	Cost Savings
1	$4,275,000
2	$4,275,000
3	$4,275,000
4	$4,275,000
5	$4,275,000
6	$4,275,000
7	$4,275,000
8	$4,275,000
9	$4,275,000
10	$4,275,000
Total 10-Years Savings	$42,750,000

4. Repeal of Staff COVID–19 Vaccine Educate and Offer Requirements in ICFs/IID (§ 483.460(a))

In section III. of this proposed rule, we have already estimated the savings for ICFs/IID not needing to update their policies and procedures related to staff COVID–19 education. Specifically, as noted in Table 11, we estimate annual savings of approximately $1.56 million for not needing to update facility policies. As part of the staff COVID–19 education requirement, ICFs/IID are required to offer the COVID–19 vaccine to staff members. To estimate the savings from repealing this requirement, we use the same methodology used to estimate its cost in the Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for LTC Facilities and ICFs-IID Residents, Clients, and Staff IFC (86 FR 26306). First, based on data from that rule, we estimate that including turnover and new employees, each year there are approximately 148,000 employees who fall under the educate and offer requirements. According to data from the CDC's NHSN, approximately 6.7 percent of nursing home staff members were vaccinated as of the week ending February 1, 2026. Since we do not have data on staff vaccination in ICFs/IID, we assume that vaccination rates are the same as the rates in LTC facilities. If this percentage remains stable for subsequent years, ICFs/IID would need to provide education on COVID–19 and offer the vaccine to approximately 138,084 (148,000 staff members × 93.3 percent) staff members annually. Since nearly 5 years have passed since the first COVID–19 vaccines were made available to the public and there is widespread information available on COVID–19 vaccines, we expect that the amount of time that facilities spend to educate each staff members has declined from 30 minutes to 15 minutes.

We assume that an RN would provide this education at $97.52 per hour. In addition, we estimate the cost for staff time at $39.24 per hour based on the mean rate for healthcare support occupations (occupation code 31–0000) doubled to account for overhead and

[348] Centers for Medicare and Medicaid Services. Medicare COVID–19 Vaccine Shot Payment. *https://www.cms.gov/medicare/payment/covid-19-vaccine-toolkit/medicare-covid-19-vaccine-shot-payment* (Accessed February 11, 2026).

fringe benefits. As indicated in Table 33 and Table 34, using these data, we expect that repealing the staff education requirement would result in annual savings of $4,721,092 and $47,210,920 over 10 years.

TABLE 33: 1-Year Burden Reduction from Removal of Staff COVID-19 Education Requirement in ICFs/IID

Staff Needing Education	RN Educator Hourly Rate	Staff Hourly Rate	Hours per Staff	RN Educator Savings	Staff Education Savings	Total Financial Savings	RN Educator Hours Saved	Staff Education Hours Saved	Total Hourly Savings
(a)	(b)	(c)	(d)	(e = a × b × d)	(f = a × c × d)	(g = e + f)	(h = a × d)	(i = a × d)	(j = h + i)
138,084	$97.52	$39.24	0.25	$3,366,488	$1,354,604	$4,721,092	34,521	34,521	69,042

TABLE 34: 10-Year Burden Reduction from Removal of Staff COVID-19 Education Requirement in ICFs/IID

Year	Financial Savings	Hourly Savings
1	$4,721,092	69,042
2	$4,721,092	69,042
3	$4,721,092	69,042
4	$4,721,092	69,042
5	$4,721,092	69,042
6	$4,721,092	69,042
7	$4,721,092	69,042
8	$4,721,092	69,042
9	$4,721,092	69,042
10	$4,721,092	69,042
Total 10-Year Savings	$47,210,920	690,420

The final component is offering the COVID–19 vaccine to staff members. We estimate that the average cost of the vaccine is the $45 that the government pays under Medicare for a single dose COVID–19 vaccine.[349] In addition, we continue with the assumption in the rule establishing this requirement that education will result in a 5-percentage point increase in staff vaccination. As indicated in Table 35 and Table 36, we estimate the repealing this part of the requirement would result in annual savings of $333,00 and 10-year savings of $3,330,000.

TABLE 35: 1-Year Burden Reduction from Removal of Staff COVID-19 Vaccination Offering in ICFs/IID

Staff Members (a)	% Point Increase in Vaccination (b)	Total Vaccines (c = a × b)	Cost per Vaccine (d)	Total Savings (c × d)
148,000	0.05	7,400	$45	$333,000

[349] Centers for Medicare and Medicaid Services. Medicare COVID–19 Vaccine Shot Payment. *https://www.cms.gov/medicare/payment/covid-19-vaccine-toolkit/medicare-covid-19-vaccine-shot-payment* (Accessed February 11, 2026).

TABLE 36: 10-Year Burden Reduction from Removal of Staff COVID-19 Vaccination Offering in ICFs-IID

Year	Cost Savings
1	$333,000
2	$333,000
3	$333,000
4	$333,000
5	$333,000
6	$333,000
7	$333,000
8	$333,000
9	$333,000
10	$333,000
Total 10-Year Savings	$3,330,000

5. OB QAPI Requirements for Hospitals (§ 482.21(b) and (e)) and CAHs (§ 485.641(d) and (e))

We are proposing to repeal OB QAPI requirements for hospitals (§ 482.21(b) and (e)) and CAHs (§ 485.641(d)(4) and (e)) that offer obstetrical services. One of the requirements is that hospitals and CAHs that offer OB services conduct at least one performance improvement project annually that focuses on improving health outcomes and disparities among the hospital's population(s) of obstetrical patients. To estimate the savings from repealing this requirement, we used the same methodology that we used to estimate the project's cost in the CY 2025 OPPS/ASC final rule (89 FR 93912). First, we estimated that each hospital and CAH would spend 30 hours annually to analyze the data and implement and document their improvement project(s). To estimate the cost, we double the mean wage rate based on 2025 BLS data for each individual involved in the project to account for overhead and fringe benefit costs. We anticipate that this would include the participation of a hospital executive (occupation code 11–1011) at $2074 ($259.26 × 8 hours), an RN (occupation code 29–1141) at $975 ($97.52 × 10 hours), a physician (occupation code 29–1210) at $2,133 ($266.60 × 8 hours), and a data scientist (occupation code 15–2051) at $488 ($121.92 × 4 hours) for an average cost of $5,670 per facility. As indicated in Table 37, we estimate that repealing this requirement would save hospitals and CAHs $17,741,430 annually. In Table 38, we estimate total savings over 10 years at $177,414,300.

TABLE 37: 1-Year Savings from Removing OB QAPI Project

Provider Type	Number of Providers (a)	Annualized Hourly Burden (b)	Financial Burden Per Facility (c)	Total Financial Savings (d = a × c)	Total Hourly Savings (e = a × b)
CAH	484	30	$5,670	$2,744,280	14,520
Hospital	2,645	30	$5,670	$14,997,150	79,350
Total	3,129			$17,741,430	93,870

TABLE 38: 10-Year Savings from Removing OB QAPI Project

Year	Financial Savings	Hourly Savings
1	$17,741,430	93,870
2	$17,741,430	93,870
3	$17,741,430	93,870
4	$17,741,430	93,870
5	$17,741,430	93,870
6	$17,741,430	93,870
7	$17,741,430	93,870
8	$17,741,430	93,870
9	$17,741,430	93,870
10	$17,741,430	93,870
Total 10-Year Savings	$177,414,300	938,700

6. OB Services Staff Training for Hospitals (§ 482.59(c)) and CAHs (§ 485.649(c))

We are proposing to repeal the requirement that hospitals (§ 482.59(c)) and Critical Access Hospitals (CAHs) (§ 485.649(c)) that provide OB services train relevant staff on select topics for improving the delivery of maternal care and can demonstrate staff knowledge on training topics. In this section, we provide the reduction in cost due to the repeal of this training and testing staff knowledge on training material. We would note that since these requirements are not effective until January 1,2027, we do not expect that hospitals and CAHs have started training relevant staff to meet this requirement.

We estimate that staff training on evidence-based best practices and protocols would take 2 hours per employee and that each facility would spend 1 hour training staff on additional topics identified by the facility's QAPI program. This leads to a total hourly burden of 3 hours per employee trained. We also expect that given the flexibility that the regulation provided hospitals and CAHs to choose which OB staff to train, they would likely require training for those medical staff who work directly with OB patients. These medical staff members include licensed practical nurses/licensed vocational nurses (LPNs, LVNs), RNs, nurse anesthetists, nurse midwives, nurse practitioners, physician assistants, physicians, and surgeons. We use data from the BLS May 2025 National Industry-Specific Occupational Employment and Wage Estimates for hospitals (NAICS 622000) to estimate the number of these medical staff members working in hospitals and CAHs and their salary. We calculated the hourly rate for each employee type by doubling the national mean salary. We doubled the mean salary since the BLS data do not include overhead costs and fringe benefits. The HHS-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for including these overhead and fringe benefit costs.

The BLS does not provide separate information on the number of medical staff members working in hospitals and CAHs, or the number of staff members working in Medicare and/or Medicaid certified hospitals and CAHs that would no longer be required to provide staff training. To estimate the savings that hospitals and CAHs would incur by repealing this requirement we assumed that the number of medical staff who they would need to train would be proportional to the size of facilities, as measured by the number of certified beds. To calculate the number of certified beds, we utilized CMS' Q4 2024 Provider of Services File—Hospitals & Non-Hospital Facilities dataset to first calculate the number of certified beds in hospitals and CAHs that are Medicare/Medicaid certified and offer obstetrical services.[350] We then calculated the total number of certified beds in all hospitals and CAHs nationwide. Finally, we calculate the share of certified beds that are in Medicare/Medicaid certified hospitals offering OB services using the following formula: Total Certified Beds in Medicare/Medicaid certified Hospitals Offering OB Services ÷ Total Certified Beds in All Hospitals and CAHs. We use the same formula to calculate the share of certified beds that are in Medicare/Medicaid certified CAHs: Total Certified Beds in Medicare/Medicaid certified CAHs offering OB Services ÷ Total Certified Beds in All Hospitals and CAHs. Using this methodology, we estimate that approximately 59 percent of certified beds nationwide are in Medicare/Medicaid certified hospitals that offer OB services, with 1 percent of certified beds in Medicare/Medicaid certified CAHs that offer OB services.

In hospitals, which have a larger number of beds, there is likely to be a greater division of medical staff among units, with some staff specifically designated to work in OB units and with pregnant patients. CAHs that are smaller in size, in contrast, are likely to have medical staff that work across units and may encounter pregnant patients in their daily work. Based on our experience, we estimate that between 10 and 30 percent of medical staff in hospitals and 60 to 100 percent of medical staff in CAHs would need the OB training. Given variation across hospitals and CAHs, we take the midpoint of each estimate and assume that 20 percent of medical staff in hospitals and 80 percent of medical staff in CAHs would need to receive the training.

To estimate the annual savings, in Table 39 we first calculate the baseline financial and hourly savings for

[350] Centers for Medicare and Medicaid Services. Provider of Services File—Hospital & Non-Hospital Facilities, Q4 2024. *https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data* (Accessed March 21, 2025).

hospitals and CAHs not needing to conduct initial training for 100 percent of applicable medical staff. Applicable medical staff, however, must receive initial training and then receive training every other year. In addition, hospitals have an annual turnover rate of approximately 21 percent [351] and would accrue savings from not needing to train new employees who they hire to replace those employees who have left. As a result, the number of employees who they would not need to train and the savings from repealing this requirement would vary each year.

The OB staff training requirement is effective January 1, 2027. When estimating the requirement's cost in the CY 2025 OPPS/ASC final rule (89 FR 93912), we assumed that given the effective date, facilities would conduct their initial training for all staff members in year 2 (13–24) months after the rule's effective date, or between January and December 2026. As such, we assume that savings from the proposed repeal of this requirement would begin in 2027 after all staff had received their initial training.

In 2027, hospitals and CAHs would incur savings from not needing to train the 21 percent of new medical staff who replaced those who left. For subsequent years, the savings that hospitals and CAHs would accrue is for the 21 percent of staff hired in the previous year to account for regular staff turnover and 79 percent of staff who received their training 2 years prior.

To calculate the annual and 10-year savings from repealing this requirement, we multiply the share of staff that will need training each year by the baseline cost for training all staff members as outlined in Table 39. Using this methodology, we estimate in Table 40 that repealing this requirement would result in average annual savings of approximately $58.3 million and total savings of $583.5 million over 10 years. In addition, repealing this requirement would give clinicians in hospitals and CAHs an average of more than 5,111 thousand hours annually to spend on direct patient safety and care.

We use two assumptions for this estimate. First, we assumed that when a staff member leaves, their replacement would be hired in the same year. If the replacement was not hired until the following year, then provider savings would be lower than we have estimated. Second, we assumed that employees who receive training and then quit 2 years after their training, would not receive their biannual training prior to leaving. If they did, then the actual savings would be higher than we have estimated.

While the proposed elimination of the OB staff training requirement would result in significant reduction in burden as discussed earlier, one concern is that its elimination could harm patients, who would benefit from having staff trained in these areas. Hospital and CAH accrediting organizations, however, already have staff training requirements to help protect patients' health and safety. Hospitals and CAHs that offer OB services must still ensure that the services must be well-organized and provided in accordance with nationally recognized acceptable standards of practice for the healthcare of pregnant, birthing, and postpartum patients. In addition, if outpatient obstetrical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered. As such, we expect that repealing of this requirement would not impose new burdens on patients.

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TABLE 39: Baseline Obstetrical Services Staff Training Elimination Annual Savings

Provider Type	Number of Providers (a)	Share of all Hospital and CAH Certified Beds (b)	Total Yearly Savings if All Hospital and CAH Medical Staff were Trained (c)	Total Hospital and CAH Medical Staff (d)	Share of Medical Staff Receiving Training (e)	Total Medical Staff Members in Facilities with OB Services (f = b × d)	Financial Savings (g = b × c × e)	Hourly Savings (h = e × f × 3)
CAH	484	0.010	$853,416,408	2,491,880	0.8	25,952	$7,110,367	62,284
Hospital	2,645	0.590	$853,416,408	2,491,880	0.2	1,470,703	$100,736,991	882,422

[351] Nursing Solutions Incorporated, *2024 NSI National Health Care Retention & RN Staffing Report*. 2024.

TABLE 40: Obstetrical Services Staff Training Elimination 10Year Savings

Year	Baseline Financial Savings for Not Needing to Train 100% of OB Staff Members Needing Training	Baseline Hourly Savings for Not Needing to Train 100% of OB Staff Members Needing Training (b)	Share of OB Staff Needing Training (c)	Total Financial Savings (d = a × c)	Total Hourly Savings (e = b × c)
1	$107,847,358	944,706	0.210	$22,647,945	198,388
2	$107,847,358	944,706	0.834	$89,955,481	787,980
3	$107,847,358	944,706	0.341	$36,782,528	322,203
4	$107,847,358	944,706	0.731	$78,789,161	690,166
5	$107,847,358	944,706	0.423	$45,603,921	399,475
6	$107,847,358	944,706	0.666	$71,820,260	629,121
7	$107,847,358	944,706	0.474	$51,109,352	447,701
8	$107,847,358	944,706	0.626	$67,470,970	591,023
9	$107,847,358	944,706	0.506	$54,545,292	477,798
10	$107,847,358	944,706	0.600	$64,756,577	567,246
10-Year Total Savings				$583,481,486	5,111,101

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7. Birth Tissue Collection for Hospitals (§ 482.59(c) and CAHs (§ (485.649(c)) That Offer OB Services

We are proposing to require that hospitals (§ 482.59(c) and CAHs (§ 485.649(c) that offer OB services and participate in the collection, storage, donation, banking, transfer, or release to patients of birth tissues must ensure that informed consent is obtained prior to the collection, storage, donation, transfer, banking, or release to patients of birth tissues. They must document this consent in the patient's medical records. Hospitals (§ 482.59(c)(2)) and CAHs (§ 485.649(c)(2)) must also have written policies and procedures that permit patients to request retention or release of birth tissue and provide these patients with instructions for safe handling, transport, storage, and disposition of the tissues. In section III. of this proposed rule, we have already estimated hospitals to develop policies and procedures to request retention or release of birth tissue for cultural, religious, or personal reasons. Specifically, we estimate in Table 16 that it will cost $19,174,512 to develop these policies and procedures.

Later in this section of the preamble, we estimate additional impacts from these proposed policies. For these analyses, we assumed that all hospitals with OB services participate in the collection, storage, donation, banking, transfer, or release to patients of birth tissues. We seek comments on this assumption as well as any sources of data on the number of hospitals and CAHs already offering these services and meeting one or more of the proposed requirements.

The first cost is obtaining informed consent from patients. While hospital staff regularly obtain informed consent from patients for a variety of services, informed consent related to birth tissue is likely to be a new process for hospitals and CAHs. As such, we expect that hospitals and CAHs will need to provide training to their staff on the informed consent process for birth tissue. We expect that all obstetricians and gynecologists that offer this service would receive the training as well as 15 percent of registered nurses, nurse practitioners, physician assistants, and family medicine physicians. We expect that it would take employees 2 hours to complete this training. We use data from the BLS May 2025 National Industry-Specific Occupational Employment and Wage Estimates for hospitals (NAICS 622000) to estimate the number of these medical staff members working in hospitals and CAHs and their salary. We calculated the hourly rate for each employee type by doubling the national mean salary. We doubled the mean salary since the BLS data do not include overhead costs and fringe benefits. The HHS-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for including these overhead and fringe benefit costs.

The BLS does not provide separate information on the number of medical

staff members working in hospitals and CAHs, or the number of staff members working in Medicare and/or Medicaid certified hospitals and CAHs that would no longer be required to provide staff training. To estimate the costs that hospitals and CAHs would incur to train staff members we assumed that the number of medical staff who they would need to train would be proportional to the size of facilities, as measured by the number of certified beds. To calculate the number of certified beds, we utilized CMS' Q4 2024 Provider of Services File—Hospitals & Non-Hospital Facilities dataset to first calculate the number of certified beds in hospitals and CAHs that are Medicare/Medicaid certified and offer obstetrical services. We then calculated the total number of certified beds in all hospitals and CAHs nationwide. Finally, we calculate the share of certified beds that are in Medicare/Medicaid certified hospitals and CAHs offering OB services using the following formula: Total Certified Beds in Medicare/Medicaid certified Hospitals and CAHs Offering OB Services ÷ Total Certified Beds in All Hospitals and CAHs. Using this methodology, we estimate that approximately 59 percent of certified beds nationwide are in Medicare/Medicaid certified hospitals that offer OB services, with 1 percent of certified beds in Medicare/Medicaid certified CAHs that offer OB services.

In Tables 41 and 42, we estimate the cost to train relevant staff members in hospitals and CAHs. For year 1 costs, we include training for an additional 21 percent of staff members to account for annual turnover rates [352] and estimate that the proposed requirement would cost $46,928,995 for hospitals and $795,407 for CAHs for a total year 1 cost of $47,724,402. For subsequent years, we assume that new staff members would need to receive this training and assume that this would be 21 percent of applicable staff members with an annual cost of $8,144,701 for hospitals and $138,046 for CAHs for a total cost of $8,282,747. In Table 43, we estimate a total 10-year cost of $121,164,757 and 1,186,133 staff hours.

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TABLE 41: Informed Consent for Birth Tissue Staff Training Costs in Hospitals

Employee Type	All Hospital and CAH Employees (a)	Loaded Wage Rate (b)	Share of All Hospital and CAH Beds (c)	Share of Staff Needing Training (d)	Staff Needing Training (e)	Hours per Employee (f)	Year 1 Financial Cost (g = b × e × f × 1.21)	Year 1 Hourly Cost ((h = e × f × 1.21)	Years 2-10 Annual Financial Cost (i = b × e × f × .21)	Years 2-10 Annual Hourly Cost (j = e × f × .21)
Registered Nurses	1,956,900	$97.22	0.59	0.15	173,186	2	$40,745,804	419109	$7,071,586	72,738
Nurse Practitioners	76,810	$133.40	0.59	0.15	6,798	2	$2,194,483	16450	$380,861	2,855
Obstetricians and Gynecologists	4,490	$262.78	0.59	1	2,649	2	$1,684,636	6411	$292,375	1,113
Physician Assistants	40,810	$133.78	0.59	0.15	3,612	2	$1,169,274	8740	$202,932	1,517
Family Medicine Physicians	21,230	$249.58	0.59	0.15	1,879	2	$1,134,798	4547	$196,948	789
Total							$46,928,995	455,257	$8,144,701	79,012

[352] Nursing Solutions Incorporated, *2024 NSI National Health Care Retention & RN Staffing Report*. 2024.

TABLE 42: Informed Consent for Birth Tissue Staff Training Costs in CAHs

Employee Type	All Hospital and CAH Employees (a)	Loaded Wage Rate (b)	Share of All Hospital and CAH Beds (c)	Share of Staff Needing Training (d)	Staff Needing Training (e = a × c × d)	Hours per Employee (f)	Year 1 Financial Cost (g = b × e × f × 1.21)	Year 1 Hourly Cost ((h = e × f × 1.21)	Years 2-10 Annual Financial Cost (i = b × e × f × .21)	Years 2-10 Annual Hourly Cost (j = e × f × .21)
Registered Nurses	1,956,900	$97.22	0.01	0.15	2,935	2	$690,607	7,104	$119,857	1,233
Nurse Practitioners	76,810	$133.40	0.01	0.15	115	2	$37,195	279	$6,455	48
Obstetricians and Gynecologists	4,490	$262.78	0.01	1	45	2	$28,553	109	$4,956	19
Physician Assistants	40,810	$133.78	0.01	0.15	61	2	$19,818	148	$3,440	26
Family Medicine Physicians	21,230	$249.58	0.01	0.15	32	2	$19,234	77	$3,338	13
Total							$795,407	7,717	$138,046	1,339

TABLE 43: 10-Year Cost for Informed Consent for Birth Tissue Staff Training

Year	Financial Cost	Hourly Cost
1	$47,724,402	462,974
2	$8,282,747	80,351
3	$8,144,701	80,351
4	$8,144,701	80,351
5	$8,144,701	80,351
6	$8,144,701	80,351
7	$8,144,701	80,351
8	$8,144,701	80,351
9	$8,144,701	80,351
10	$8,144,701	80,351
10-Year Total	$121,164,757	1,186,133

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The next impact is for providing informed consent to patients. Consent for collection of birth tissue would require hospital and CAH staff to inform each patient giving birth about tissue collection. We estimate that educating the patient about birth tissue would take 5 to 10 minutes while obtaining informed consent would take 2 to 5 minutes per patient. This gives us a range of 7 to 15 minutes per patient. We take the midpoint of these two values and assume that it would take staff members 11 minutes per patient. We expect that a combination of registered nurses, nurse practitioners, physician assistants, family medicine physicians, obstetricians and gynecologists would provide this information at an average cost of $175.35 based on the mean loaded wage rate for these professions, leading to an average per patient cost of $32.15 (11 minutes per patient × $175.35/hour). We estimate the cost for patients using the average wage rate for all occupations that we double to account for overhead and fringe benefits leading to an hourly cost of $65.32. This leads to an average patient cost of $11.98 (11 minutes per patient × $65.32/hour).

According to the Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project (QHCUP), in 2019 there was an estimated 3,583,224 delivery hospitalizations. We do not have data, however, on what percentage of births that occur in hospitals and CAHs offering OB services. For the purposes of this estimate, therefore, we assume that the share of births occurring in these hospitals is proportional to their share of all beds across hospitals and CAHs as estimated above—1 percent for CAHs and 59 percent for hospitals. As such we estimate that 2,114,102 (0.59 × 3,583,224) patients in hospitals and 35,832 (0.01 × 3,583,224) patients in CAHs would need to receive education and complete informed consent for birth tissue. As indicated in Table 44, we expect that this requirement would have

an average annual cost of $69,120,378 and take 394,155 hours to complete. As provided in Table 45, we expect total costs of approximately $691.2 million and 3.94 million hours over 10 years.

TABLE 44: 1-Year Cost for Providing Informed Consent to Patients

	Patients Needing Education (a)	Financial Cost per Patient (b)	Hourly Cost per Patient (c)	Total Financial Cost (d = a × b))	Total Hourly Cost (e = a × c)
Hospitals	2,114,102	$32.15	0.183	$67,968,379	387,585
CAHs	35,832	$32.15	0.183	$1,151,999	6,569
Total				$69,120,378	394,155

TABLE 45: 10-Year Cost for Providing Informed Consent to Patients

Year	Total Financial Cost	Total Hourly Cost
1	$69,120,378	394,155
2	$69,120,378	394,155
3	$69,120,378	394,155
4	$69,120,378	394,155
5	$69,120,378	394,155
6	$69,120,378	394,155
7	$69,120,378	394,155
8	$69,120,378	394,155
9	$69,120,378	394,155
10	$69,120,378	394,155
10-Year Total	$691,203,780	3,941,550

The final impact is related to providing additional education on safe tissue handling for those individuals who choose to retain their birth tissue. Given that 3 percent of patients currently donate cord tissue,[353] we double the share of patients who would want this service and estimate that 6 percent of births would require education on safe tissue handling, leading to education for 126,846 (2,114,102 × 0.06) in hospitals and 2,150 patients (35,832 × 0.06) patients in CAHs. We assume that this education would also take 11 minutes per patient. As shown in Table 46, using this estimate, we expect that the rule would have an average annual cost of approximately $4.15 million for hospitals and CAHs and $1.55 million for patients. Over 10 years, the total cost would be approximately $41.47 million for hospitals and CAHs as shown in Table 47.

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TABLE 46: 1-Year Cost for Providing Education on Safe Tissue Handling

	Patients Needing Education (a)	Financial Cost Per Patient (b)	Hourly Cost per Patient (c)	Financial Cost (d = a × b)	Hourly Cost (e = a × c)
Hospitals	126,846	$32.15	0.183	$4,078,099	23,213
CAHs	2,150	$32.15	0.183	$69,123	393
Total				$4,147,221	23,606

[353] ConsumerAffairs. ''Cord blood banking statistics 2026 [2024]'' *ConsumerAffairs.com.* January 25, 2024, *https://www.consumeraffairs.com/health/cord-blood-banking-statistics.html.*

TABLE 47: 10-Year Cost for Providing Education on Safe Tissue Handling

Year	Total Financial Cost	Total Hourly Cost
1	$4,147,221	23,606
2	$4,147,221	23,606
3	$4,147,221	23,606
4	$4,147,221	23,606
5	$4,147,221	23,606
6	$4,147,221	23,606
7	$4,147,221	23,606
8	$4,147,221	23,606
9	$4,147,221	23,606
10	$4,147,221	23,606
10-Year Total Cost	$41,472,214	236,063

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8. Emergency Services Readiness Staff Training for Hospitals (§ 482.55(c)(3)) and CAHs (§ 485.618(e)(2))

We are proposing to repeal the requirement that hospitals (§ 482.55(c)(3)) and CAHs (§ 485.618(e)(2)) that offer emergency services train staff on provisions and protocols to meet the emergency needs of patients.

The training requirement provides flexibility to hospitals and CAHs to choose which staff receive this training and we assume that they would require training for medical staff working in emergency departments. These medical staff members include licensed practical nurses/licensed vocational nurses (LPNs, LVNs), RNs, nurse anesthetists, nurse midwives, nurse practitioners, physician assistants, physicians, and surgeons. We use data from the BLS May 2025 National Industry-Specific Occupational Employment and Wage Estimates for hospitals (NAICS 622000) to estimate the number of these medical staff members working in hospitals and CAHs and their salary. We calculated the hourly rate for each employee type by doubling the national mean salary. We doubled the mean salary since the BLS data do not include overhead costs and fringe benefits.

The BLS does not provide separate information on the number of medical staff members working in hospitals and CAHs, or the number of staff members working in Medicare and/or Medicaid certified hospitals and CAHs that would no longer be required to train staff on provisions and protocols to meet the emergency needs of patients. To estimate the savings that hospitals and CAHs would incur by repealing this requirement we assumed that the number of medical staff who they would need to train would be proportional to the size of facilities, as measured by the number of certified beds. To calculate the number of certified beds, we utilized CMS' Q4 2024 Provider of Services File—Hospitals & Non-Hospital Facilities dataset to first calculate the number of certified beds in hospitals and CAHs that are Medicare/Medicaid certified and offer emergency services.[354] We then calculated the total number of certified beds in all hospitals and CAHs nationwide. Finally, we calculated the share of certified beds that are in Medicare/Medicaid certified hospitals offering emergency services using the following formula: Total Certified Beds in Hospitals Offering Emergency Services ÷ Total Certified Beds in All Hospitals and CAHs. Similarly, we calculate the share of certified beds in Medicare/Medicaid certified CAHs offering emergency services using the following formula: Total Certified Beds in CAHs Offering Emergency Services ÷ Total Certified Beds in All Hospitals and CAHs. Using this methodology, we estimate that approximately 66.9 percent of certified beds nationwide are in Medicare/Medicaid certified hospitals that offer emergency services, with 2.7 percent of certified beds located in Medicare/Medicaid certified CAHs that offer emergency services.

Based on our experience, we expect that initial staff training takes 3 hours per employee. For subsequent years, we expect that refresher training takes 1 hour per employee. Since the rules went into effect on July 1, 2025, we expect that hospitals and CAHs have already provided employees with initial training prior to the proposed removal of this requirement. As such, we expect that hospitals and CAHs would save 1 hour per employee who has already completed initial training and 3 hours per new employee who would need to complete the initial staff training. With an annual hospital turnover rate of approximately 21 percent,[355] we expect that 21 percent of employees each year would need the initial 3-hour training, and the remaining 79 percent of employees would need the 1-hour refresher training.

In hospitals, which have a larger number of beds, there is likely to be a greater division of staff among units, with medical staff specifically designated to work in emergency departments. In contrast, CAHs, which are smaller in size, are likely to have medical staff that work across units. We assume, therefore, that 20 percent of medical staff in hospitals and 100 percent of medical staff in CAHs would receive the training.

As indicated in Table 48, using this methodology, we estimate that repealing the emergency services training requirement would save hospitals and CAHs more than $65 million and 570 thousand hours annually. Table 49 shows that eliminating this requirement

[354] Centers for Medicare and Medicaid Services. Provider of Services File—Hospital & Non-Hospital Facilities, Q1 2024. *https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data* (Accessed March 21, 2025).

[355] Nursing Solutions Incorporated, *2024 NSI National Health Care Retention & RN Staffing Report*. 2024.

would result in total 10-year savings of $651 million and would give clinicians in hospitals and CAHs more than 5.7 million hours to spend on direct patient safety and care.

While the proposed elimination of the emergency services staff training requirement would result in significant reduction in burden as discussed previously, one concern is that its elimination could harm patients, who would benefit from having staff trained in these areas. Hospital and CAH accrediting organizations, however, already have staff training requirements to help protect patients' health and safety. In addition, hospitals and CAHs are still required to have adequate provisions and protocols to meet the emergency needs of patients in accordance with the complexity and scope of services offered. As such, we expect that repealing this requirement would not impose new burdens on patients.

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TABLE 48: Annual Emergency Service Training Elimination Savings

Provider Type	Number of Providers (a)	Share of all Hospital and CAH Certified Beds (b)	Total Yearly Cost if All Hospital and CAH Medical Staff were Trained (c)	Total Hospital and CAH Medical Staff (d)	Share of Medical Staff Receiving Training (e)	Total Medical Staff Members in Facilities with Emergency Services (f = b × d)	Financial Savings (g = b × c × e)	Hourly Savings from Refresher Training (h = e × f × 79% × 1 Hr)	Hourly Savings from Initial Training (h = e × f × 21% × 3 Hrs)	Total Hourly Savings (j = h + i)
CAH	1,329	0.027	$403,950,433	2,491,880	1	68,234	$11,061,162	53,905	42,987	96,892
Hospital	3,319	0.669	$403,950,433	2,491,880	0.2	1,667,532	$54,063,623	263,470	210,109	473,579

TABLE 49: Emergency Services Staff Training Elimination 10-Year Savings

Year	Total Financial Savings	Total Hourly Savings
1	$65,124,785	570,471
2	$65,124,785	570,471
3	$65,124,785	570,471
4	$65,124,785	570,471
5	$65,124,785	570,471
6	$65,124,785	570,471
7	$65,124,785	570,471
8	$65,124,785	570,471
9	$65,124,785	570,471
10	$65,124,785	570,471
10-Year Total Savings	$651,247,851	5,704,712

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9. Staff Transfer Protocols Training for Hospitals (§ 482.43(c))

We are proposing to repeal the requirement at (§ 482.43(c)) for acute care hospitals to conduct annual training for relevant staff (as determined by the facility) on hospital policies and procedures for transferring patients under its care.

Since hospital inpatients are included in those who may need to be transferred, we expect that medical staff across hospitals, and not just those in emergency departments, receive training on transfer protocols. Specifically, we expect that all surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists in hospitals receive this training. We do

not expect, however, that LPNs receive this training and similarly expect that most RNs do not receive this training. Rather, we expect that among RNs, only experienced RNs who serve as transfer coordinators receive it and estimate that this is only five percent of RNs nationwide. We estimate that hospitals spend one hour training each employee.

The BLS does not provide separate information on the number of medical staff members working in hospitals, or the number of staff members working in Medicare and/or Medicaid certified hospitals that would no longer be required to train staff on hospital policies and procedures for transferring patients under its care. To estimate hospital savings from repealing this requirement we assumed that the number of medical staff who they would need to train would be proportional to the size of facilities, as measured by the number of certified beds. To calculate the number of certified beds, we utilized CMS' Q4 2024 Provider of Services File—Hospitals & Non-Hospital Facilities dataset to first calculate the number of certified beds in hospitals that are Medicare/Medicaid certified.[356] We then calculated the total number of certified beds in all hospitals and CAHs nationwide. Finally, we calculated the share of certified beds that are in Medicare/Medicaid certified hospitals using the following formula: Total Certified Beds in Medicare/Medicaid certified Hospitals ÷ Total Certified Beds in All Hospitals and CAHs. Using this methodology, we estimate that approximately 78.9 percent of certified beds nationwide are in Medicare/Medicaid certified hospitals.

We expect that this training would take one hour per staff member. As indicated in Table 50, after increasing the estimated burden by 21 percent to account for the average annual turnover in hospitals,[357] we expect that repealing this requirement would save hospitals $81,569,162 and 445,535 hours annually. As indicated in Table 51, we expect that over 10 years, repealing this requirement would save more than $815 million and 4.46 million hours.

While the proposed elimination of the transfer protocol staff training requirement would result in significant reduction in burden as discussed previously, one concern is that its elimination could harm patients, who would benefit from having staff trained in the proper procedures for transfers. Hospitals, however, are still required to have policies and procedures in place for patient transfer. Given the importance of ensuring that patients can be transferred to the appropriate level of care in a timely manner, we expect that they already have employees trained in these procedures. As such, we expect that repealing this requirement would not impose new burden on patients.

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TABLE 50: Annual Transfer Protocol Staff Training Elimination Savings

Provider Type	Number of Providers (a)	Share of all Hospital and CAH Certified Beds (b)	Total Yearly Cost if All Hospital and CAH Medical Staff were Trained (c)	Total Hospital and CAH Medical Staff (d)	Share of Medical Staff Receiving Training (e)	Total Number of Staff Members (f = b × d)	Financial Savings (g = b × c × e)	Hourly Savings (h = e × f)
Hospital	4,861	0.789	$85,475,399	466,872	1.21	368,211	$81,569,162	445,535

[356] Centers for Medicare and Medicaid Services. Provider of Services File—Hospital & Non-Hospital Facilities, Q1 2024. *https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data* (Accessed March 21, 2025).

[357] Nursing Solutions Incorporated, *2024 NSI National Health Care Retention & RN Staffing Report*. 2024.

TABLE 51: Transfer Protocol Staff Training Elimination 10-Year Savings

Year	Total Financial Savings	Total Hourly Savings
1	$81,569,162	445,535
2	$81,569,162	445,535
3	$81,569,162	445,535
4	$81,569,162	445,535
5	$81,569,162	445,535
6	$81,569,162	445,535
7	$81,569,162	445,535
8	$81,569,162	445,535
9	$81,569,162	445,535
10	$81,569,162	445,535
10-Year Total Savings	$815,691,619	4,455,354

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10. Proposal To Amend Status and Location Requirements (§ 485.610(c) and (e))

We are proposing to modify the current distance eligibility requirement at § 485.610(c) and § 485.610(e)(2). This requirement states that critical access hospitals (CAHs) must be located more than a 35-mile drive on primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH. This proposed change would codify CMS' 2016 sub-regulatory guidance, which stated that the distance eligibility requirement is determined based on proximity to an acute care hospital or another CAH. The guidance specifically states that psychiatric hospitals, long-term care hospitals, and rehabilitation hospitals are not considered acute care hospitals for purposes of the location requirements. We are also proposing to modify the distance requirement related to CAHs to indicate that a CAH, as described in section 241 of CAA 2026, is not subject to the distance requirements.

The changes we are proposing in this rule would codify current sub-regulatory guidance for CAHs as well as existing federal law and would have several benefits. First, these proposed changes would ensure continue accessed to acute care for individuals living in rural communities. There are currently 52 CAHs that are currently co-located or within a 35-mile drive on primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) of a psychiatric, rehabilitation, or long-term care hospital and they could be at risk of losing their CAH designation under the current regulatory standards. The loss of their CAH designation under current regulatory standards could result in their closure due to financial pressures, negatively impacting access to care. Second, the proposed change could result in new CAHs opening since it would allow more facilities to satisfy the distance requirements. In addition, four CAHs would be impacted by the changes in section 241 of CAA 2026. Third, if CAHs were forced to close or new CAHs could not open, then individuals would be forced to travel longer distances to obtain necessary medical care, resulting in additional transportation costs. Beyond transportation costs, in urgent and life-threatening situations, the delay in care could result in long-term harm that would impose ongoing physical or financial costs for these individuals, or even death. Quicker access to care could also result in significant financial savings for patients, as well as payors including Medicare and Medicaid, by helping them avoid delays in receiving care that may result in the need for additional care or more intensive treatment. While we cannot quantify the financial benefits of our proposed changes, we seek comments on sources of information that we can use to estimate their health and financial savings.

While the proposed changes for CAHs have many benefits, they could also impose new costs on the federal government. CAHs receive additional financial support from Medicare since they qualify for cost-based reimbursement, instead of the Medicare Prospective Payment System. These proposed changes could eliminate the potential for the 52 facilities to lose their CAH status, resulting in a continued stream of higher transfers from Medicare to these facilities. In addition, the changes we are proposing could lead other rural hospitals to seek CAH status, resulting in more Medicare transfers. While we are unable to estimate the level of costs that Medicare would incur since we do not know how many of the current CAHs would lose their status in the absence of these changes and the number of new facilities that may seek CAH status due to these proposed changes, we seek comments on the ways to quantify these financial effects.

11. COVID–19 and Seasonal Influenza Reporting for REHs (§ 485.526(e)) and COVID–19 Vaccination of REH Staff (§ 485.526(g))

We are proposing to repeal the requirement (§ 485.526(e)) that REHs electronically report information about COVID–19 and seasonal influenza in a standardized format specified by the Secretary. We are also proposing to repeal the requirement (§ 485.526(g)) that REHs must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. The COVID–19 and seasonal influenza reporting requirement ended on April 30, 2024, while the requirement that REHs must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19 ended on November 4, 2024. As such, we do not expect that REHs would see a reduction in costs from repealing this regulatory requirement.

12. Adoption of the 2024 Edition of the Life Safety Code (National Fire Protection Association (NFPA) 101) and the 2024 Edition of the Health Care Facilities Code (National Fire Protection Association (NFPA) 99)

For most providers, we expect that the proposed changes related to the adoption of the 2024 Edition of the Life Safety Code (NFPA 101), the 2024 Edition of the Health Care Facilities Code (NFPA 99), the 2022 edition of the Standard for Emergency and Standby Power Systems (NFPA 110), the 2022 edition of the Standard for the Installation of Sprinkler Systems (NFPA 13), and the 2023 edition of the Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems (NFPA 25). NPFA editions would lead to unquantifiable but important benefits by promoting consistency across facilities, reinforcing fire emergency readiness and protecting the well-being of all occupants. These benefits would be further enhanced by our proposal that CMS may issue categorical waivers to provide hospitals, CAHs, REHs, ASCs, ICFs/IID, hospice inpatient care facilities, PACE centers, RNHCIs, and ESRD facilities with flexibility in complying with specific provisions of newer editions of the LSC or HCFC. We identified several specific updates to the NPFA editions that we expect would have a positive impact on patient care and reduce or increase provider costs. For each of these updates, we seek comments on ways to quantify the benefits and the costs for the proposed NPFA edition updates, as well as any additional benefits and costs that may result from the proposed changes. We also note that for both the costs and benefits, the potential impact is likely to vary depending on the NFPA edition that States and/or local authorities are currently requiring providers to meet and we seek comments on public sources of data that would allow us to identify the current NFPA edition that local and state governments are requiring providers to meet.

a. Benefits

First, updates to the 2024 edition of the LSC (NFPA 101) allow facilities to use coded announcements to staff instead of activating fire alarm notification appliances such as loud horns and strobe lights that can startle residents and patients. For residents and patients, allowing coded announcements can reduce fear and confusion that emerge from alarm notification systems that can only signal something is wrong without providing context. In contrast, the coded announcements support a patient-centered environment while maintaining resident and patient health and safety. Given the large number of patients and residents in healthcare, we expect that this change would have large intangible benefits to facility residents and patients. We seek comments on peer reviewed research that quantifies the financial or health benefits of the reduction in fear and confusion for residents and patients.

Second, updates in the 2021 edition of the LSC (NFPA 101) that remain in the 2024 edition of the LSC modified requirements related to doors and door frames located in barriers that are not required to have a fire-resistance rating under the life safety plans. Specifically, for these doors, facilities would no longer be required to comply with NFPA 80, Standard for Fire Doors and Other Opening Protectives. Providers would benefit from this update by alleviating the need for an annual inspection and rating of the door assembly. While we do not have information on the number of doors across all the provider types that the proposed update to the LSC would impact, industry estimates suggest that a single door can take 20 to 30 minutes to inspect.[358] With inspections required on an annual basis and the potential for multiple doors within a single facility to be impacted by this change, updating this requirement would likely lead to significant time and cost savings for providers. We seek comments from providers of different sizes on the estimated savings they will accrue from this requirement change both on a per door basis, as well as a facility basis.

Third, updates to the 2021 edition of the LSC (NFPA 101) increased the maximum size of receptacles for soiled linen and trash not located in hazard areas from 32 to 64 gallons. In addition, a 2018 update to the LSC removed the restriction that limits the capacity of containers within any 64-square-foot area. Allowing these changes would improve flexibility for environmental services staff and potentially increase staff efficiency since a larger container capacity would allow them to collect double the trash or soiled linens before emptying receptacles. Although we do not quantify how much these changes could increase efficiency, given the large amounts of trash and soiled linen that healthcare facilities generate daily, we expect that it could have a significant financial and staff resources impact and seek comments from providers on expected savings from this change.

Fourth, updates to the 2024 edition of the LSC (NFPA 101) include a new definition of ''gross floor area'' that no longer requires the inclusion of stairs and shafts within the boundary of smoke compartments or suites to be included in the area calculation. This change in suite size calculation provides more flexibility for providers and utilizing this edition would allow them to utilize most up-to-date best practices regarding the extent of smoke detection, the use of quick-response sprinklers, and direct supervision requirements.

Fifth, updates to the 2024 edition of the LSC (NPFA 101) include changes to the alternative care sites (ACS) requirements that would permit the use of an ACS for healthcare during an urgent need to provide additional capability for communities. Specifically, this change applies to new and existing healthcare organizations and allows an ACS to temporarily convert to an HCO with an approved fire emergency plan and comply with alternate construction, design, protection, operational, and occupancy classification requirements. Updating provider requirements to the 2024 edition of the LSC would benefit both providers and patients by allowing HCOs to address urgent surges in demand and ensure that affected communities have safe, code-compliant capacity during times of public health emergencies or other crises.

Finally, as part of the updates to the LSC, we are proposing to remove the requirement that hospitals, CAHS, RNHCIs, LTC facilities, and hospice inpatient care facilities have outside windows and doors in every patient sleeping area. While we cannot quantify the savings from this proposed change, we expect that removing this requirement would provide providers with more flexibility regarding construction of new facilities and renovation of existing facilities to best meet patient needs.

b. Costs

While we expect that requiring facilities to meet the standards in the 2024 NFPA edition would have positive benefits for patient health and safety and reduce overall burden for providers, we also expect that it could lead to increases in provider costs.

First, a new section has been added to the 2024 Edition of the HCFC (NFPA 99) that includes requirements and prescriptive intervals for routine inspection, maintenance, and testing of

[358] Midsummer Fire Protection. Fire Door Inspections: What to Expect. *https://midsummerfirepro.co.uk/fire-door-inspections-expect/#:~:text=How%20Long%20Does%20a%20Fire,leaving%20no%20potential%20risks%20unaddressed.* (Updated 27 September 2024).

electrical system components. Specifically, it codifies the requirement that routine inspection, maintenance, and testing ''must'' occur at regular intervals rather than saying that it ''should'' occur at regular intervals. While many providers are likely to already be conducting these tasks at regular intervals, it is likely that some providers are not. Depending on the number of providers who are not conducting these tasks at regular intervals, the financial cost of this change could vary greatly. We seek comments from providers on the additional burden, if any, they expect to incur from this new requirement.

Second, updates to the 2024 edition of the LSC (NFPA 101) require facilities to have CO detection and warning equipment. For new healthcare occupancies (HCOs) and residential board and care occupancies (RBOCs), the 2024 edition of the LSC added new requirements for CO detection requirements for cooking facilities open to the corridor, to ceilings of rooms containing fuel-burning appliances or fireplaces, and within 36 inches of the first air vent from fuel-burning heating, ventilation and air-conditioning (HVAC) systems. It also added requirements for CO detection where new residential board and care facilities have attached garages, s, fuel-burning appliances, or fuel burning fireplaces. Given uncertainty about the number of new HCOs and RBCOs that would emerge in coming years and would be affected by this proposed requirement, we seek comments on ways to estimate the burden.

Third, a new requirement was added that establishes minimum fire safety requirements for the design, construction, maintenance, and operation of heliports. These changes would apply mainly to new heliports or major modifications to accommodate new VTOL (Vertical Takeoff and Landing) aircraft or larger existing heliports. While we do not expect many providers to be building new heliports or engaging in major renovations or modifications to accommodate larger aircraft or new VTOL aircraft, the updated standards could lead to additional burden when this occurs. We seek comments from providers with heliports, or those providers that are considering constructing heliports, on the expected burden from these new requirements.

In addition to the above costs across multiple provider types, we detail expected costs for provisions that would specifically affect ICFs/IID, ASCs, and dialysis facilities.

i. Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs/IID) (§ 483.470)

We anticipate the proposed requirement at § 483.470(j)(1)(i) which updates the LSC (NFPA 101) reference year to 2024 would result in an economic impact cost. The reason being the 2024 edition of the LSC (NFPA 101) revised the portable fire extinguisher requirement in existing large Residential Boarding Care Occupancy (RBCOs) or ICFs/IID to be provided throughout the facility rather than only near hazardous areas.

To determine the cost of this proposed update to existing ICFs/IID, we estimate the number of additional portable fire extinguishers ICFs/IID would have to purchase and install to be in compliance. To estimate the number of additional portable fire extinguishers ICFs-IID would have to place throughout the facility rather than only near hazardous areas we must make assumptions as CMS data does not provide details on specific hazard areas or the layout of each ICF/IID.

In the absence of data, we estimate one portable first extinguisher would be purchased per 14 bedrooms per ICF/IID provider. We base this estimation on the following calculation. According to the current LSC (NFPA 101), Standard for Portable Fire Extinguishers, RBCOs must place a portable fire extinguisher with a minimum travel distance of 75 feet. If we assume one bedroom is approximately 10 feet wide and 7 bedrooms organized in a linear fashion create a hallway, then we can anticipate an ICF/IID would place a fire extinguisher at the end of the hallway. If we add a hallway north, south and east, then the portable fire extinguisher would remain in the middle with a 28-bedroom radius. Depending on the facility layout of the ICF/IID, the number of portable fire extinguishers can vary from 1 portable fire extinguisher to every 7 bedrooms to 1 portable fire extinguisher to every 28 bedrooms. To estimate the best total cost to all ICFs/IID we assume a ratio of 14 bedrooms per portable fire extinguisher. According to 2026 CMS data there were 400 existing large (16 residents or more) ICFs/IID with a total of 25,192 bedrooms.[359] This means 1,799 (25,192 bedrooms ÷ 14 bedrooms per fire extinguisher) additional portable fire extinguishers would need to be purchased. ABC portable fire extinguishers range between $50–$110. Assuming an average cost of $80 per portable fire extinguisher, we estimate a cost of $143,920 (1799 fire extinguishers × $80/fire extinguisher). We assume that these fire extinguishers would need to be replaced every 2 years.

As portable fire extinguishers may be subject to tampering by residents, we assume an ICF/IID would place portable fire extinguishers in locked fire extinguisher cabinets. The cost per lockable fire extinguisher cabinet ranges between $95–$240. We take the midpoint of these estimates and assume that the locked fire extinguisher cabinets would have a one-time cost of $168 per cabinet for a total one-time cost of $302,232 ($168 cabinet × 1799). Fire extinguisher cabinets would also require installation, and the cost of installation would vary depending on whether it is surface mounted or needs to be recessed into the wall. We assume it would take one (1) hour for a general contractor at a labor cost of $56 per hour for a one-time cost of cost of $100,744 (1799 cabinets × $56/cabinet). As indicated in Table 52, we estimate that total costs over 10 years would be $1,122,576 for all 400 ICFs/IID, with an average per provider cost of $2,806 ($1,122,576 ÷ 400 facilities). Average annual costs are estimated to be $112,258 for all providers and $281 per provider.

[359] QCOR. CASPER (07/28/2026) available at *https://qcor.cms.gov/active_nh.jsp?which=2&report=active_nh.jsp.*

TABLE 52: 10-Year ICFs/IID Life Safety Update Costs

Year	Financial Costs
1	$546,896
2	$0
3	$143,920
4	$0
5	$143,920
6	$0
7	$143,920
8	$0
9	$143,920
10	$0
Total 10-Year Cost	$1,122,576

ii. Ambulatory Surgical Centers (ASCs) (§ 416.44)

The 2024 edition of the LSC requires ASCs occupying a space in a high-rise building that was (1) constructed prior to the effective date of CMS adoption of the 2012 LSC on July 5, 2016, and (2) is currently not sprinklered to ensure the building and their facility are sprinklered throughout or relocate to a compliant building within 12 years of the 2024 LSC adoption by CMS. While we expect that all high-rise buildings constructed after July 5, 2016 are fully sprinklered and all ASCs within those buildings would be compliant with the regulation, we seek comments on the number of ASCs that occupy an existing (constructed before July 2016) high-rise building that is currently not sprinklered to develop burden estimates.

iii. End-Stage Renal Disease (ESRD) Providers/Dialysis Facilities (§ 494.60)

The 2024 edition of the LSC requires dialysis facilities, occupying a space in a high-rise building that was (1) constructed prior to the effective date of CMS adoption of the 2012 LSC on July 5, 2016, and (2) is currently not sprinklered to ensure the building and their facility are sprinklered throughout or relocate to a compliant building within 12 years of the 2024 LSC adoption by the authority having jurisdiction (CMS). While we expect that all high-rise buildings constructed after July 5, 2016 are fully sprinklered and all ESRD facilities within those buildings would be compliant with the regulation, we seek comments on the number of ESRD facilities that occupy an existing (constructed before July 2016) high-rise building that is currently not sprinklered to develop burden estimates.

13. Medicaid Institutional Payment Transparency Reporting Requirements (§§ 438.72 and 442.43)

We are proposing regulatory changes at §§ 438.72 and 442.43 to rescind requirements for States to report annually, at the facility level, on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff, and the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff. These proposals are expected to benefit the States and providers by reducing administrative burden. In addition, they are expected to benefit the Federal Government because these Medicaid costs are split between States and the Federal Government.

The proposed rescission of these requirements would reduce the information collection requirements for the States and providers. The burden associated with these information collection requirements was included in the Collection of Information (COI) section of the 2024 Minimum Staffing final rule. New burden reduction estimates associated with these recissions are included in the COI. The proposed quantitative benefits are wholly associated with the removal of the burden associated with the information collection requirements documented in the COI section of the 2024 Minimum Staffing final rule related to the requirements for States to report annually, at the facility level, on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff, and the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff. For ease of reference, and for projection purposes, we are including the Federal government, States, and provider share of those savings here in Table 53, projected from 2027 through 2036 (in 2025 dollars). For the Federal Government, we estimate total savings of $687,600 as a result of the proposed regulations over 10 years. For the States, we estimate total savings of $687,600 as a result of the proposed regulations over 10 years. For providers, we estimate $304,159,413 in savings over 10 years. Because savings are projected over 10 years, the total estimated savings exceed the amounts shown in the COI section of the 2024 Minimum Staffing final rule. Savings displayed in Table 53 are inclusive of both one-time and ongoing costs. The other potential benefits associated with the rescission of these requirements cannot be monetarily quantified at this time.

TABLE 53: Projected Benefits to the Federal Government, States, and Providers of Proposed Regulatory Changes at §§ 438.72 and 442.43 (in 2025 dollars)

Year	Federal Savings	State Savings	Provider Savings	Total Savings
2027	$336,690	$336,690	$41,958,507	$42,631,887
2028	$38,990	$38,990	$29,133,434	$29,211,414
2029	$38,990	$38,990	$29,133,434	$29,211,414
2030	$38,990	$38,990	$29,133,434	$29,211,414
2031	$38,990	$38,990	$29,133,434	$29,211,414
2032	$38,990	$38,990	$29,133,434	$29,211,414
2033	$38,990	$38,990	$29,133,434	$29,211,414
2034	$38,990	$38,990	$29,133,434	$29,211,414
2035	$38,990	$38,990	$29,133,434	$29,211,414
2036	$38,990	$38,990	$29,133,434	$29,211,414
Total 10-Year Savings	$687,600	$687,600	$304,159,413	$305,534,613

As we discussed in the COI section, we believe the recission of three of the four reporting requirements will result in financial and administrative burden reductions for the Federal government, States, and providers. We do not believe that the proposed changes would impose any new or revised collection of information requirements or burden including those associated with the creation or revision of State plan or other State-owned policy documents. Further, as we discussed in the 2024 Minimum Staffing proposed rule, the Medicaid institutional payment transparency reporting requirement sought to address access to care that is being affected by direct care and support staff workforce shortages. The proposal was intended to support the sufficiency of the direct care and support staff workforce through public reporting of the direct payments to these workers. We believe that promoting public transparency is important for holding States accountable for ensuring that Medicaid payments are sufficient to enlist enough workers so that quality LTSS care is available to the beneficiaries who want and require such care. However, those benefits were difficult to quantify and were not estimated in the 2024 Minimum Staffing proposed rule or the 2024 Minimum Staffing final rule and as such, are not included in the burden reduction estimates in this proposed rule.

14. Summary of Regulatory Impact Analysis

Table 54, Table 55, and Table 56 provide an estimate of the total annual and 10-year financial and hourly impact that would be achieved through the changes proposed in this rule. In Table 57, we also provide a summary estimate that aggregates the annual and 10-year financial and hourly impacts for providers from all the proposed provisions. These estimates exclude the annual savings of approximately $112 million and more than 3.20 million hours gained by reducing Medicaid institutional payment transparency reporting requirements and other collection of information requirements, as well as new information collection costs related to birth tissue as summarized in Tables24, 25and 26. Overall, we estimate that these proposed changes would save providers more than $2.08 billion and more than 20.5 million hours over 10 years.

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TABLE 54: Regulatory Impact Analysis Financial and Hourly Savings Part I

Year	Transfer Notices for Emergent Care		Covid-19 Staff Education in LTC Facilities		Covid-19 Staff Vaccination in LTC Facilities	Covid-19 Staff Education in ICFs/IID		Covid-19 Staff Vaccination in ICFs/IID	Total Savings	
	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Financial Savings ($ Million)	Hourly Savings
1	$1.00	10,264	$60.61	886,350	$4.28	$4.72	69,042	$0.33	$70.94	965,656
2	$1.00	10,264	$60.61	886,350	$4.28	$4.72	69,042	$0.33	$70.94	965,656
3	$1.00	10,264	$60.61	886,350	$4.28	$4.72	69,042	$0.33	$70.94	965,656
4	$1.00	10,264	$60.61	886,350	$4.28	$4.72	69,042	$0.33	$70.94	965,656
5	$1.00	10,264	$60.61	886,350	$4.28	$4.72	69,042	$0.33	$70.94	965,656
6	$1.00	10,264	$60.61	886,350	$4.28	$4.72	69,042	$0.33	$70.94	965,656
7	$1.00	10,264	$60.61	886,350	$4.28	$4.72	69,042	$0.33	$70.94	965,656
8	$1.00	10,264	$60.61	886,350	$4.28	$4.72	69,042	$0.33	$70.94	965,656
9	$1.00	10,264	$60.61	886,350	$4.28	$4.72	69,042	$0.33	$70.94	965,656
10	$1.00	10,264	$60.61	886,350	$4.28	$4.72	69,042	$0.33	$70.94	965,656
10-Year Total Savings	$10.01	102,640	$606.09	8,863,500	$42.75	$47.21	690,420	$3.33	$709.39	9,656,560

TABLE 55: Regulatory Impact Analysis Financial and Hourly Savings Part II

Year	OB QAPI Project		OB Staff Training		Birth Tissue Collection - Staff Training		Birth Tissue Collection - Informed Consent		Birth Tissue - Safe Handling		Total Savings	
	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million	Hourly Savings
1	$17.74	93,870	$22.65	198,388	-$47.72	-462,974	-$69.12	-394,155	-$4.15	-23,606	-$80.60	-588,477
2	$17.74	93,870	$89.96	787,980	-$8.28	-80,351	-$69.12	-394,155	-$4.15	-23,606	$26.15	383,738
3	$17.74	93,870	$36.78	322,203	-$8.14	-80,351	-$69.12	-394,155	-$4.15	-23,606	-$26.89	-82,039
4	$17.74	93,870	$78.79	690,166	-$8.14	-80,351	-$69.12	-394,155	-$4.15	-23,606	$15.12	285,924
5	$17.74	93,870	$45.60	399,475	-$8.14	-80,351	-$69.12	-394,155	-$4.15	-23,606	-$18.07	-4,767
6	$17.74	93,870	$71.82	629,121	-$8.14	-80,351	-$69.12	-394,155	-$4.15	-23,606	$8.15	224,879
7	$17.74	93,870	$51.11	447,701	-$8.14	-80,351	-$69.12	-394,155	-$4.15	-23,606	-$12.56	43,459
8	$17.74	93,870	$67.47	591,023	-$8.14	-80,351	-$69.12	-394,155	-$4.15	-23,606	$3.80	186,781
9	$17.74	93,870	$54.55	477,798	-$8.14	-80,351	-$69.12	-394,155	-$4.15	-23,606	-$9.13	73,556
10	$17.74	93,870	$64.76	567,246	-$8.14	-80,351	-$69.12	-394,155	-$4.15	-23,606	$1.09	163,004
10-Year Total Savings	$177.41	938,700	$583.48	5,111,101	-$121.16	-1,186,133	-$691.20	-3,941,550	-$41.47	-236,060	-$92.94	686,058

TABLE 56: Regulatory Impact Analysis Financial and Hourly Savings, Part III

Emergency Services Training		Transfer Protocol Training		Life Safety Code Updates in ICFs-IID	Total Savings	
Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Hourly Savings	Financial Savings ($ Million)	Financial Savings ($ Million)	Hourly Savings
$65.12	570,471	$81.57	445,535	-$0.55	$146.15	1,016,006
$65.12	570,471	$81.57	445,535	$0.00	$146.69	1,016,006
$65.12	570,471	$81.57	445,535	-$0.14	$146.55	1,016,006
$65.12	570,471	$81.57	445,535	$0.00	$146.69	1,016,006
$65.12	570,471	$81.57	445,535	-$0.14	$146.55	1,016,006
$65.12	570,471	$81.57	445,535	$0.00	$146.69	1,016,006
$65.12	570,471	$81.57	445,535	-$0.14	$146.55	1,016,006
$65.12	570,471	$81.57	445,535	$0.00	$146.69	1,016,006
$65.12	570,471	$81.57	445,535	-$0.14	$146.55	1,016,006
$65.12	570,471	$81.57	445,535	$0.00	$146.69	1,016,006
$651.25	5,704,712	$815.69	4,455,354	-$1.12	$1,465.82	10,160,066

TABLE 57: Provider Regulatory Impact Analysis Summary Table for All Provisions

Year	Financial Savings ($ Million)	Hourly Savings
1	$136.48	1,393,185
2	$243.78	2,365,400
3	$190.60	1,899,623
4	$232.75	2,267,586
5	$199.42	1,976,895
6	$225.78	2,206,541
7	$204.93	2,025,121
8	$221.43	2,168,443
9	$208.36	2,055,218
10	$218.72	2,144,666
10-Year Total Savings	$2,082.26	20,502,684

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D. Alternatives Considered

When developing these burden reduction policies, we considered a variety of alternative policies that may also achieve our goal of reducing regulatory burden by removing obsolete, duplicative, and unnecessary requirements to free up resources for direct patient care.

1. Ongoing and PHE Acute Infectious Disease Data Reporting for LTC Facilities

We considered proposing to revise, rather than remove, the ongoing illness data reporting requirement for LTC facilities. Specifically, in the 2025 deregulatory RFI, interested parties asked us to examine the burden of this requirement. Some adjustments we considered were requiring fewer elements to be reported on an ongoing basis, allowing for yes/no answers, or adjusting the frequency of data reporting from weekly to monthly. These approaches would have led to only a marginal reduction in provider burden. For example, if we were to reduce the number of reported elements required by 50 percent and assuming each element takes the same amount of time for LTC facility staff to enter, then based on our estimate in Table 3, LTC facilities would save only $313 million over 10 years rather than the estimated $626 million that they would save for its total elimination. We believe that these alternatives would have continued to impose administrative burden without directly contributing to patient health and safety. Therefore, we believe removing this requirement altogether would have the greatest benefit for facilities.

When reviewing PHE data reporting, we considered changing the requirement to apply only to declared PHEs related to communicable diseases as opposed to our proposed policy that would allow the Secretary to require data reporting for a declared PHE related to any infectious disease. A communicable disease would be one that has a primary mode of disease spread from person to person, whereas an infectious disease, as the term is used in this proposed rule, would be one that cannot be transmitted directly from one person to another and one that can be transmitted from person to person. The terms ''communicable'' and ''infectious'' are often used interchangeably; however, there is a difference. While all communicable diseases are infectious, not all infectious diseases are communicable. Some noncommunicable infectious diseases that could lead to a Secretary-declared PHE include legionnaires' disease, dengue fever, rabies, and certain foodborne illnesses like Salmonella or E. Coli. Noncommunicable disease outbreaks can strain healthcare facilities in the same ways communicable diseases can. Ultimately, we believe that the potential for reduced reporting burden that is associated with limiting the PHE data reporting requirement to just communicable diseases does not outweigh the risks associated with limiting the Secretary's regulatory authority, thus reducing the availability of data essential for a coordinated response to broad scale health emergencies.

2. OB–QAPI Requirements for Hospitals and CAHs

We considered several approaches for revising the hospital and CAH OB-specific QAPI requirements. One option was to exempt rural hospitals and CAHs from these requirements to avoid imposing disproportionate operational and administrative burdens on facilities with limited staffing and financial resources, while retaining the requirement for non-rural hospitals. As discussed in section II.A.1 of this proposed rule, commenters responding to the 2025 deregulatory RFI indicated that the OB-specific requirements could be overly burdensome and may contribute to financial strain or decisions to reduce or discontinue labor and delivery services in rural areas. We ultimately did not adopt this approach because retaining the requirements for non-rural hospitals would continue to be duplicative of the long standing QAPI requirements. Existing hospital and CAH CoPs already apply broadly to all facility services, including inpatient and outpatient obstetric care, and require hospitals and CAHs to maintain comprehensive, ongoing, and data-driven quality assessment and performance improvement programs.

3. OB Services Staff Training for Hospitals and CAHs

We propose to remove the OB services staff training requirement for hospitals and CAHs. We considered maintaining the OB services staff training requirements while reducing the frequency of required training or limiting applicability to staff with primarily obstetric responsibilities. We did not propose this approach because it would continue to impose prescriptive federal training requirements by requiring hospitals and CAHs to define specific staff roles, training intervals, and competencies, increasing administrative complexity for hospitals and oversight burden for CMS. While it would marginally reduce provider burden, it would not fully address commenters concerns regarding redundancy with existing hospital requirements, accreditation standards, and professional certification and continuing education requirements.

4. Patient's Rights for Birth Tissue Collection in Hospitals and CAHs

We considered relying on existing patient rights CoPs that provide patients or their representatives the right to make informed decisions regarding their care, including being involved in care planning and treatment, as well as existing medical record CoPs that require the medical record to contain properly executed informed consent forms for procedures and treatments. Ultimately, however, we decided against this approach given variation in hospital and CAH practices around informed consent and patient knowledge about how to request retention or release of birth tissue, which may have significant cultural, religious, personal or familial significance to patients and their families. We also did not utilize this approach given concerns from investigations about the commercialization of birth tissues, often without families' awareness.

5. 2024 Edition of the Life Safety Code (NFPA 101) and the 2024 Edition of the Health Care Facilities Code (NFPA 99)

We propose to adopt both the 2024 edition of the NFPA 101 and the NFPA 99. We considered waiting to publish a proposed rule until the release of the 2027 editions of both the NFPA 101 and the NFPA 99 so that we could propose to adopt those editions. We determined that waiting until the 2027 editions are issued to begin the rulemaking process was not in the best interest of regulated providers or healthcare consumers because the 2024 edition of the NFPA 101 and the NFPA 99 offer meaningful improvements to occupant safety and meaningful flexibilities and advances for healthcare facilities in their daily operations and long-term renovation and construction planning. We concluded that continuing to require facilities to comply with the 2012 editions of the NFPA 101 and the NFPA 99 for a longer period of time would not be in the best interest of providers and patients.

We welcome comments on this alternative approach that we considered and other suggestions for additional reforms that CMS should consider.

6. Outside Window and Door Requirements

We propose to repeal the outdoor window and door requirements for hospitals, CAHs, RNHCIs, LTC facilities, and hospice inpatient care facilities. We considered proposing to revise the current outside window and door requirements by adding new flexibilities for sleeping rooms intended for occupancy for less than 24 hours and for special care units, while retaining the existing window and door requirements, which already deem windows in atrium walls to be considered outside windows. For sleeping rooms intended for occupancy for less than 24 hours, we considered removing the requirement that these spaces must have an outside window or door, given the short-term nature of their occupancy, thereby reducing burden on the facilities. For hospitals and CAHs, individual patient sleeping cubicles within special care units (for example, neonatal intensive care units (NICUs), intensive care units (ICUs), cardiac care units (CCUs)) would no longer be required to have an outside window or outside door in each cubicle, provided that not less than one outside window or outside door is provided in the suite. These exceptions would allow for greater flexibility in both new construction projects and renovations of existing healthcare facilities, while continuing to provide the benefits of outside windows for the mental well-being of patients.

7. Medicaid Institutional Payment Transparency Reporting

We propose to rescind requirements for States to report annually, at the facility level, on the percentage of Medicaid payments for nursing facility services that is spent on compensation for direct care workers, the percentage of Medicaid payments for nursing facility services that is spent on compensation for support staff, and the percentage of Medicaid payments for ICF/IID services that is spent on compensation for support staff.

We considered whether we could advise States that they could approximate the time that direct care workers spend caring for Medicaid residents in calculating the percentage of Medicaid payments spent on compensation for direct care workers. However, as we discussed in section I, we believe that we could make such an approximation using existing data sources, thereby reducing burden on facilities without necessarily impacting the accuracy of the reporting.

We considered maintaining the reporting requirements based on concerns about imposing additional costs if States, nursing facilities, and ICFs/IID had already begun planning for and implementing operational or system changes to comply with these reporting requirements. Given the June 21, 2028, applicability date for the requirements, we believe that the costs that they may have incurred to date are minimal. We believe that any costs they have incurred to comply with the requirements are substantially less than any remaining initial implementation and ongoing costs they would incur if required to comply with the requirements as finalized. Additionally, we considered maintaining the reporting requirements based on whether Medicaid beneficiaries, direct care workers, and support staff have relied on the institutional payment transparency reporting requirements. As mentioned previously, since the applicability date for the requirements has not yet occurred, beneficiaries, direct care workers, and support staff have not experienced any benefits from the requirements. As such, we do not believe that they have relied on the institutional payment transparency reporting requirements.

E. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. As estimated in the Collection of Information (Section III.) and the Regulatory Impact Analysis (Section IV.) of this proposed rule, we estimated that the proposed changes would have quantifiable financial effects on 26,292 hospitals, CAHs, LTC facilities, and ICFs-IIDs. It would also have unquantifiable effects on hospices, PACE, REHs, ASCs, and ESRD facilities. We assume that all providers that the rule has a quantifiable effect on financially, would review this rule. We acknowledge that this assumption may

understate or overstate the cost of reviewing this rule. It is possible that more than one individual from each provider may review this rule, or that entities other than providers, such as beneficiary advocacy groups, may review this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule and subsequent final rule.

We also recognize that different types of entities are affected by mutually exclusive sections of this proposed rule, or that some entities may not find it necessary to fully read each section of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer will read approximately 50 percent of this proposed rule. We seek comments on this assumption.

Using the wage information from the May 2025 BLS data medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $135.54 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 155 minutes (77,600 words ÷ 250 words/minute) hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is $349.70 (2.58 hours × $135.54). Therefore, we estimate that the total cost of reviewing this regulation is $9,194,312 ($349.70 × 26,292).

F. Accounting Statement

As required by OMB Circular A–4 (available online at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*), we have prepared an accounting statement in Table 58 showing classification of the costs, benefits, and overall impacts associated with the provisions of this proposed rule. This includes the total benefits and costs as estimated in Table 24, Table 25, Table 26, Table 54, Table 55, and Table 56, as well as the regulatory review costs. There are no transfer costs associated with the proposed changes. This statement provides our best estimate for the Medicare and Medicaid provisions of this proposed rule.

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TABLE 58: Accounting Statement ($Millions)

Category	Estimate	Units		
		Year Dollar	Discount Rate	Period Covered
Unquantified Benefits	Continued patient access for those utilizing care in CAHs affected by co-location requirements. Greater provider flexibility related to LSC edition update.			
Annualized Monetized Costs ($million/year) for Providers	-318	2025	7%	2027-2036
Annualized Monetized Costs ($million/year) for Providers	-319	2025	3%	2027-2036
Annualized Monetized Costs ($million/year) for State Governments	-1.08	2025	7%	2027-2036
Annualized Monetized Costs ($million/year) for State Governments	-1.07	2025	3%	2027-2036
Annualized Monetized Costs ($million/year) for Federal Government	-0.04	2025	7%	2027-2036
Annualized Monetized Costs ($million/year) for Federal Government	-0.04	2025	3%	2027-2036
Unquantified Costs	Reduced public transparency related to the Medicaid institutional payment transparency proposals			

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G. Initial Regulatory Flexibility Act (IRFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. HHS defines a significant impact as a 3 to 5 percent change in revenues that affects 5 percent or more of the affected entities within the industry. For the purpose of the IRFA, we estimate that almost all skilled nursing facilities (NAICS 6231) and ICFs/IID (NAICS 6232) are considered small businesses, as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions), or by meeting the Small Business Administration's size standards with total revenues of $34.0 million or less in any single year for skilled nursing facilities and $19.0 million or less in any single year for ICFs/IID. Most hospitals and CAHs (NAICS 6221) are also considered small businesses either by the Small Business Administration's size standards with total revenues of

$47.0 million or less in any single year or by the hospital's not-for-profit status. In Table 59, we used the most recent revenue data available from the 2022 SUSB from the Census Bureau to determine the number of small entities and their revenue. Since this is an IRFA, we seek comments on all our estimates and whether there are additional costs or savings we should have included for any provider types affected by this proposed rule.

TABLE 59: SBA Size Standards for Applicable NAICS Industry Codes

NAICS Code	Description	SBA Size Standard/Entity Threshold (Millions $)	Total Small Business Count
Providers			
6221	General Medical and Surgical Hospitals	$47	1,169
6231	Nursing Care Facilities (Skilled Nursing Facilities)	$34	9,709
6232	Residential Intellectual and Developmental Disability, Mental Health, and Substance Abuse Facilities	$19	10,581

CMS considered including the 2023 Nonemployer Statistics (NES) data from the Census Bureau to supplement the SUSB data on small providers in particular. However, considering the industries impacted by this proposal and the nature of the healthcare services which most frequently require prior authorization and meeting a variety of regulatory requirements, we do not expect that self-employed providers with no employees would be impacted by the proposed policy. As such, we do not include them in the analysis and in the total count of small provider entities.

The financial impacts of the policies in this proposed rule differ based on the provider type, the services they offer, and the number of employees that work in the provider. Repealing the COVID–19 staff education and vaccination requirements in ICFs/IID and LTC facilities, and the hospital and CAH staff training requirements will reduce cost more for large providers that have many employees than small providers that have fewer employees. Similarly, the new requirements for birth tissues in hospitals and CAHs will also increase costs more for large providers that have many employees than small providers that have few employees. As such, we analyze the impact on small entities separately for three groups: (1) LTC facilities, (2) hospitals and CAHs, and (3) ICFs/IID. We provide separate tables for each group showing the estimated impact on firms, which are legal business entities that may own multiple locations, and establishments, which are a single physical location where business activity occurs. While IRFAs typically show the impact only on firms, we examine the impact on establishments as well since throughout the rule, we calculate the impact on each group, which correlates more directly to establishments than firms. For each group, we provide a summary of the impacts identified in both this proposed rule's regulatory impact analysis and collection of information section.

1. Long-Term Care (LTC) Facilities

To estimate the impact on LTC facilities, we first calculated the average annual collection of information savings per LTC facility using the estimate summarized in Table 25 in section III. of this proposed rule. These savings include non-PHE respiratory illness reporting at $4,252, ombudsmen notices of transfer for emergent care at $111, updates to facility policies regarding staff COVID–19 education at $585, and staff documentation of COVID–19 education at $326 for a total per provider reduction in information collection costs of $5,274.

To these savings, we add the savings from not needing to educate staff on the COVID–19 vaccination and provide the COVID–19 vaccine to unvaccinated staff members who request it. Using the data from Table 29, we estimate that it costs $34.19 per staff member who needs education with an estimated 93.3 percent of staff members needing education. For the purposes of the IRFA, in Tables 33 and 34, respectively, we estimate the average impact on firms and entities in each enterprise size group using the following formulas: (1) Firm Impact = ($34.19/employee × 93.3 percent employees × Employment) ÷ Firms in Enterprise Size Group; and (2) Establishment Impact = ($34.19/employee × 93.3 percent employees × Employment) ÷ Establishments in Enterprise Size Group.

To estimate savings from not providing the COVID–19 vaccine to staff members, we used the same methodology used to estimate its savings in Table 31. Specifically, we assumed that the education would result in a 5-percentage point increase in staff vaccination rates. We also assumed that staff vaccination would cost $45 per staff member. Using these numbers, we estimate the per firm and entity savings by enterprise size using the following formulas: (1) Firm Impact = (Employment × 5 percent × $45/employee) ÷ Firms in Enterprise Size Group; and (2) Establishment Impact = (Employment × 5 percent × $45/employee) ÷ Establishments in Enterprise Size Group.

Finally, to estimate the savings from repealing the three Medicaid institutional payment transparency reporting requirements, we calculate annual savings per facility separately for each provider type. For nursing facilities, Table 24 shows annual savings of $26,553,423 across 13,605 facilities, or approximately $1,952 per facility. For ICFs/IID, Table 24 shows annual savings of $2,580,011 across 5,262 facilities, or approximately $490 per facility. We apply the nursing facility estimate of $1,952 in Tables 60 and 61 and the ICF/IID estimate of $490 in Tables 62 and 63.

In this section of the rule, in certain situations, a provider can be regarded as a firm, while in others, a provider may actually be considered an establishment. However, there is not a definitive method to determine whether a particular provider should be classified as a firm or an establishment. As such, for LTC facilities, we utilize all enterprise size groups in the analysis except for enterprises with less than $100,000 in annual revenue. According to the SUSB data, there are 592 firms in this enterprise size group with a total of 745 employees and average revenue of $41,255. However, not all skilled nursing facilities (NAICS 6231) listed in the SUSB data are Medicare/Medicaid-certified. In particular, the latest CMS data only shows 10 nursing homes that

had, on average, less than 2 residents per day.[360] With the average yearly cost for nursing homes in 2026 estimated at $119,340, we expect that there are no Medicare/Medicaid-certified nursing homes that fall into this smallest category.[361] As shown in Tables 60 through 67, for all other enterprise size groups, the average per firm and establishment savings from the proposed policies are less than 3 percent of revenues. As such, our IRFA suggests that the proposed requirements do not have a significant impact on LTC facilities as measured by a 3 to 5 percent change in revenues.

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[360] Centers for Medicare & Medicaid Services. Provider Information: Nursing Homes including Rehab Services. *https://data.cms.gov/provider-data/dataset/4pq5-n9py* (Accessed May 5, 2026).

[361] American Council on Aging. 2026 Nursing Home Costs by State and Region. *https://www.medicaidplanningassistance.org/nursing-home-costs/* (Accessed May 5, 2026).

TABLE 60: LTC Facility Impact for Firms by Enterprise Size Group

Enterprise Size ($1,000)	Firms	Employment	Receipts ($1,000)	Per Facility Collection of Information Savings	Covid-19 Education Savings per Firm (($34.19/employee × 93.3% employees × Employment)) ÷ Firms)	COVID-19 Vaccination Savings per Firm ((Employment × 5% × $45/employee) ÷ Firms)	Medicaid Institutional Payment Transparency Reporting Savings	Regulatory Review Costs	Total per Firm Savings	Average Per Firm Revenue (Receipts × $1000)/Firms)	Per Firm Savings as % of Average Firm Revenues
02: <100	592	745	24,423	$5,274	$40	$3	$1,952	$350	$6,919	$41,255	16.77%
03: 100-499	1,096	5,564	289,015	$5,274	$162	$11	$1,952	$350	$7,049	$263,700	2.67%
04: 500-999	566	7,319	408,649	$5,274	$412	$29	$1,952	$350	$7,318	$721,995	1.01%
05: 1,000-2,499	895	21,932	1,522,162	$5,274	$782	$55	$1,952	$350	$7,713	$1,700,740	0.45%
06: 2,500-4,999	1,537	71,838	5,772,946	$5,274	$1,491	$105	$1,952	$350	$8,472	$3,755,983	0.23%
07: 5,000-7,499	1,421	98,539	8,737,925	$5,274	$2,212	$156	$1,952	$350	$9,244	$6,149,138	0.15%
08: 7,500-9,999	1,155	106,679	9,915,195	$5,274	$2,946	$208	$1,952	$350	$10,030	$8,584,584	0.12%
09: 10,000-14,999	1,316	154,222	15,575,006	$5,274	$3,738	$264	$1,952	$350	$10,878	$11,835,111	0.09%
10: 15,000-19,999	605	91,881	9,881,097	$5,274	$4,845	$342	$1,952	$350	$12,062	$16,332,392	0.07%
11: 20,000-24,999	268	50,209	5,476,742	$5,274	$5,976	$422	$1,952	$350	$13,274	$20,435,604	0.06%
12: 25,000-29,999	149	29,905	3,535,945	$5,274	$6,402	$452	$1,952	$350	$13,730	$23,731,174	0.06%
13: 30,000-34,999	109	22,235	2,591,999	$5,274	$6,507	$459	$1,952	$350	$13,842	$23,779,807	0.06%
14: 35,000-39,999	73	17,776	2,068,507	$5,274	$7,768	$548	$1,952	$350	$15,192	$28,335,712	0.05%
15: 40,000-49,999	111	29,357	3,370,664	$5,274	$8,437	$595	$1,952	$350	$15,908	$30,366,342	0.05%
16: 50,000-74,999	130	50,972	5,199,434	$5,274	$12,507	$882	$1,952	$350	$20,266	$39,995,646	0.05%
17: 75,000-99,999	75	36,821	3,864,295	$5,274	$15,661	$1,105	$1,952	$350	$23,641	$51,523,933	0.05%
18: 100,000+	403	588,498	58,824,731	$5,274	$46,582	$3,286	$1,952	$350	$56,744	$145,967,074	0.04%

Source: United States Census Bureau. 2022 SUSB Annual Data Tables by Establishment Industry – Data by Enterprise Receipts Size.

TABLE 61: LTC Facility Impact for Establishments by Enterprise Size Group

Establishments	Employment	Receipts ($1,000)	Per Facility Collection of Information Savings	Covid-19 Education Savings per Establishment (($34.19/employee × 93.3% employees × Employment)) ÷ Establishments)	COVID-19 Vaccination Savings per Establishment ((Employment × 5% × $45/employee) ÷ Establishments)	Medicaid Institutional Payment Transparency Reporting	Regulatory Review Costs	Total per Establishment Savings	Average Per Establishment Revenue (Receipts × $1000)/ Establishments)	Per Establishment Savings as % of Average Establishment Revenues
592	745	24,423	$5,274	$40	$3	$1,952	$350	$6,919	$41,255	16.77%
1,099	5,564	289,015	$5,274	$161	$11	$1,952	$350	$7,049	$262,980	2.68%
573	7,319	408,649	$5,274	$407	$29	$1,952	$350	$7,312	$713,175	1.03%
915	21,932	1,522,162	$5,274	$765	$54	$1,952	$350	$7,695	$1,663,565	0.46%
1,586	71,838	5,772,946	$5,274	$1,445	$102	$1,952	$350	$8,423	$3,639,941	0.23%
1,450	98,539	8,737,925	$5,274	$2,168	$153	$1,952	$350	$9,197	$6,026,155	0.15%
1,232	106,679	9,915,195	$5,274	$2,762	$195	$1,952	$350	$9,833	$8,048,048	0.12%
1,423	154,222	15,575,006	$5,274	$3,457	$244	$1,952	$350	$10,577	$10,945,190	0.10%
715	91,881	9,881,097	$5,274	$4,099	$289	$1,952	$350	$11,264	$13,819,716	0.08%
375	50,209	5,476,742	$5,274	$4,271	$301	$1,952	$350	$11,448	$14,604,645	0.08%
218	29,905	3,535,945	$5,274	$4,376	$309	$1,952	$350	$11,561	$16,219,931	0.07%
168	22,235	2,591,999	$5,274	$4,222	$298	$1,952	$350	$11,396	$15,428,565	0.07%
133	17,776	2,068,507	$5,274	$4,263	$301	$1,952	$350	$11,440	$15,552,684	0.07%
295	29,357	3,370,664	$5,274	$3,174	$224	$1,952	$350	$10,274	$11,425,980	0.09%
488	50,972	5,199,434	$5,274	$3,332	$235	$1,952	$350	$10,443	$10,654,578	0.10%
421	36,821	3,864,295	$5,274	$2,790	$197	$1,952	$350	$9,863	$9,178,848	0.11%
6,294	588,498	58,824,731	$5,274	$2,983	$210	$1,952	$350	$10,069	$9,346,160	0.11%

Source: United States Census Bureau. 2022 SUSB Annual Data Tables by Establishment Industry – Data by Enterprise Receipts Size.

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2. Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs/IID)

To estimate the impact on ICFs/IID, we first calculated the average annual collection of information savings per ICF/IID using the estimate summarized in Table 26 in section III. of this proposed rule. These savings are for not updating the ICF/IID policies regarding staff COVID–19 education that we estimate at $293 per provider.

To these savings we add the savings from not needing to educate staff on the COVID–19 vaccination and provide the COVID–19 vaccine to unvaccinated staff members who request it. Using the data from Table 33, we estimate that it costs $34.19 per staff member who needs education with an estimated 93.3 percent of staff members needing education. For the purpose of the IRFA, in Table 62 and 63, respectively, we estimate the average impact on firms and entities in each enterprise size group using the following formulas: (1) Firm Impact = ($34.19/employee × 93.3 percent employees × Employment) ÷ Firms in Enterprise Size Group; and (2) Establishment Impact = ($34.19/employee × 93.3 percent employees × Employment) ÷ Establishments in Enterprise Size Group.

To estimate savings from not providing the COVID–19 vaccine to staff members, we used the same methodology used to estimate its savings in Table 35. Specifically, we assumed that the education would result in a 5-percentage point increase in staff vaccination rates. We also assumed that staff vaccination would cost $45 per staff member. Using these numbers, we estimate the per firm and entity savings by enterprise size using the following formulas: (1) Firm Impact = (Employment × 5 percent × $45/employee) ÷ Firms in Enterprise Size Group; and (2). Establishment Impact = (Employment × 5 percent × $45/employee) ÷ Establishments in Enterprise Size Group. Next, we add the new costs related to life safety code updates that we estimate to cost an average of $1,024 per provider. Finally, we add the savings related to repealing the Medicaid institutional payment transparency support staff reporting requirement for ICFs/IID, estimated at approximately $490 per facility based on Table 23. As shown in Tables 62 and 63, the average per firm and establishment savings from the proposed policies are less than 3 percent of revenues. As such, our IRFA suggests that the proposed requirements do not have a significant impact on ICFs/IID as measured by a 3 to 5 percent change in revenues.

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TABLE 62: ICFs/IID Impact for Firms by Enterprise Size Group

Enterprise Size ($1,000)	Firms	Employment	Receipts ($1,000)	Collection of Information Savings	Covid-19 Education Savings per Firm (($34.19/employee ×93.3% employees × Employment)) ÷ Firms)	COVID-19 Vaccination Savings per Firm ((Employment × 5% × $45/employee) ÷ Firms)	Life Safety Code Updates Savings	Medicaid Institutional Payment Transparency Reporting Savings	Regulatory Review Costs	Total per Firm Savings	Average Per Firm Revenue (Receipts × $1000)/ Firms)	Per Firm Savings as % of Average Firm Revenues
01: Total	11,709	747,869	60,164,782	$293	$2,037	$144	-$1,024	$490	$350	$1,590	$5,138,336	0.03
02: <100	1,183	2,536	51,565	$293	$68	$5	-$1,024	$490	$350	-$518	$43,588	-1.19
03: 100-499	2,760	12,195	780,658	$293	$141	$10	-$1,024	$490	$350	-$440	$282,847	-0.16
04: 500-999	1,639	17,165	1,172,317	$293	$334	$24	-$1,024	$490	$350	-$233	$715,264	-0.03
05: 1,000-2,499	1,838	40,991	2,903,727	$293	$711	$50	-$1,024	$490	$350	$171	$1,579,830	0.01
06: 2,500-4,999	1,256	53,792	4,166,552	$293	$1,366	$96	-$1,024	$490	$350	$872	$3,317,318	0.03
07: 5,000-7,499	633	43,443	3,274,696	$293	$2,189	$154	-$1,024	$490	$350	$1,753	$5,173,295	0.03
08: 7,500-9,999	435	37,330	3,037,563	$293	$2,737	$193	-$1,024	$490	$350	$2,340	$6,982,903	0.03
09: 10,000-14,999	516	57,706	4,644,757	$293	$3,567	$252	-$1,024	$490	$350	$3,228	$9,001,467	0.04
10: 15,000-19,999	321	48,097	3,741,738	$293	$4,780	$337	-$1,024	$490	$350	$4,526	$11,656,505	0.04
11: 20,000-24,999	204	36,607	2,864,945	$293	$5,724	$404	-$1,024	$490	$350	$5,537	$14,043,848	0.04
12: 25,000-29,999	148	27,848	2,259,327	$293	$6,002	$423	-$1,024	$490	$350	$5,835	$15,265,723	0.04
13: 30,000-34,999	120	27,284	2,271,152	$293	$7,253	$512	-$1,024	$490	$350	$7,173	$18,926,267	0.04
14: 35,000-39,999	79	18,183	1,392,485	$293	$7,342	$518	-$1,024	$490	$350	$7,269	$17,626,392	0.04
15: 40,000-49,999	124	28,153	2,592,477	$293	$7,242	$511	-$1,024	$490	$350	$7,162	$20,907,073	0.03
16: 50,000-74,999	167	54,445	4,535,474	$293	$10,400	$734	-$1,024	$490	$350	$10,542	$27,158,527	0.04
17: 75,000-99,999	78	33,243	2,914,458	$293	$13,595	$959	-$1,024	$490	$350	$13,963	$37,364,846	0.04
18: 100,000+	208	208,851	17,560,891	$293	$32,030	$2,259	-$1,024	$490	$350	$33,698	$84,427,361	0.04

Source: United States Census Bureau. 2022 SUSB Annual Data Tables by Establishment Industry – Data by Enterprise Receipts Size.

TABLE 63: ICFs/IID Impact for Establishments by Enterprise Size Group

Establishments	Employment	Receipts ($1,000)	Collection of Information Savings	Covid-19 Education Savings per Establishment (($34.19/employee × 93.3% employees × Employment)) : Establishments)	COVID-19 Vaccination Savings per Establishment ((Employment × 5% × $45/employee) : Establishments)	Life Safety Code Updates Savings	Medicaid Institutional Payment Transparency Reporting Savings	Regulatory Review Costs	Total per Establishment Savings	Average Per Establishment Revenue (Receipts × $1000)/ Establishments)	Per Establishment Savings as % of Average Establishment Revenues
44,474	747,869	60,164,782	$293	$536	$38	-$1,024	$490	$350	-$17	$1,352,808	0.00
1,186	2,536	51,565	$293	$68	$5	-$1,024	$490	$350	-$518	$43,478	-1.19
2,785	12,195	780,658	$293	$140	$10	-$1,024	$490	$350	-$441	$280,308	-0.16
1,703	17,165	1,172,317	$293	$322	$23	-$1,024	$490	$350	-$247	$688,383	-0.04
2,324	40,991	2,903,727	$293	$563	$40	-$1,024	$490	$350	$11	$1,249,452	0.00
2,723	53,792	4,166,552	$293	$630	$44	-$1,024	$490	$350	$84	$1,530,133	0.01
2,288	43,443	3,274,696	$293	$606	$43	-$1,024	$490	$350	$57	$1,431,248	0.00
2,118	37,330	3,037,563	$293	$562	$40	-$1,024	$490	$350	$11	$1,434,166	0.00
3,088	57,706	4,644,757	$293	$596	$42	-$1,024	$490	$350	$47	$1,504,131	0.00
2,688	48,097	3,741,738	$293	$571	$40	-$1,024	$490	$350	$20	$1,392,016	0.00
1,875	36,607	2,864,945	$293	$623	$44	-$1,024	$490	$350	$76	$1,527,971	0.00
1,424	27,848	2,259,327	$293	$624	$44	-$1,024	$490	$350	$77	$1,586,606	0.00
1,245	27,284	2,271,152	$293	$699	$49	-$1,024	$490	$350	$157	$1,824,218	0.01
925	18,183	1,392,485	$293	$627	$44	-$1,024	$490	$350	$80	$1,505,389	0.01
1,834	28,153	2,592,477	$293	$490	$35	-$1,024	$490	$350	-$67	$1,413,564	0.00
2,670	54,445	4,535,474	$293	$650	$46	-$1,024	$490	$350	$105	$1,698,679	0.01
1,635	33,243	2,914,458	$293	$649	$46	-$1,024	$490	$350	$103	$1,782,543	0.01
11,963	208,851	17,560,891	$293	$557	$39	-$1,024	$490	$350	$5	$1,467,934	0.00

Source: United States Census Bureau. 2022 SUSB Annual Data Tables by Establishment Industry – Data by Enterprise Receipts Size.

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3. Hospitals and Critical Access Hospitals (CAHs)

To estimate the impact on hospitals and CAHs, we first calculated the average annual collection of information savings per hospital and CAH using the estimate summarized in Table 16. In this proposed rule, the collection of information impacts are for hospitals and CAHs that offer obstetrical (OB) services, which are less than half of all hospitals and CAHs.[362] Using these data, we calculate average annual savings of $462 related to QAPI information technology infrastructure updates, $975 in savings related to QAPI data stratification and monitoring, and $613 in new costs related to the development of birth tissue policies and procedures for an average annual savings of $824 per hospital and CAH that offer obstetrical services.

We do not expect hospitals and CAHs in the two lowest enterprise size groups (<$100k and $100k–$499k) to be offering these services since according to the SUSB data there are only 233 employees in these 209 facilities, or an average of 1.11 employee per firm. As such, we do not include these savings for the repeal of requirements related to OB services for firms in these enterprise size groups.

To these impacts, we add the savings from the proposed repeal of the OB-specific QAPI project that we estimate costs an average of $5,670 per hospital and CAH. We also add expected savings from hospitals and CAHs with OB services not needing to provide staff training. As we noted earlier, hospitals and CAHs that offer OB services are a subset of all general medical and surgical hospitals, and we do not expect hospitals and CAHs with revenues under $500k are offering these services. Second, the SUSB data do not distinguish between hospitals and CAHs. This creates uncertainty since as outlined in the regulatory impact analysis, we expect a different share of employees in hospitals and CAHs to receive this training.

We use the following strategy to address these challenges. First, according to the BLS May 2025 National Industry-Specific Occupational Employment and Wage Estimates for hospitals (NAICS 622000) there are 6,712,760 individuals employed in hospitals. As indicated in Table 16, we estimate that there are 1,496,655 employees working in the 3,129 hospitals and CAHs that offer OB services that are receiving this training. This means that approximately 22.3 (1,4496,655 ÷ 6,712,760) percent of all hospital and CAH employees are receiving this training. For each enterprise size group with revenues of at least $500k in Table 64, we assume that 22.3 percent of employees in the enterprise size group received the training and calculated the total number of employees (22.3 percent × employees) in that enterprise size group who received the training. Next, to calculate estimated savings per firm and establishment by enterprise size, we identified the percentage of all employees across all enterprise size groups that came from each enterprise size group using the following formula: enterprise size group employees trained ÷ all employees trained. Afterwards, we multiple this percentage by the average annual savings ($58,348,149) by repealing this training requirement as provided in Table 40 to find the total savings for all firms and establishments in that enterprise size group. Finally, we calculate the savings per firm and

[362] In both sections III. and V. of this proposed rule, we assume that all hospitals and CAHs with OB services will also offer tissue collection and we seek comment in this assumption in the section III. of this proposed rule.

establishment using the following formulas: firm(establishment) savings = total enterprise size group savings ÷ firms(establishments) in enterprise size group.

The next policy we include is staff training on informed consent for birth tissue that would add new costs to hospitals and CAHs with OB services. According to the BLS May 2025 National Industry-Specific Occupational Employment and Wage Estimates for hospitals (NAICS 622000) there are 6,712,760 individuals employed in hospitals. As indicated in Table 41 and Table 42, we expect that including training new team members due to annual turnover, 231,488 staff members would need this training. This means that approximately 3.45 (231,488 ÷ 6,712,760) percent of all hospital and CAH employees would need this training. For each enterprise size group with revenues of at least $500k in Table 64, we assume that 3.45 percent of employees in the enterprise size group received the training and calculated the total number of employees (3.45 percent × employees) in that enterprise size group who received the training. Next, to calculate estimated costs per firm and establishment by enterprise size, we identified the percentage of all employees across all enterprise size groups that came from each enterprise size group using the following formula: enterprise size group employees trained ÷ all employees trained. Afterwards, we multiple this percentage by the average annual cost ($12,116,476) from this training as provided in Table 43 to find the total cost for all firms and establishments in that enterprise size group. Finally, we calculate the cost per firm and establishment using the following formulas: firm(establishment) cost = total enterprise size group cost ÷ firms(establishments) in enterprise size group.

In addition to conducting staff training, hospitals and CAHs that offer OB services would need to obtain informed consent from birthing patients. As indicated in Table 45, we expect that they would need to provide education to 2,149,934 patients annually at a cost of $69,120,378, or $32.15 per patient. Since we do not have data on the number of births that occur at each hospital and CAH, we estimate impact by enterprise size by assuming that the share of births occurring in each enterprise size group is proportional to the total number of employees in each enterprise size group relative to the number of employees across all enterprise size groups. Afterwards, we multiple this percentage by the average annual cost ($69,120,378) to find the total cost for all firms and establishments in that enterprise size group. Finally, we calculate the cost per firm and establishment using the following formulas: firm(establishment) cost = total enterprise size group cost ÷ firms(establishments) in enterprise size group.

The final cost related to birth tissue is for providing education for those patients who choose to retain their birth tissue. As indicated in Table 46, we expect that they would need to provide education to 128,996 patients annually at a cost of $4,147,221, or $32.15 per patient. Since we do not have data on the number of births that occur at each hospital and CAH, we estimate impact by enterprise size by assuming that the share of patients wanting to receive this education from each enterprise size group is proportional to the total number of employees in each enterprise size group relative to the number of employees across all enterprise size groups. Afterwards, we multiple this percentage by the average annual cost ($4,147,221) to find the total cost for all firms and establishments in that enterprise size group. Finally, we calculate the cost per firm and establishment using the following formulas: firm(establishment) cost = total enterprise size group cost ÷ firms(establishments) in enterprise size group.

The next policy is staff training for hospitals and CAHs that provide emergency services. To estimate the impact on firms and establishments by enterprise size group, we again use to the May 2025 National Industry-Specific Occupational Employment and Wage Estimates for hospitals (NAICS 622000) that estimates 6,712,760 individuals employed in hospitals. As indicated in Table 48, we estimate that there are 1,735,766 employees in hospitals and CAHs that offer emergency services that are receiving this training. This means that approximately 25.86 (1,735,766 ÷ 6,712,760) percent of all hospital and CAH employees are receiving this training. For each enterprise size group in Table 64, we assume that 25.86 percent of employees in the enterprise size group received the training and calculated the total number of employees (25.86 percent × employees) in that enterprise size group who received the training. Next, to calculate estimated savings per firm and establishment by enterprise size, we identified the percentage of all employees across all enterprise size groups that came from each enterprise size group using the following formula: enterprise size group employees trained ÷ all employees trained. Afterwards, we multiple this percentage by the average annual savings ($65,124,785) by repealing this training requirement as provided in Table 50 to find the total savings for all firms and establishments in that enterprise size group. Finally, we calculate the savings per firm and establishment using the following formulas: firm(establishment) savings = total enterprise size group savings ÷ firms(establishments) in enterprise size group.

The final policy is transfer protocol training for hospital staff. To estimate the impact on firms and establishments by enterprise size group, we again use to the May 2025 National Industry-Specific Occupational Employment and Wage Estimates for hospitals (NAICS 622000) that estimates 6,712,760 individuals employed in hospitals. As indicated in Table 39, we estimate that including training for new employees due to turnover, 430,928 hospital employees are receiving this training. This means that approximately 6.42 (430,928 ÷ 6,712,760) percent of all hospital employees are receiving this training. For each enterprise size group in Table 63, we assume that 6.42 percent of employees in the enterprise size group received the training and calculated the total number of employees (6.42 percent × employees) in that enterprise size group who received the training. Next, to calculate estimated savings per firm and establishment by enterprise size, we identified the percentage of all employees across all enterprise size groups that came from each enterprise size group using the following formula: enterprise size group employees trained ÷ all employees trained. Afterwards, we multiple this percentage by the average annual savings ($81,569,162) by repealing this training requirement as provided in Table 51 to find the total savings for all firms and establishments in that enterprise size group. Finally, we calculate the savings per firm and establishment using the following formulas: firm(establishment) savings = total enterprise size group savings ÷ firms(establishments) in enterprise size group.

As shown in Tables 65 and 67, the average per firm and establishment savings from all the proposed policies affecting hospitals and CAHs are less than 3 percent of revenues. As such, our IRFA suggests that the proposed requirements do not have a significant impact on hospitals and CAHs as measured by a 3 to 5 percent change in revenues.

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TABLE 64: Hospital and CAH Impact for Firms by Enterprise Size Group Part I

Enterprise Size ($1,000)	Firms	Employment	Receipts ($1,000)	Collection of Information Savings	OB QAPI Project Savings	OB Services Training per Firm Savings	Informed Consent Training per Firm Costs	Informed Consent for Patient per Firm Costs	Safe Handling Education for Patient per Firm Costs
02: <100	59	49	2,920	$0	$0	$0	$0	$0	$0
03: 100-499	150	184	40,570	$0	$0	$0	$0	$0	$0
04: 500-999	54	173	37,628	$824	$5,670	$33	$7	$39	$2
05: 1,000-2,499	28	7,087	42,616	$824	$5,670	$2,615	$543	$3,098	$186
06: 2,500-4,999	28	1,094	104,704	$824	$5,670	$404	$84	$478	$29
07: 5,000-7,499	35	2,361	227,943	$824	$5,670	$697	$145	$826	$50
08: 7,500-9,999	51	4,053	436,080	$824	$5,670	$821	$171	$973	$58
09: 10,000-14,999	124	12,588	1,460,447	$824	$5,670	$1,049	$218	$1,242	$75
10: 15,000-19,999	132	17,375	2,243,098	$824	$5,670	$1,360	$282	$1,611	$97
11: 20,000-24,999	121	20,627	2,709,157	$824	$5,670	$1,761	$366	$2,086	$125
12: 25,000-29,999	100	19,628	2,668,690	$824	$5,670	$2,028	$421	$2,402	$144
13: 30,000-34,999	99	22,506	3,101,656	$824	$5,670	$2,349	$488	$2,782	$167
14: 35,000-39,999	66	15,849	2,350,764	$824	$5,670	$2,481	$515	$2,939	$176
15: 40,000-49,999	122	32,286	5,146,495	$824	$5,670	$2,734	$568	$3,239	$194
16: 50,000-74,999	206	70,372	11,884,595	$824	$5,670	$3,529	$733	$4,181	$251
17: 75,000-99,999	101	51,439	8,239,981	$824	$5,670	$5,262	$1,093	$6,233	$374
18: 100,000+	1,097	5,369,973	1,222,121,552	$824	$5,670	$50,576	$10,502	$59,911	$3,595

Source: United States Census Bureau. 2022 SUSB Annual Data Tables by Establishment Industry – Data by Enterprise Receipts Size.

TABLE 65: Hospital and CAH Impact for Firms by Enterprise Size Group Part II

Enterprise Size ($1,000)	Firms	Employment	Receipts ($1,000)	Emergency Services per Firm Savings	Transfer Protocol per Firm Savings	Regulatory Review Costs	Average per Firm Savings from All Requirements	Average Revenue per Firm	Firm Savings as % of Revenue
02: <100	59	49	2,920	$10	$12	$350	-$328	$49,492	-0.66
03: 100-499	150	184	40,570	$14	$18	$350	-$318	$270,467	-0.12
04: 500-999	54	173	37,628	$37	$46	$350	$6,212	$696,815	0.89
05: 1,000-2,499	28	7,087	42,616	$2,919	$3,656	$350	$11,507	$1,522,000	0.76
06: 2,500-4,999	28	1,094	104,704	$451	$564	$350	$6,972	$3,739,429	0.19
07: 5,000-7,499	35	2,361	227,943	$778	$974	$350	$7,573	$6,512,657	0.12
08: 7,500-9,999	51	4,053	436,080	$916	$1,148	$350	$7,828	$8,550,588	0.09
09: 10,000-14,999	124	12,588	1,460,447	$1,171	$1,466	$350	$8,295	$11,777,798	0.07
10: 15,000-19,999	132	17,375	2,243,098	$1,518	$1,901	$350	$8,933	$16,993,167	0.05
11: 20,000-24,999	121	20,627	2,709,157	$1,966	$2,462	$350	$9,756	$22,389,727	0.04
12: 25,000-29,999	100	19,628	2,668,690	$2,263	$2,835	$350	$10,303	$26,686,900	0.04
13: 30,000-34,999	99	22,506	3,101,656	$2,621	$3,283	$350	$10,961	$31,329,859	0.03
14: 35,000-39,999	66	15,849	2,350,764	$2,769	$3,468	$350	$11,232	$35,617,636	0.03
15: 40,000-49,999	122	32,286	5,146,495	$3,052	$3,822	$350	$11,751	$42,184,385	0.03
16: 50,000-74,999	206	70,372	11,884,595	$3,939	$4,934	$350	$13,382	$57,692,209	0.02
17: 75,000-99,999	101	51,439	8,239,981	$5,873	$7,356	$350	$16,935	$81,583,970	0.02
18: 100,000+	1,097	5,369,973	1,222,121,552	$56,447	$70,701	$350	$109,860	$1,114,057,933	0.01

Source: United States Census Bureau. 2022 SUSB Annual Data Tables by Establishment Industry – Data by Enterprise Receipts Size.

TABLE 66: Hospital and CAH Impact for Establishments by Enterprise Size Group Part I

Enterprise Size ($1,000)	Establishments	Employment	Receipts ($1,000)	Collection of Information Savings	OB QAPI Project Savings	OB Services Training per Establishment Savings	Informed Consent Training per Establishment Costs	Informed Consent for Patients per Establishment Costs	Safe Handling Education for Patients per Establishment Costs
02: <100	59	49	2,920	$0	$0	S0	$0	$0	$0
03: 100-499	150	184	40,570	$0	$0	S0	$0	$0	$0
04: 500-999	55	173	37,628	$824	S5,670	$32	$7	$38	$2
05: 1,000-2,499	28	7,087	42,616	$824	S5,670	$2,615	$543	$3,098	S186
06: 2,500-4,999	28	1,094	104,704	$824	S5,670	$404	$84	$478	$29
07: 5,000-7,499	37	2,361	227,943	$824	S5,670	$659	$137	$781	$47
08: 7,500-9,999	53	4,053	436,080	$824	S5,670	$790	$164	$936	$56
09: 10,000-14,999	127	12,588	1,460,447	$824	S5,670	$1,024	$213	$1,213	$73
10: 15,000-19,999	141	17,375	2,243,098	$824	S5,670	$1,273	$264	$1,508	$90
11: 20,000-24,999	123	20,627	2,709,157	$824	S5,670	$1,733	$360	$2,052	S123
12: 25,000-29,999	102	19,628	2,668,690	$824	S5,670	$1,988	$413	$2,355	S141
13: 30,000-34,999	101	22,506	3,101,656	$824	S5,670	$2,302	$478	$2,727	S164
14: 35,000-39,999	67	15,849	2,350,764	$824	S5,670	$2,444	$508	$2,895	S174
15: 40,000-49,999	132	32,286	5,146,495	$824	S5,670	$2,527	$525	$2,993	S180
16: 50,000-74,999	228	70,372	11,884,595	$824	S5,670	$3,189	$662	$3,777	S227
17: 75,000-99,999	111	51,439	8,239,981	$824	S5,670	$4,788	$994	$5,672	S340
18: 100,000+	4,506	5,369,973	1,222,121,552	$824	S5,670	$12,313	$2,557	$14,585	$875

Source: United States Census Bureau. 2022 SUSB Annual Data Tables by Establishment Industry – Data by Enterprise Receipts Size.

TABLE 67: Hospital and CAH Impact for Establishments by Enterprise Size Group Part II

Enterprise Size ($1,000)	Establishments	Employment	Receipts ($1,000)	Emergency Services per Establishment Savings	Transfer Protocol per Establishment Savings	Regulatory Review Costs	Average per Establishment Savings from All Requirements	Average Revenue per Establishment	Establishment Savings as % of Revenue
01: Total	6,048	5,647,644	1,262,818,896						
02: <100	59	49	2,920	$10	$12	$350	-$328	$49,492	-0.66
03: 100-499	150	184	40,570	$14	$18	$350	-$318	$270,467	-0.12
04: 500-999	55	173	37,628	$36	$45	$350	$6,306	$684,145	0.92
05: 1,000-2,499	28	7,087	42,616	$2,919	$3,656	$350	$19,160	$1,522,000	1.26
06: 2,500-4,999	28	1,094	104,704	$451	S564	$350	$8,153	$3,739,429	0.22
07: 5,000-7,499	37	2,361	227,943	$736	S922	$350	$9,425	$6,160,622	0.15
08: 7,500-9,999	53	4,053	436,080	$882	$1,104	$350	$10,077	$8,227,925	0.12
09: 10,000-14,999	127	12,588	1,460,447	$1,143	$1,432	$350	$11,241	$11,499,583	0.10
10: 15,000-19,999	141	17,375	2,243,098	$1,421	$1,780	$350	$12,481	$15,908,496	0.08
11: 20,000-24,999	123	20,627	2,709,157	$1,934	$2,422	$350	$14,768	$22,025,667	0.07
12: 25,000-29,999	102	19,628	2,668,690	$2,219	$2,779	$350	$16,040	$26,163,627	0.06
13: 30,000-34,999	101	22,506	3,101,656	$2,570	$3,218	$350	$17,603	$30,709,465	0.06
14: 35,000-39,999	67	15,849	2,350,764	$2,728	$3,417	$350	$18,309	$35,086,030	0.05
15: 40,000-49,999	132	32,286	5,146,495	$2,820	$3,533	$350	$18,722	$38,988,598	0.05
16: 50,000-74,999	228	70,372	11,884,595	$3,559	$4,458	$350	$22,016	$52,125,417	0.04
17: 75,000-99,999	111	51,439	8,239,981	$5,344	$6,693	$350	$29,975	$74,234,063	0.04
18: 100,000+	4,506	5,369,973	1,222,121,552	$13,742	$17,212	$350	$67,429	$271,220,939	0.02

Source: United States Census Bureau. 2022 SUSB Annual Data Tables by Establishment Industry – Data by Enterprise Receipts Size.

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Individuals and States are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. As indicated in Tables 60 through 67, our IRFA suggests that this rule will not have a significant economic impact as measured on a substantial number of small businesses or other small entities as measured by a change in revenue of 3 to 5 percent.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. With estimated average savings from all requirements ranging from $22 annually in the smallest hospitals and CAHs to less than $18 thousand annually in hospitals and CAHs with annual revenues between $75 million to less than $100 million, we expect that this proposed rule would have a negligible impact on small rural hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

The previous analysis, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1-year of $100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately $193 million. This proposed rule does not mandate any requirements for State, local, or tribal governments. This proposed rule would not impose a mandate that would result in the expenditure by State, local, and Tribal Government, in the aggregate, of more than $193 million in any one year. Based on the cost estimates discussed in this section, we have assessed the various costs and benefits of the final updates to the conditions of participation. For the private sector facilities, the regulatory impact analysis, together with the remainder of the preamble, constitutes the analysis required under UMRA.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the provisions in this proposed rule in accordance with E.O. 13132, Federalism, and have determined that they would not have a substantial direct effect on State, local, or tribal governments, preempt State law, or otherwise have a federalism implication.

J. E.O. 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, entitled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' We followed the implementation guidance from OMB–M–25–20 (*https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-20-*

Guidance-Implementing-Section-3-of-Executive-Order-14192-Titled-Unleashing-Prosperity-Through-Deregulation.pdf) when estimating the proposed rule's impact related to the executive order. Specifically, we used a 7 percent discount rate when estimating the costs and cost savings for the purposes of the E.O 14192-The E.O 14192 looks at the long-term impact based on a 20-year window. For most of the policies we are proposing in this rule, the impacts remain the same for all years after year 1 and we assume that they will continue for years 11through 20. However, the costs and cost savings estimates for PHE reporting and OB training are influenced by several key assumptions related to the historical frequency of PHE reporting data and the annual fluctuation in staff who require OB training, respectively.

For PHE reporting, we identified a recurring pattern of significant public health emergencies occurring about once every 5 years. This pattern is central to our 20-year cost savings projection. Instead of assuming a steady annual likelihood, we modeled the projection with no PHE reporting activity in years 5 and 15, while anticipating a 32-week (7.5-month) acute infectious illness event in years 10 and 20. This approach provides a more realistic reflection of the cyclical nature of such emergencies, rather than a uniform annual occurrence.

For the OB staff training, we factored in an annual staff turnover rate of approximately 21 percent in hospitals. This, coupled with new hires, means that the number of staff requiring OB training fluctuates each year.

In summary, both the PHE reporting data and OB training requirements introduce variability to our costs and cost savings calculations.

VI. Conclusion

Eliminating unnecessary and duplicative regulatory requirements is essential to ensuring that patients will have continued access to care and allowing providers to focus on patients over paperwork. The changes that we are proposing in this rule would have significant impacts on LTC facilities, hospitals, ICFs/IID, and CAHs. As outlined in Table 25, Table 26, Table 54, Table 55, and Table 56, we expect that modifications to the current CoPs would reduce provider burden by approximately $289 million annually and more than $2.89 billion over 10 years. In addition, over 10 years it will return nearly 29.36 million hours of clinician time to providers, allowing them to prioritize patients over paperwork. As shown in Table 24, we also estimate cost savings of $687,600 over 10 years for the Federal Government, $ 687,600 over 10 years for States, and $ 304,159,413 over 10 years and more than 3.3 million hours for providers associated with the Medicaid institutional payment transparency proposals.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 15, 2026.

List of Subjects

42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Incorporation by reference, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Incorporation by reference, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Incorporation by reference, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 438

Citizenship and naturalization, Civil rights, Grant programs-health, Individuals with disabilities, Medicaid, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 442

Administrative practice and procedure, Aged, Grant programs-health, Health facilities, Health professions, Individuals with disabilities, Medicaid, Nursing homes, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Incorporation by reference, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 482

Grant programs-health, Hospitals, Incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Incorporation by reference, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 485

Grant programs-health, Health facilities, Incorporation by reference, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 494

Diseases, Health Facilities, Incorporation by reference, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 403.744 is amended by:
■ a. Revising paragraph (a)(1);
■ b. Removing paragraph (a)(6); and
■ c. Revising paragraphs (b) and (c).

The revisions read as follows:

§ 403.744 Condition of participation: Fire safety.

(a) * * *

(1) Except as otherwise provided in this section—

(i) The RNHCI must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Life Safety Code (NFPA 101).

(ii) Notwithstanding paragraph (a)(1)(i) of this section, corridor doors must be provided with positive latching hardware, excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code. Roller latches and other devices capable of keeping doors closed when a 5 pound-force is applied at the latch edge are prohibited on corridor doors required to have positive latching hardware.

(iii) The RCNHI must use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) if the facility uses the Fire Safety Evaluation System (FSES) to show compliance with the provisions of the 2024 LSC (NFPA 101).

* * * * *

(b) *Exceptions.*

(1) After a recommendation by the State survey agency and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Life Safety Code which would result in unreasonable hardship upon a RNHCI facility, but only if the waiver will not

adversely affect the health and safety of the patients.

(2) The provisions of the Life Safety Code do not apply where CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in a RNHCI facility.

(3) If CMS determines that a specific updated provision of the Life Safety Code (NFPA 101) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (c)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(c) *Incorporation by reference.* The material listed in this paragraph (c) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (c).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone: 1.617.770.3000; website: *www.nfpa.org.*

(i) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(ii) NFPA 101A, Guide on Alternative Approaches to Life Safety, 2025 edition, issued April 22, 2024.

(2) [Reserved]

■ 3. Section 403.745 is amended by:
■ a. Revising paragraphs (a) and (c);
■ b. Redesignating paragraph (d) as paragraph (e);
■ c. Adding new paragraph (d); and
■ d. Revising newly designated paragraph (e).

The revisions and addition read as follows:

§ 403.745 Condition of participation: Building safety.

(a) *Standard: Building safety.* Except as otherwise provided in this section the RNHCI must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Health Care Facilities Code (NFPA 99) and Tentative Interim Amendments (TIA) 24–1 and 24–2.

* * * * *

(c) *Waiver.* After a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Health Care Facilities Code which would result in unreasonable hardship upon a facility, but only if the waiver does not adversely affect the health and safety of patients.

(d) If CMS determines that a specific updated provision of the Health Care Facilities Care (NFPA 99) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(e) *Incorporation by reference.* The material listed in this paragraph (e) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (e).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone: 1.617.770.3000; website: *http://www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) TIA–24–1 to NFPA 99, issued August 25, 2023.

(iii) TIA–24–2 to NFPA 99, issued August 25, 2023.

(iv) [Reserved]

(2) [Reserved]

PART 416—AMBULATORY SURGICAL SERVICES

■ 4. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b–8, and 1395hh.

■ 5. Section 416.44 is amended by revising paragraphs (b), (c), and (f) to read as follows:

§ 416.44 Condition for coverage—Environment.

* * * * *

(b) *Standard: Fire Safety.*

(1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the 2024 edition of the Life Safety Code (NFPA 101).

(2) After of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Life Safety Code which would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply where CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in an ASC.

(4) If CMS determines that a specific updated provision of the Life Safety Code (NFPA 101) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (f)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(5) An ASC may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(6) When a sprinkler system is shut down for more than 10 hours, the ASC must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(c) *Standard: Building safety.* Except as otherwise provided in this section, the ASC must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Health Care Facilities Code (NFPA 99) and Tentative Interim Amendments (TIA) 24–1 and 24–2.

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC.

(2) After consideration of a recommendation by the State survey agency or approved accrediting organization, at and the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Health Care Facilities Code which would result in unreasonable hardship upon a facility, but only if the waiver does not adversely affect the health and safety of patients.

(3) If CMS determines that a specific updated provision of the Health Care Facilities Care (NFPA 99) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (f)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

* * * * *

(f) *Incorporation by reference.* The material listed in this paragraph (f) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (f).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone: 1.617.770.3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) TIA–24–1 to NFPA 99, issued August 25, 2023.

(iii) TIA–24–2 to NFPA 99, issued August 25, 2023.

(iv) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(2) [Reserved]

PART 418—HOSPICE CARE

■ 6. The authority citation for part 418 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 7. Section 418.110 is amended by revising paragraphs (d), (e), and (q) to read as follows:

§ 418.110 Condition of participation: Hospices that provide inpatient care directly.

* * * * *

(d) *Standard: Fire Safety.*

(1) Except as otherwise provided in this section—

(i) The hospice must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Life Safety Code (NFPA 101).

(ii) Notwithstanding paragraph (d)(1)(i) of this section, corridor doors must be provided with positive latching hardware, excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code. Roller latches and other devices capable of keeping doors closed when a 5 pound-force is applied at the latch edge are prohibited on corridor doors required to have positive latching hardware.

(iii) The hospice must use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) if the facility uses the Fire Safety Evaluation System (FSES) to show compliance with the provisions of the 2024 LSC (NFPA 101).

(2) After consideration of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Life Safety Code which would result in unreasonable hardship upon a hospice facility, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply where CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in a hospice.

(4) If CMS determines that a specific updated provision of the Life Safety Code (NFPA 101) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (q)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(5) A hospice may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against access by vulnerable populations.

(6) When a sprinkler system is shut down for more than 10 hours, the hospice must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(e) *Standard: Building safety.* Except as otherwise provided in this section, the hospice must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Health Care Facilities Code (NFPA 99) and Tentative Interim Amendments (TIA) 24–1 and 24–2.

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a hospice.

(2) After consideration of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Health Care Facilities Code which would result in unreasonable hardship upon a facility, but only if the waiver does not adversely affect the health and safety of patients.

(3) If CMS determines that a specific updated provision of the Health Care Facilities Care (NFPA 99) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (q)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

* * * * *

(q) *Incorporation by reference.* The material listed in this paragraph (q) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD 21244;

phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (q).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, phone: 1.617.770.3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued September 14, 2023.

(ii) TIA–24–1 to NFPA 99, issued August 25, 2023.

(iii) TIA–24–2 to NFPA 99, issued August 25, 2023.

(iv) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(v) NFPA 101A, Guide on Alternative Approaches to Life Safety, 2025 edition, issued April 22, 2024.

(2) [Reserved]

PART 438—MANAGED CARE

■ 8. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 9. Section 438.72 is amended by revising paragraph (a) to read as follows:

§ 438.72 Additional requirements for long-term services and supports.

(a) *Services delivered in Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID).* The State must comply with the requirements in § 442.43 for ICF/IID services.

* * * * *

PART 442—STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

■ 10. The authority citation for part 442 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 11. Section 442.43 is amended by:

■ a. Revising paragraph (a)(1) introductory text;

■ b. Removing paragraph (a)(3);

■ c. Redesignating paragraph (a)(4) as paragraph (a)(3);

■ d. Revising newly redesignated paragraphs (a)(3) introductory text, (a)(3)(i) and (ii);

■ e. Revising paragraphs (b) introductory text, (b)(1), (c)(1), (d) introductory text, and (f).

The revisions read as follows:

§ 442.43 Payment Transparency Reporting.

(a) * * *

(1) *Compensation* means, with respect to direct care workers delivering services authorized under this part:

* * * * *

(3) *Excluded costs* means costs reasonably associated with delivering Medicaid-covered ICF/IID services that are not included in the calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers. Such costs are limited to:

(i) Costs of required training for direct care workers (such as costs for qualified trainers and training materials);

(ii) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and

* * * * *

(b) *Reporting requirements.* The State must report to CMS annually, by facility, the percentage of Medicaid payments (not including excluded costs) for services specified in paragraph (b)(1) of this section, that is spent on compensation for direct care workers, at the time and in the form and manner specified by CMS. For the purposes of this part, Medicaid payment for fee-for-service (FFS) includes base and supplemental payments as defined in section 1903(bb)(2) of the Social Security Act, and for payments from an MCO or PIHP (as these entities are defined in § 438.2 of this chapter) includes the MCO's or PIHP's contractually negotiated rate, State directed payments as defined in § 438.6(c) of this chapter, and any other payments from the MCO or PIHP.

(1) *Services.* Except as provided in paragraphs (b)(2) and (3) of this section, reporting must be based on all Medicaid payments (including but not limited to FFS base and supplemental payments, and payments from an MCO or PIHP, as applicable) made to ICF/IID providers for Medicaid-covered services.

* * * * *

(c) * * *

(1) *Contents.* Reporting must provide information necessary to identify, at the facility level, the percentage of Medicaid payments spent on compensation to direct care workers at each ICF/IID.

* * * * *

(d) *Availability and accessibility requirements.* The State must operate a website consistent with § 435.905(b) of this chapter that provides the results of the reporting requirements specified in paragraphs (b) and (c) of this section. In the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), and/or 1115(a) of the Act and that includes ICF/IID services in their MCO or PIHP contracts, the State may meet this requirement by linking to individual MCO's or PIHP's websites. The State must:

* * * * *

(f) *Applicability date.* States must comply with the requirements in this section beginning 4 years after June 21, 2024 and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a) or 1115(a) of the Act and includes ICF/IID services, the first rating period for contracts with the MCO or PIHP beginning on or after 4 years after June 21, 2024.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 12. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 13. Section 460.72 is amended by revising paragraphs (b), (d), and (e) to read as follows:

§ 460.72 Physical environment.

* * * * *

(b) *Fire Safety*—

(1) *General rule.* Except as otherwise provided in this section—

(i) A PACE center must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Life Safety Code (NFPA 101).

(ii) Notwithstanding paragraph (b)(1)(i) of this section, corridor doors must be provided with positive latching hardware, excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code. Roller latches and other devices capable of keeping doors closed when a 5 pound-force is applied at the latch edge are prohibited on corridor doors required to have positive latching hardware.

(iii) A PACE center must use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) if the facility uses the Fire Safety Evaluation System (FSES) to may compliance with the provisions of the 2024 LSC (NFPA 101).

(2) *Exceptions.*

(i) The provisions of the Life Safety Code do not apply where CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in a PACE center.

(ii) After consideration of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Life Safety Code which would result in unreasonable hardship upon a PACE facility, but only if the waiver will not adversely affect the health and safety of the patients.

(iii) If CMS determines that a specific updated provision of the Life Safety Code (NFPA 101) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(3) *Alcohol-Based Dispensers:* A PACE center may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(4) *Sprinkler System:* When a sprinkler system is shut down for more than 10 hours in a 24-hour period, the PACE must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

* * * * *

(d) *Standard: Building Safety.* Except as otherwise provided in this section, a PACE center must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Health Care Facilities Code (NFPA 99) and Tentative Interim Amendments (TIA) 24–1 and 24–2.

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a PACE center.

(2) After consideration of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Health Care Facilities Code which would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

(3) If CMS determines that a specific updated provision of the Health Care Facilities Care (NFPA 99) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(e) *Incorporation by reference.* The material listed in this paragraph (e) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (e).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, phone: 1.617.770.3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) TIA–24–1 to NFPA 99, issued August 25, 2023.

(iii) TIA–24–2 to NFPA 99, issued August 25, 2023.

(iv) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(v) NFPA 101A, Guide on Alternative Approaches to Life Safety, 2025 edition, issued April 22, 2024.

(2) [Reserved]

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 14. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, 1395rr, unless otherwise noted.

■ 15. Section 482.15 is amended by revising paragraphs (e) and (h) to read as follows:

§ 482.15 Condition of participation: Emergency preparedness.

* * * * *

(e) *Emergency and standby power systems.* The hospital must install and maintain emergency and standby power systems, in accordance with the 2024 edition of the Health Care Facilities Code (HCFC) (NFPA 99), the 2024 edition of the Life Safety Code (LSC) (NFPA 101), and the 2022 edition of the Emergency and Standby Power Systems (NFPA 110), based on the emergency plan set forth in paragraph (a) of this section and in the policies and procedures plan set forth in paragraphs (b)(1)(i) and (ii) of this section.

(1) *Emergency power supply location.* The emergency power supply must be located in accordance with the location requirements found in the 2024 edition of the Health Care Facilities Code (HCFC) (NFPA 99), the 2024 edition of the Life Safety Code (LSC) (NFPA 101), and the 2022 edition of the Emergency and Standby Power Systems (NFPA 110), when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency power supply inspection and testing.* The hospital must implement the emergency power supply inspection, testing, and maintenance requirements found in the 2024 edition of HCFC (NFPA 99), the 2024 edition of the LSC (NFPA 101), and the 2022 edition of the Emergency and Standby Power Systems (NFPA 110).

(3) *Emergency power supply fuel.* Hospitals that maintain an onsite fuel source to power the emergency power supply to power the emergency power supply and must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

* * * * *

(h) *Incorporation by reference.* The material listed in this paragraph (h) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (h).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, phone: 1.617.770.3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(iii) NFPA 110, Standard for Emergency and Standby Power Systems, 2022 edition, issued March 18, 2021.

(2) [Reserved]

§ 482.21 [Amended]

■ 16. Section 482.21 is amended by:
■ a. Removing paragraphs (b)(4) and (e); and
■ b. Redesignating paragraphs (f) and (g) as paragraphs (e) and (f), respectively.

§ 482.41 [Amended]

■ 17. Section 482.41 is amended by:
■ a. Revising paragraph (b) heading and paragraphs (b)(1) through (3);
■ b. Removing paragraph (b)(9);
■ c. Redesignating paragraphs (b)(4) through (8) as paragraphs (b)(5) through (9) respectively;
■ d. Adding a new paragraph (b)(4); and
■ e. Revising paragraphs (c) and (e).

The revisions and addition read as follows:

§ 482.41 Condition of participation: Physical environment.

* * * * *

(b) *Standard: Fire Safety*

(1) Except as otherwise provided in this section—

(i) The hospital must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Life Safety Code (LSC) (NFPA 101). Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

(ii) Notwithstanding paragraph (b)(1)(i) of this section, corridor doors a must be provided with positive latching hardware, excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code. Roller latches and other devices capable of keeping doors closed when a 5 pound-force is applied at the latch edge are prohibited on corridor doors required to have positive latching hardware.

(iii) The hospital must use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) if the facility uses the Fire Safety Evaluation System (FSES) to show compliance with the provisions of the 2024 LSC (NFPA 101).

(2) After consideration of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive, for periods deemed appropriate specific provisions of the Life Safety Code which would result in unreasonable hardship upon a hospital, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply where CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in hospitals.

(4) If CMS determines that a specific updated provision of the Life Safety Code (NFPA 101) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

* * * * *

(c) *Standard: Building safety.* Except as otherwise provided in this section, the hospital must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Health Care Facilities Code (NFPA 99) and Tentative Interim Amendments (TIA) 24–1 and 24–2.

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a hospital

(2) After consideration of a recommendation by the State survey agency or approved accrediting organization, at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Health Care Facilities Code which would result in unreasonable hardship upon a facility, but only if the waiver does not adversely affect the health and safety of patients.

(3) If CMS determines that a specific updated provision of the Health Care Facilities Care (NFPA 99) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

* * * * *

(e) *Incorporation by reference.* The material listed in this paragraph (e) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD, 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (e).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone: 1.617.770.3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) TIA–24–1 to NFPA 99, issued August 25, 2023.

(iii) TIA–24–2 to NFPA 99, issued August 25, 2023.

(iv) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(v) NFPA 101A, Guide on Alternative Approaches to Life Safety, 2025 edition, issued April 22, 2024.

(2) [Reserved]

§ 482.42 [Amended]

■ 18. Section 482.43 is amended by revising paragraph (c) to read as follows:

§ 482.43 Condition of participation: Discharge planning.

* * * * *

(c) *Standard: Transfer protocols.* The hospital must have written policies and procedures for transferring patients under its care (inclusive of inpatient services) to the appropriate level of care (including to another hospital) as needed to meet the needs of the patient.

* * * * *

§ 482.55 [Amended]

■ 19. Section 482.55 is amended by removing paragraph (c)(3).
■ 20. Section 482.59 is amended by revising paragraph (c).

§ 482.59 Condition of participation: Obstetrical services.

* * * * *

(c) *Birth tissue collection.* For hospitals that furnish obstetrical services and participate in the collection, storage, donation, banking, transfer, or release to patients of birth tissues the following standards apply. For purposes of this section, birth tissues are defined as human cells, tissues, and cellular and tissue-based products obtained during or immediately following labor and delivery (including cesarean-section delivery), such as umbilical cord blood,

umbilical cord tissue, placenta, amniotic membrane, amniotic fluid, and other tissues or biological materials associated with live childbirth.

(1) *Standard: Informed consent.* The hospital must ensure informed consent is obtained from the patient or patient's representative prior to the collection, storage, donation, transfer, banking, or release to patients of birth tissues, consistent with the hospital's scope of services and role in those activities. This consent must be documented consistent with the requirements for medical records at 482.24(c)(4)(v). The informed consent process must include, as applicable:

(i) A description of the birth tissues to be collected;

(ii) The intended use (including commercial and research uses) of the birth tissues;

(iii) Disclosure of any third-party involvement and any conflicts of interest;

(iv) Information regarding risks, limitations, and infection prevention and quality control considerations;

(v) Notice that patient's or patient's representative's refusal to provide informed consent will not affect access to care or treatment; and

(vi) Any other information required under applicable Federal or State law.

(2) *Standard: Policies and procedures for cultural, religious, or personal uses.* The hospital must have written policies and procedures that permit patients to request retention or release of birth tissues for cultural, religious, or personal reasons, consistent with State law and the hospital's infection prevention and control program requirements under § 482.42.

(i) The policies and procedures must address:

(A) Processes for patient requests for retention or release of birth tissues;

(B) Safe handling, packaging, storage, and release practices;

(C) Circumstances under which retention or release may be limited or denied due to infection prevention and control concerns, biohazard risks, certain clinical conditions, emergency cases, or other applicable legal requirements; and

(D) Staff education regarding the hospital's procedures for responding to patient requests.

(ii) The hospital must provide patients who request retention or release of birth tissues with instructions for safe handling, transport, storage, and disposition of the tissues, as applicable.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 21. The authority citation for part 483 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r.

■ 22. Section 483.15 is amended by revising paragraph (c)(3)(i) to read as follows:

§ 483.15 Admission, transfer, and discharge rights.

* * * * *

(c) * * *

(3) * * *

(i) Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. The facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman, except when the resident is transferred on an emergency basis to an acute care facility.

* * * * *

■ 23. Section 483.71 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 483.71 Facility assessment.

* * * * *

(b) * * *

(1) * * *

(ii) Direct care staff, including but not limited to, RNs, LPNs/LVNs, and NAs.

* * * * *

■ 25. Section 483.73 is amended by revising paragraphs (e) and (g) to read as follows:

§ 483.73 Emergency preparedness.

* * * * *

(e) *Emergency and standby power systems.* The LTC facility must install and maintain emergency and standby power, in accordance with the 2024 edition of the Health Care Facilities Code (NFPA 99), the 2024 edition of the Life Safety Code (NFPA 101), and the 2022 edition of the Emergency and Standby Power Systems (NFPA 110), based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency power supply location.* The emergency power supply must be located in accordance with the location requirements found in the 2024 edition of the Health Care Facilities Code (HCFC) (NFPA 99), the 2024 edition of the Life Safety Code (LSC) (NFPA 101), and the 2022 edition of the Emergency and Standby Power Systems (NFPA 110), when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency power supply inspection and testing.* The LTC facility must implement the emergency power supply inspection, testing, and maintenance requirements found in the 2024 edition of the HCFC (NFPA 99), the 2024 edition of the LSC (NFPA 101) and the 2022 edition of the Emergency and Standby Power Systems (NFPA 110).

(3) *Emergency power supply fuel.* LTC facilities that maintain an onsite fuel source to power the emergency power supply and must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

* * * * *

(g) *Incorporation by reference.* The material listed in this paragraph (g) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD, 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (g).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone: 1.617.770.3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(iii) NFPA 110, Standard for Emergency and Standby Power Systems, 2022 edition, issued March 18, 2021.

(2) [Reserved]

■ 25. Section 483.80 is amended by revising paragraphs (d)(3) and (g) to read as follows:

§ 483.80 Infection control.

* * * * *

(d) * * *

(3) *COVID–19 immunizations.* The LTC facility must develop and implement policies and procedures to ensure all the following:

(i) Before offering the COVID–19 immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;

(ii) Each resident is offered a COVID–19 immunization, including all recommended doses and any applicable booster doses, unless the immunization is medically contraindicated or the resident has already been immunized;

(iii) The resident or the resident's representative has the opportunity to refuse immunization; and

(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of COVID–19 immunization, including, where a multi-dose series is required, education regarding the number of doses, recommended dosing schedule, and the importance of completing the full immunization series; and

(B) That the resident either received the COVID–19 immunization (including where a multi-dose series is required, each dose administered in accordance with the recommended dosing schedule), or did not receive the COVID–19 immunization due to medical contraindication or refusal.

* * * * *

(g) *Public health emergency (PHE): Reporting of data related to acute infectious diseases*—In the event that the Secretary has declared a national, State, or local PHE for an acute infectious illness, the LTC facilities must electronically report data elements in a standardized format and frequency specified by the Secretary, including but not limited to the following:

(1) Facility census (defined as the total number of residents occupying a bed at this facility for at least 24 hours during the week of data collection).

(2) Confirmed, resident cases of a set of viral and bacterial pathogens and infectious diseases, as specified by the Secretary.

(3) Hospitalized residents with confirmed cases of a set of viral and bacterial pathogens and infectious diseases, as specified by the Secretary.

(4) Relevant confirmed infections for staff.

(5) Supply inventory shortages.

(6) Staffing shortages.

(7) Relevant medical countermeasures and therapeutic inventories, usage, or both.

■ 26. Section 483.90 is amended by:

■ a. Revising paragraphs (a) and (b);

■ b. Removing paragraph (c);

■ c. Redesignating paragraphs (d) through (j) as paragraphs (c) through (i), respectively; and

■ d. Revising newly redesignated paragraphs (d)(1)(i), (e), and (i).

The revisions read as follows:

§ 483.90 Physical environment.

* * * * *

(a) *Fire safety.*

(1) Except as otherwise provided in this section—

(i) The LTC facility must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Life Safety Code (NFPA 101).

(ii) Notwithstanding paragraph (a)(1)(i) of this section, corridor doors must be provided with positive latching hardware, excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code. Roller latches and other devices capable of keeping doors closed when a 5 pound-force is applied at the latch edge are prohibited on corridor doors required to have positive latching hardware.

(iii) The LTC facility must use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) if the facility uses the Fire Safety Evaluation System (FSES) to show compliance with the provisions of the 2024 LSC (NFPA 101).

(iv) Notwithstanding paragraph (a)(1)(iii) of this section, an LTC facility may not use the Fire Safety Evaluation System (FSES) to address non-compliance with NFPA 13 and NFPA 25.

(2) After consideration of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Life Safety Code which would result in unreasonable hardship upon a long-term care facility, but only if the waiver will not adversely affect the health and safety of the residents.

(3) The provisions of the Life Safety Code do not apply in a State where CMS determines, in accordance with applicable provisions of sections 1819(d)(2)(B)(ii) and 1919(d)(2)(B)(ii) of the Act, that a fire and safety code imposed by State law adequately protects patients, residents and personnel in LTC facilities.

(4) A long-term care facility may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(5) If CMS determines that a specific updated provision of the Life Safety Code (NFPA 101) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (i)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance, provided that CMS has determined that the waiver does not adversely affect the health and safety of residents or personnel. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(6) An LTC facility must do both of the following:

(i) Install an approved, supervised automatic sprinkler system in accordance with NFPA 13, *Standard for the Installation of Sprinkler Systems,* as incorporated by reference, throughout the building.

(ii) Test, inspect, and maintain an approved, supervised automatic sprinkler system in accordance with NFPA 25, *Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems,* as incorporated by reference.

(7) When a sprinkler system is shut down for more than 10 hours, the LTC facility must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(b) *Standard: Building safety.* Except as otherwise provided in this section, the LTC facility must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Health Care Facilities Code (NFPA 99) and Tentative Interim Amendments (TIA) 24–1 and 24–2.

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a LTC facility.

(2) After consideration of a recommendation by the State survey agency, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Health Care Facilities Code which would result in unreasonable hardship upon a facility, but only if the waiver does not adversely affect the health and safety of residents.

(3) If CMS determines that a specific updated provision of the Health Care Facilities Care (NFPA 99) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (i)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance, provided that CMS has determined that the waiver does not adversely affect the health and safety of residents or personnel. A facility that wishes to comply with the

updated provision must formally elect to do so and document their decision in their records.

* * * * *

(d) * * *

(1) * * *

(i) Accommodate no more than four residents. For facilities that receive approval of building construction and reconstruction plans by the State and local authorities after November 28, 2016, each bedroom must accommodate no more than two residents per room.

* * * * *

(e) *Bathroom facilities.* Each resident room must:

(1) Be equipped with or located near toilet and bathing facilities.

(2) For facilities that receive approval of building construction plans by State and local authorities after November 28, 2016, be equipped with its own bathroom with at least a commode and sink.

* * * * *

(i) *Incorporation by reference.* The material listed in this paragraph (i) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD, 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (i).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone: 1.617.770.3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) TIA–24–1 to NFPA 99, issued August 25, 2023.

(iii) TIA–24–2 to NFPA 99, issued August 25, 2023.

(iv) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(v) NFPA 101A, Guide on Alternative Approaches to Life Safety, 2025 edition, issued April 22, 2024.

(vi) NFPA 13, Standard for the Installation of Sprinkler Systems, 2022 edition, issued August 26, 2021.

(vii) NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, 2023 edition, issued August 12, 2022.

(2) [Reserved]

■ 27. Section 483.460 is amended by revising paragraph (a)(4) to read as follows:

§ 483.460 Condition of participation: Health care services.

(a) * * *

(4) The intermediate care facility for individuals with intellectual disabilities (ICF/IID) must develop and implement policies and procedures to ensure all of the following:

(i) Before offering the COVID–19 immunizations, each client or the client's representative receives education regarding the benefits and potential side effects of the immunizations;

(ii) Each client is offered a COVID–19 immunization, including all recommended doses and any applicable booster doses, unless the immunization is medically contraindicated or the client has already been immunized;

(iii) The client or the client's representative has the opportunity to refuse any or all of the immunization; and

(iv) The client's medical record includes documentation that indicates, at a minimum, the following:

(A) That the client or client's representative was provided education regarding the benefits and potential side effects of the COVID–19 immunization, including, where a multi-dose series is required, education regarding the number of doses, recommended dosing schedule, and the importance of completing the full immunization series; and

(B) That the client either received the COVID–19 immunizations (including where a multi-dose series is required, each dose administered in accordance with the recommended dosing schedule), or did not receive the COVID–19 immunizations due to medical contraindication or refusal.

* * * * *

■ 28. Section 483.470 is amended by:

■ a. Removing paragraph (b)(2);

■ b. Redesignating paragraphs (b)(3) and (4) as (b)(2) and (3), respectively; and

■ c. Revising paragraphs (j) and (m).

The revisions read as follows:

§ 483.470 Condition of Participation: Physical Environment

* * * * *

(j) *Standard: Fire Safety*

(1) General. Except as otherwise provided in this section—

(i) The facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter and must proceed in accordance with the 2024 edition of the Life Safety Code (LSC) (NFPA 101).

(ii) Notwithstanding paragraph (j)(1)(i) of this section, corridor doors must be provided with positive latching hardware, excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code. Roller latches and other devices capable of keeping doors closed when a 5 pound-force is applied at the latch edge are prohibited on corridor doors required to have positive latching hardware.

(iii) The ICF/IID must use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) if the facility uses the Fire Safety Evaluation System (FSES) to show compliance with the provisions of the 2024 LSC (NFPA 101).

(iv) Chapters 32.3.2.11.2 and 33.3.2.11.2 of the adopted 2024 edition of the Life Safety Code (NFPA 101) do not apply to a facility.

(2) The State survey agency may apply a single chapter of the LSC to the entire facility or may apply different chapters to different buildings or parts of buildings as permitted by the LSC.

(3) A facility that meets the LSC definition of a residential board and care occupancy must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the Fire Safety Evaluation System for Board and Care facilities (FSES/BC).

(4) The provisions of the Life Safety Code do not apply where CMS determines that a fire and safety code imposed by State law adequately protects clients and personnel in ICFs/IID.

(5) Facilities that meet the Life Safety Code definition of a health care occupancy:

(i) After consideration of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Life Safety Code which would result in unreasonable hardship upon a residential board and care facility, but only if the waiver will not adversely affect the health and safety of the clients.

(ii) A facility may install alcohol-based hand rub dispensers if the dispensers are installed in a manner that adequately protects against inappropriate access.

(iii) When a sprinkler system is shut down for more than 10 hours, the ICF/IID must:

(A) Evacuate the building or portion of the building affected by the system

outage until the system is back in service, or

(B) Establish a fire watch until the system is back in service.

(iv) Except as otherwise provided in this section, the ICF/IID must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Health Care Facilities Code (NFPA 99) and Tentative Interim Amendments (TIA) 24–1 and 24–2.

(A) Chapters 7, 8, 12 and 13 of the adopted Health Care Facilities Code do not apply to an ICF/IID.

(B) After consideration of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Health Care Facilities Code which would result in unreasonable hardship upon a facility, but only if the waiver does not adversely affect the health and safety of clients.

(C) If CMS determines that a specific updated provision of the Health Care Facilities Care (NFPA 99) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (m)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(6) If CMS determines that a specific updated provision of the Life Safety Code (NFPA 101) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (m)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

* * * * *

(m) *Incorporation by reference.* The material listed in this paragraph (m) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (m).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone: 1–617–770–3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) TIA–24–1 to NFPA 99, issued August 25, 2023.

(iii) TIA–24–2 to NFPA 99, issued August 25, 2023.

(iv) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(v) NFPA 101A, Guide on Alternative Approaches to Life Safety, 2025 edition, issued April 22, 2024.

(2) [Reserved]

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 29. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 485.516 [Amended]

■ 30. Section 485.516 is amended in paragraph (c)(5) by removing the reference ''§ 485.618(e)'' and adding in its place the reference ''§ 485.618(f)''.

■ 31. Section 485.526 is amended by removing paragraphs (e), (f), and (g).

■ 32. Section 485.542 is amended by revising paragraphs (e) and (g) to read as follows:

§ 485.542 Condition of participation: Emergency preparedness.

* * * * *

(e) *Emergency and standby power systems.* The REH must install and maintain emergency and standby power systems, in accordance with the 2024 edition of the Health Care Facilities Code (NFPA 99), the 2024 edition of the Life Safety Code (NFPA 101), and the 2022 edition of the Emergency and Standy Power Systems (NFPA 110), based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency power supply location.* The emergency power supply must be located in accordance with the location requirements found in the 2024 edition of the Health Care Facilities Code (HCFC) (NFPA 99), the 2024 edition of the Life Safety Code (LSC) (NFPA 101), and the 2022 edition of the Emergency and Standby Power Systems (NFPA 110), when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency power supply inspection and testing.* The REH must implement an emergency power supply inspection and testing requirements found in the 2024 edition of the HCFC (NFPA 99), the 2024 edition of the LSC (NFPA 101), and the 2022 edition of the Emergency and Standby Power Systems (NFPA 110).

(3) *Emergency power supply fuel.* REHs that maintain an onsite fuel source to power the emergency power supply and must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

* * * * *

(g) *Incorporation by reference.* The material listed in this paragraph (g) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (g).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone: 1–617–770–3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(iii) NFPA 110, Standard for Emergency and Standby Power Systems, 2022 edition, issued March 18, 2021.

(2) [Reserved]

■ 33. Section 485.544 is amended by revising paragraphs (c) through (e) to read as follows:

§ 485.544 Condition of participation: Physical environment.

* * * * *

(c) *Standard: Fire Safety*

(1) Except as otherwise provided in this section, the REH must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the 2024 edition of the Life Safety Code (NFPA 101).

(2) After consideration of a recommendation by the State survey

agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an REH, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply where CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in REHs.

(4) If CMS determines that a specific updated provision of the Life Safety Code (NFPA 101) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(d) *Standard: Building safety.* Except as otherwise provided in this section, the REH must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Health Care Facilities Code (NFPA 99) and Tentative Interim Amendments (TIA) 24–1 and 24–2.

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an REH.

(2) After a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Health Care Facilities Code which would result in unreasonable hardship upon a facility, but only if the waiver does not adversely affect the health and safety of patients.

(3) If CMS determines that a specific updated provision of the Health Care Facilities Care (NFPA 99) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(e) *Incorporation by reference.* The material listed in this paragraph (e) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (e).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone; 1–617–770–3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) TIA–24–1 to NFPA 99, issued August 25, 2023.

(iii) TIA–24–2 to NFPA 99, issued August 25, 2023.

(iv) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(v) NFPA 101A, Guide on Alternative Approaches to Life Safety, 2025 edition, issued April 22, 2024.

(2) [Reserved]

■ 34. Section 485.610 is amended by:

■ a. Revising paragraph (c)(1);

■ b. Adding paragraph (c)(3); and

■ c. Revising paragraph (e)(2).

The revisions and addition read as follows:

§ 485.610 Condition of participation: Status and location.

* * * * *

(c) * * *

(1) Except for a facility as described in section 241 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75), the CAH is located more than a 35-mile drive on primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from an acute care hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

* * * * *

(3) For purposes of paragraphs (c)(1) and (e)(2) of this section, an acute care hospital means a hospital as defined under section 1861(e) of the Act, and does not include a psychiatric hospital as defined under section 1861(f) of the Act, a long-term care hospital as described under § 412.23(e) of this chapter, a rehabilitation hospital as described under § 412.23(b) of this chapter, or a rural emergency hospital as described under § 485.502 of this chapter.

* * * * *

(e) * * *

(2) Except for a facility as described in section 241 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75), if a CAH or a necessary provider CAH operates an off-campus provider-based location, excluding an RHC as defined in § 405.2401(b) of this chapter, but including a department or remote location, as defined in § 413.65(a)(2) of this chapter, or an off-campus distinct part psychiatric or rehabilitation unit, as defined in § 485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of paragraph (c) of this section only if the off-campus provider-based location or off-campus distinct part unit is located more than a 35-mile drive on primary roads, as defined in paragraph (c)(2) of this section (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from an acute care hospital or another CAH.

* * * * *

§ 485.618 [Amended]

■ 35. Section 485.618 is amended by removing and reserving paragraph (e)(2).

■ 36. Section 485.623 is amended by revising paragraphs (c) through (e) to read as follows:

§ 485.623 Condition of participation: Physical plant and environment.

* * * * *

(c) *Standard: Fire Safety.* (1) Except as otherwise provided in this section—

(i) The CAH must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Life Safety Code (NFPA 101).

(ii) Notwithstanding paragraph (c)(1)(i) of this section, corridor doors must be provided with positive latching hardware, excluding corridor doors to auxiliary spaces not classified as hazardous areas as defined by the Life Safety Code. Roller latches and other devices capable of keeping doors closed when a 5 pound-force is applied at the latch edge are prohibited on corridor doors required to have positive latching hardware.

(iii) The CAH must use the 2025 edition of the Guide on Alternative Approaches to Life Safety (NFPA 101A) if the facility uses the Fire Safety Evaluation System (FSES) to show

compliance with the provisions of the 2024 LSC (NFPA 101).

(2) After consideration of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Life Safety Code which would result in unreasonable hardship upon a CAH, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply where CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in CAHs.

(4) If CMS determines that a specific updated provision of the Life Safety Code (NFPA 101) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(5) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

(6) A CAH may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(7) When a sprinkler system is shut down for more than 10 hours, the CAH must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(d) *Standard: Building safety.* Except as otherwise provided in this section, the CAH must meet the applicable provisions and must proceed in accordance with the 2024 edition of the Health Care Facilities Code (NFPA 99) and Tentative Interim Amendments (TIA) 24–1 and 24–2.

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a CAH.

(2) After consideration of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Health Care Facilities Code which would result in unreasonable hardship upon a facility, but only if the waiver does not adversely affect the health and safety of patients.

(3) If CMS determines that a specific updated provision of the Health Care Facilities Care (NFPA 99) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (e)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(e) *Incorporation by reference.* The material listed in this paragraph (e) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore MD 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (e).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone: 1–617–770–3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) TIA–24–1 to NFPA 99, issued August 25, 2023.

(iii) TIA–24–2 to NFPA 99, issued August 25, 2023.

(iv) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(v) NFPA 101A, Guide on Alternative Approaches to Life Safety, 2025 edition, issued April 22, 2024.

(2) [Reserved]

■ 37. Section 485.625 is amended by revising paragraphs (e) and (g) to read as follows:

§ 485.625 Condition of participation: Emergency preparedness.

* * * * *

(e) *Emergency and standby power systems.* The CAH must install and maintain emergency and standby power systems, in accordance with the 2024 edition of the HCFC (NFPA 99), the 2024 edition of the LSC (NFPA 101), and the 2022 edition of the Emergency and Standby Power Systems (NFPA 110), based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency power supply location.* The emergency power supply must be located in accordance with the location requirements found in the 2024 edition of the Health Care Facilities Code (HCFC) (NFPA 99), the 2024 edition of the Life Safety Code (LSC) (NFPA 101), and the 2022 edition of the Emergency and Standby Power Systems (NFPA 110), when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency power supply inspection and testing.* The CAH must implement the emergency power supply inspection and testing requirements found in the 2024 edition of the HCFC (NFPA 99), the 2024 edition of the LSC (NFPA 101), and the 2022 edition of the Emergency and Standby Power Systems (NFPA 110).

(3) *Emergency power supply fuel.* CAHs that maintain an onsite fuel source to power the emergency power supply and must have a plan for how it will keep emergency power systems operational during the emergency unless it evacuates.

* * * * *

(g) *Incorporation by reference.* The material listed in this paragraph (g) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (g).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone: 1–617–770–3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023.

(ii) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(iii) NFPA 110, Standard for Emergency and Standby Power Systems, 2022 edition, issued March 18, 2021.

(2) [Reserved]

§ 485.641 [Amended]

■ 38. Section 485.641 is amended by removing paragraphs (d)(4) and removing and reserving (e)(2).

■ 39. Section 485.649 is amended by revising paragraph (c) to read as follows:

§ 485.649 Condition of participation: Obstetrical services.

* * * * *

(c) *Birth tissue collection.* For CAHs that furnish obstetrical services and participate in the collection, storage, donation, banking, transfer, or release to patients of birth tissues the following standards apply. For purposes of this section, birth tissues are defined as human cells, tissues, and cellular and tissue-based products obtained during or immediately following labor and delivery (including cesarean-section delivery), such as umbilical cord blood, umbilical cord tissue, placenta, amniotic membrane, amniotic fluid, and other tissues or biological materials associated with live childbirth.

(1) *Standard: Informed consent.* The CAH must ensure informed consent is obtained from the patient or patient's representative prior to the collection, storage, donation, transfer, banking, or release to patients of birth tissues, consistent with the CAH's scope of services and role in those activities. This consent must be documented consistent with the requirements for clinical records at 485.638(a)(4)(i). The informed consent process must include, as applicable:

(i) A description of the birth tissues to be collected;

(ii) The intended use (including commercial and research uses) of the birth tissues;

(iii) Disclosure of any third-party involvement and any conflicts of interest;

(iv) Information regarding risks, limitations, and infection prevention and quality control considerations;

(v) Notice that a patient's or patient's representative's refusal to provide informed consent will not affect access to care or treatment; and

(vi) Any other information required under applicable Federal or State law.

(2) *Standard: Policies and procedures for cultural, religious, or personal uses.* The CAH must have written policies and procedures that permit patients to request retention or release of birth tissues for cultural, religious, or personal reasons, consistent with State law and the CAH's infection prevention and control program requirements under § 485.640.

(i) The policies and procedures must address:

(A) Processes for patient requests for retention or release of birth tissues;

(B) Safe handling, packaging, storage, and release practices;

(C) Circumstances under which retention or release may be limited or denied due to infection prevention and control concerns, biohazard risks, certain clinical conditions, emergency cases, or other applicable legal requirements; and

(D) Staff education regarding the CAH's procedures for responding to patient requests.

(ii) The CAH must provide patients who request retention or release of birth tissues with instructions for safe handling, transport, storage, and disposition of the tissues, as applicable.

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 40. The authority citation for part 494 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 41. Section 494.60 is amended by revising paragraphs (d), (e), and (f) to read as follows:

§ 494.60 Condition: Physical environment.

* * * * *

(d) *Standard: Fire safety.* (1) Except as provided in paragraph (d)(2) of this section, dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level must comply with provisions of the 2024 edition of the Life Safety Code (NFPA 101) applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

(2) Notwithstanding paragraph (d)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008 that require sprinkler systems are those housed in multi-story buildings construction Types II(000), III(200), or V(000), as defined in the Life Safety Code, section 21.1.6.1, which were constructed after January 1, 2008, and those housed in high rise buildings over 75 feet in height, which were constructed after January 1, 2008.

(3) The provisions of the Life Safety Code do not apply where CMS determines that a fire and safety code imposed by State law adequately protects patients and personnel in dialysis facilities.

(4) After consideration of a recommendation by the State survey agency or approved accreditation organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Life Safety Code which would result in unreasonable hardship upon a dialysis facility, but only if the waiver will not adversely affect the health and safety of the patients.

(5) No dialysis facility may operate in a building that is adjacent to an industrial high hazard area, as described in sections 20.1.3.7 and 21.1.3.7 of the Health Care Facilities Code (NFPA 99 and the Tentative Interim Amendments TIA 24–1 and TIA 24–2).

(6) If CMS determines that a specific updated provision of the Life Safety Code (NFPA 101) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (f)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(e) *Standard: Building Safety.* (1) Dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level must meet the applicable provisions of the 2024 edition of the Health Care Facilities Code and its Tentative Interim Amendments TIA 24–1 and TIA 24–2.

(2) Chapters 7, 8, 12, and 13 of the Health Care Facilities Code do not apply to a dialysis facility.

(3) After consideration of a recommendation by the State survey agency or approved accrediting organization, and at the discretion of the Secretary, CMS may waive for periods deemed appropriate specific provisions of the Health Care Facilities Code which would result in unreasonable hardship upon a facility, but only if the waiver does not adversely affect the health and safety of patients.

(4) If CMS determines that a specific updated provision of the Health Care Facilities Care (NFPA 99) provides an equal or superior means of ensuring patient safety as compared to the publications referenced in paragraph (f)(1) of this section, CMS will announce the availability of a voluntary waiver in favor of the updated provision via subregulatory guidance. A facility that wishes to comply with the updated provision must formally elect to do so and document their decision in their records.

(f) *Incorporation by reference.* The material listed in this paragraph (f) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at CMS and at the National Archives

and Records Administration (NARA). Contact CMS at 7500 Security Boulevard, Baltimore, MD 21244; phone: 410–786–6633; email: *HealthandSafetyInquiries@cms.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following source in this paragraph (f).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169; phone: 1–617–770–3000; website: *www.nfpa.org.*

(i) NFPA 99, Health Care Facilities Code, 2024 edition, issued August 25, 2023 September 14, 2023.

(ii) TIA–24–1 to NFPA 99, issued August 25, 2023.

(iii) TIA–24–2 to NFPA 99, issued August 25, 2023.

(iv) NFPA 101, Life Safety Code, 2024 edition, issued August 25, 2023.

(2) [Reserved]

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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