Generic Information Collections

1. *Title of Information Collection:* CHIP State Plan Eligibility; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* The revised template (General Eligibility—Incarcerated CHIP Beneficiaries) and an associated implementation guide are intended to conform with Division G, Title I, Section 205 of the Consolidated Appropriations Act of 2024 which expands the prohibition of terminating an individual's CHIP eligibility because they are an inmate of a public institution to targeted low-income pregnant women. Effective January 1, 2026, states must cease terminating CHIP eligibility for targeted low-income pregnant women but may instead suspend their coverage during the enrollee's incarceration. States that elect to suspend coverage may implement either a benefits or eligibility suspension. *Form Number:* CMS–10398 #17 (OMB control number: 0938–1148); *Frequency:* Once and Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 2,800. (For policy questions regarding this collection contact: Mary Beth Hance at 443–934–2613.)

2. *Title of Information Collection:* Medicaid Managed Care Rate Development Guide; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* States must submit to CMS for review and approval all rate certifications for managed care plans. The state's actuary is responsible for certifying that the managed care program's capitation rates are actuarially sound for a specific time period and documents the rate development process and the final certified capitation rates in a rate certification. The Medicaid Managed Care Rate Development Guides outline the rate development standards and CMS' expectations for documentation included in rate certifications such as descriptions of base data used, trend factors to base data, projected benefit and non-benefit costs, and any other considerations or adjustments used when setting capitation rates. CMS is required to update the rate guide at least annually. To meet this requirement the 2026–2027 rate guide revises the 2025–2026 rate guide. *Form Number:* CMS–10398 #37 (OMB control number: 0938–1148); *Frequency:* Once and Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 47; *Total Annual Responses:* 137; *Total Annual Hours:* 754. (For policy questions regarding this collection contact: Rebecca Burch Mack at 303–844–7355.)

3. *Title of Information Collection:* Medicaid and the Children's Health Insurance Program (CHIP) Parity Tools; *Type of Information Collection Request:* New; *Use:* CMS has created a set of tools in the form of Excel workbook templates with accompanying instructions, both to assist states in complying with Mental Health Parity and Addiction Equity Act requirements and to simplify and standardize collecting information for state and CMS review. The tools will be made available for optional state use. CMS encourages states to use the tools and provide feedback to CMS. CMS will require that states use these tools as applicable to the state's program(s), and submit them to CMS, at a future date, which will be communicated through notice and comment rulemaking. *Form Number:* CMS–10398 #96 (OMB control number: 0938–1148); *Frequency:* Once and on occasion; *Affected Public:* Private Sector and State, Local, or Tribal Governments; *Number of Respondents:* 525; *Total Annual Responses:* 83; *Total Annual Hours:* 1,925. (For policy questions regarding this collection contact: Marlana Thieler at 410–786–6274.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–22184 Filed 12–5–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3474–FN]

Medicare and Medicaid Programs: Approval of Application by DNV Healthcare, Inc. for Initial CMS Approval of Its Ambulatory Surgical Center (ASC) Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice acknowledges the approval of an application from DNV Healthcare, Inc. for initial CMS approval of its Ambulatory Surgical Centers as a national accrediting organization that wishes to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is applicable from December 8, 2025 to December 10, 2029.

FOR FURTHER INFORMATION CONTACT:

Joy Webb (410) 786–1667.

Kristin Shifflett (410) 786–4133.

SUPPLEMENTARY INFORMATION:

I. Background

Ambulatory Surgical Centers (ASCs) are distinct entities that operate exclusively for the purpose of furnishing outpatient surgical services to patients. Under the Medicare program, eligible beneficiaries may receive covered services from an ASC provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for a facility seeking designation as an ASC. Regulations concerning provider agreements are at 42 CFR part 489, and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 416 specify the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for ASCs.

Generally, to enter into an agreement, an ASC must first be certified by a State survey agency (SA) as complying with the conditions or requirements set forth in part 416 of our Medicare regulations. Thereafter, the ASC is subject to regular surveys by an SA to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may deem that provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. The AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5.

This is DNV Healthcare, Inc.'s (DNV's) initial application and does not

have a current term for the ASC program.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application. Due to the federal lapse in appropriated funding, certain parts of CMS operations were temporarily halted on September 30, 3025. This lapse in funding led to a government shutdown, and operations in particular areas have remained non-operational. Therefore, this notice was impacted and did not publish on or before October 15, 2025 (the 210-day statutory requirement).

III. Provisions of the Proposed Notice

On April 28, 2025, CMS published a proposed notice in the **Federal Register** (90 FR 17599), announcing DNV's request for initial approval of its Medicare ASC accreditation program. In the April 28, 2025, proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of DNV's initial ASC accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An administrative review of DNV's: (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its ASC surveyors; (4) ability to investigate and respond appropriately to complaints against accredited ASCs; and (5) survey review and decision-making process for accreditation.
- The equivalency of DNV's standards for ASCs as compared with Medicare's Conditions for Coverage (CfCs) for ASCs.
- DNV's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of DNV's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ DNV's processes and procedures for monitoring an ASC found out of compliance with DNV's program requirements. These monitoring procedures are used only when DNV identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c)(1).

++ DNV's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ DNV's capacity to provide CMS with electronic data and reports necessary for the effective validation and assessment of the organization's survey process.

++ The adequacy of DNV's staff and other resources, and its financial viability.

++ DNV's capacity to adequately fund required surveys.

++ DNV's policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced.

++ DNV's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ DNV's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the April 28, 2025, proposed notice also solicited public comments regarding whether DNV's requirements met or exceeded the Medicare CfCs for ASCs. No comments were received in response to our proposed notice.

V. Provisions of the Final Notice

A. Differences Between DNV's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared DNV's ASC accreditation requirements and survey process with the Medicare CfCs at 42 CFR part 416, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of DNV's ASC application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, DNV has completed revising its standards and certification processes in order to do all of the following:

- Meet the standard's requirements of all of the following regulations:

++ Section 416.42(a)(1)(ii) to clarify as defined at § 410.69(b) who must examine the patient for anesthesia risk.

++ Section 416.42(c)(1) to revise to include an attestation from the State's Governor to opt-out of the physician supervision requirements.

++ Sections 416.43(a)(2) and (c)(2) to revise to include how the ASC will measure, analyze and track adverse patent events.

++ Section 416.43(c)(3) to revise that staff are familiar with the ASC's preventive strategies.

++ Section 416.44(b)(1) to ensure ASCs meet the provisions applicable to Ambulatory Health Care Occupancies and address the Life Safety Code (LSC) Tentative Interim Amendments (TIAs), TIA 12–2, TIA 12–3, and TIA 12–4 requirements.

++ Section 416.44(c) to incorporate the requirement for ASCs to comply with Health Care Facilities Code (HCFC) NFPA 99, and Tentative Interim Amendments (TIAs), TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6 and remove for Ambulatory Health Care Occupancies for consistency.

++ Section 416.44(d) to clarify LSC policies to include the requirement that the ASC medical staff and governing body coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room.

++ Section 416.44(e) to clarify policies to include the requirement that personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

++ Section 416.45(a) to revise polices to allow the ASC's governing body to make privileging decisions and to solicit recommendations from qualified medical personnel.

++ Section 416.50(d)(5) to ensure that the ASC investigates all grievances made by the patient, patient representative and patient surrogate.

++ Section 416.51(a) to specify that infection control standards adhere to

professionally acceptable standards of practice.

++ Section 416.51(b)(3) to ensure that the ASC's infection control program provides a plan of action for infections and communicable diseases and immediately implements corrective and preventive measures.

++ Section 416.52 to ensure that each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are done.

We also reviewed DNV's comparable survey processes, which were conducted as described in section III. of this final notice, and yielded the following areas where, as of the date of this notice, DNV has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Ensuring DNV's policies allow for the survey team to include at least one RN or Physician with hospital or ASC survey experience.

++ Updating DNV's policy and procedures to include 488.26(b) for determining manner and degree, when evaluating multiple standards and elevating to a higher deficiency level.

++ Providing clarification to DNV's policy on timeframes for notifying CMS of terminations and withdrawals.

++ A process to ensure that during survey, an Infection Control Worksheet is completed to confirm safe injection practices.

B. Term of Approval

Based on our review described in section III. and section V. of this final notice, we approve DNV as an initial national accreditation organization for ASCs that request participation in the Medicare program. The decision announced in this final notice is effective December 8, 2025 to December 10, 2029. In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years. Generally, when an AO is seeking an initial approval for a specific program type, CMS may approve for a term no greater than 4 years.

VI. Collection of Information and Regulatory Impact Statement

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Center for Medicare & Medicaid Services.

[FR Doc. 2025–22203 Filed 12–5–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–6461]

Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) is announcing its Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot (''TEMPO pilot''), in connection with the Center for Medicare and Medicaid Innovation (CMMI) Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model, to promote access to certain digital health devices while safeguarding patient safety.

DATES: FDA is seeking statements of interest for participation in the TEMPO pilot beginning January 2, 2026. See below for instructions on how to submit a statement of interest for participation in the TEMPO pilot.

FOR FURTHER INFORMATION CONTACT: Jessica Paulsen, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–6883, *FDA-TEMPOPilot@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. TEMPO Pilot

FDA is announcing its TEMPO pilot, in connection with the CMMI ACCESS model (Ref. 1), to promote access to certain digital health devices while safeguarding patient safety. Through the CMMI ACCESS model, the Centers for Medicare and Medicaid Services (CMS) will test a new payment option that emphasizes patient outcomes, enabling clinicians to offer innovative technology-supported care to improve patients' health and prevent and manage chronic disease (Ref. 1). The CMMI ACCESS model introduces Outcome-Aligned Payments, which are recurring payments for managing a patient's qualifying condition, with payment tied to achieving measurable health outcomes (Ref. 1). CMS has designed the CMMI ACCESS model to include several safeguards to support clinical quality and accountability; under the CMMI ACCESS model, CMS will monitor performance and may terminate organizations who fail to meet quality, safety, or outcome standards, and will publish risk-adjusted outcomes in a public directory (Ref. 1).

In general, if the manufacturer of a digital health device wishes to offer its device for an intended use to improve patient outcomes (*e.g.,* measurable changes in chronic disease outcomes), the device must, among other things, be authorized by FDA for that use. If a manufacturer seeks to offer its device for an intended use to improve patient outcomes such that it may be used to provide care covered by the CMMI ACCESS model, FDA generally expects the device to be FDA-authorized for that use. However, manufacturers of certain digital health devices that are not already authorized by FDA for such use may request to participate in FDA's TEMPO pilot by following the procedures described in this notice and requesting that FDA exercise enforcement discretion and not enforce certain applicable requirements when their device is offered to or by CMMI ACCESS participants [1] for an intended use to improve patient outcomes, to be used in providing care expected to be covered by the CMMI ACCESS model. For example, such manufacturers might request that FDA exercise enforcement discretion and not enforce premarket authorization requirements, investigational device exemption (IDE) requirements, requirements under 21 CFR parts 50 and 56, or other applicable requirements. As is often the case when FDA exercises enforcement discretion and informs a manufacturer that FDA does not intend to enforce certain applicable requirements, FDA will work with participants in the TEMPO pilot to identify the circumstances when enforcement discretion may be appropriate for that manufacturer's device, including, for example, when the labeling includes appropriate cautions, and when FDA requests that certain records be maintained (as may

[1] This may include, for example, when the manufacturer is itself a participating organization under the CMMI ACCESS model, or when the manufacturer offers the device to other entities that are participants under the CMMI ACCESS model for an intended use to improve patient outcomes.