DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2026–1684]

Target Product Profile for a Rapid Diagnostic Test for West Nile Virus Disease: Request for Information

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain comment on the proposed *Target Product Profile for a Rapid Diagnostic Test for West Nile Virus Disease for Use in Hospitals and Clinical Laboratories.* This Request for Information (RFI) invites comments and suggestions on the proposed target product profile. HHS/CDC is publishing this target product profile to improve the likelihood of developing a commercially available diagnostic assay that can be used to rapidly diagnose West Nile virus infection. Public input is a valuable component in developing a useful target product profile.

DATES: Written comments must be received on or before January 15, 2027.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2026–1684, by either of the methods listed below. Do not submit comments by email. CDC does not accept comments by email.

Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.

Mail: Dr. Randall Nett, Branch Chief, Arboviral Diseases Branch, Division of Vector-Borne Diseases, Centers for Disease Control and Prevention, 3156 Rampart Rd., MS–PO2, Fort Collins, CO 80521.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Randall Nett, Branch Chief, Arboviral Diseases Branch, Division of Vector-Borne Diseases, Centers for Disease Control and Prevention, 3156 Rampart Rd., MS–PO2, Fort Collins, CO 80521; Telephone: 970.221.6400; Email: *vectorpolicy@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on the questions for consideration in section II of this document.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near-duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comments by email.

I. Background

CDC has developed a proposed *Target Product Profile for a Rapid Diagnostic Test for West Nile Virus Disease for Use in Hospitals and Clinical Laboratories.*

Statutory authority for this effort is located in Public Health Service Act Sections 301(a) [42 U.S.C. 241(a)] and 317U [42 U.S.C. 247b–23]. Target product profiles are tools used to establish priorities and expectations for a product development process. A target product profile summarizes the characteristics of a product intended to meet an unmet clinical need, including the minimally acceptable and preferred performance characteristics. All comments will be considered in the final target product profile. We anticipate publishing the target product profile in a peer-reviewed scientific journal in the next six months. Following publication, the target product profile will be available on the journal's website.

The proposed target product profile is included as supplemental information in docket CDC–2026–1684 on *www.regulations.gov.*

II. Information Requested/Questions

CDC invites input from stakeholders throughout the scientific research, advocacy, and clinical practice communities, as well as the general public, on the proposed target product profile for a rapid West Nile virus diagnostic test. Additionally, we request input on the following questions:

(1) Would a rapid West Nile virus diagnostic assay be useful for improving clinical care? (2) Would a rapid West Nile virus diagnostic assay help in evaluating potential prophylactic or therapeutic treatments? (3) Does a commercial market for a rapid West Nile virus diagnostic assay likely exist? (4) Are there proposed changes or considerations that you recommend the government consider when finalizing the draft target product profile?

This input is a valuable component in developing a useful target product profile.

III. How To Submit Your Response

Please respond concisely, in plain language, and in narrative format in *www.regulations.gov* or via mail. You may respond to some or all of the topic areas covered in the RFI, and you may suggest other factors or relevant questions. You may also include links to online material or interactive presentations. Clearly mark any proprietary information and place it in its own section or file.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

[FR Doc. 2026–23204 Filed 11–13–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6102–N2]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Extension and Modification of the Nationwide Temporary Moratorium on Enrollment of Hospices

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

ACTION: Notice of extension and modification of a temporary moratorium.

SUMMARY: This notice announces the extension and modification of the nationwide temporary moratorium on the enrollment of new Medicare hospices.

DATES: The extension and modification of the moratorium is effective November 12, 2026.

FOR FURTHER INFORMATION CONTACT: Frank Whelan, (410) 786–1302.

I. Background

A. CMS' Authority To Impose Temporary Enrollment Moratoria

1. Statutory and Regulatory Background

Under the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act), Congress provided the Secretary of the Department of Health and Human Services (the Secretary) with new tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). One of these was section 6401(a) of the Affordable Care Act, which added a new section 1866(j)(7) to the Social Security Act (the Act). It provided the Secretary with authority to impose a temporary moratorium on the enrollment of new-fee-for-service (FFS) Medicare, Medicaid or CHIP providers and suppliers—including categories of providers and suppliers—if the Secretary determines that a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs.

Section 6401(b) of the Affordable Care Act added specific moratorium language applicable to Medicaid at section 1902(kk)(4) of the Act, requiring States to comply with any moratorium imposed by the Secretary unless the State determines that the imposition of such moratorium would adversely impact Medicaid beneficiaries' access to care. Section 6401(c) of the Affordable Care Act amended section 2107(e)(1) of the Act to provide that all the Medicaid provisions in sections 1902(a)(77) and 1902(kk) are also applicable to CHIP.

In February 2011, in accordance with the aforementioned authority, CMS published a final rule with comment period titled, ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers'' (76 FR 5862). This final rule implemented section 1866(j)(7) of the Act by establishing new regulations at 42 CFR 424.570. Under § 424.570(a)(2)(i) and (iv), CMS—or CMS in consultation with the Department of Health and Human Services Office of Inspector General (HHS–OIG) or the Department of Justice (DOJ) or both—may impose a temporary moratorium on newly enrolling Medicare providers and suppliers if CMS determines that there is a significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type or particular geographic areas or both.

2. Particulars of a Moratorium as Outlined in § 424.570

a. Length

In accordance with § 424.570(b), a temporary enrollment moratorium imposed by CMS remains in effect for 6 months. If CMS deems it necessary, the moratorium may be extended in 6-month increments. CMS evaluates whether to extend or lift the moratorium before the end of the initial 6-month period and, if applicable, before the expiration of any subsequent moratorium periods. If the moratorium announced in this notice is extended, CMS will publish a document regarding such extension(s) in the **Federal Register**.

b. Cessation

As provided in § 424.570(d), CMS may lift a moratorium at any time if: (1) the President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act; (2) circumstances warranting the imposition of a moratorium have abated or CMS has implemented program safeguards to address the program vulnerability; (3) the Secretary has declared a public health emergency; or (4) in the judgment of the Secretary, the moratorium is no longer needed. Once a moratorium is lifted, the provider or supplier types that were unable to enroll because of the moratorium will be assigned to the ''high'' screening level in accordance with §§ 424.518(c)(3)(iii) and 455.450(e)(2) if such provider or supplier applies for enrollment at any time within 6 months from the date the moratorium was lifted.

c. Circumstances Where Moratorium Is Inapplicable

Under current § 424.570(a)(1)(iii), a temporary moratorium does not apply to any of the following:

- Changes in practice location (except if the location is changing from a location outside the moratorium area to a location inside the moratorium area).
- Changes in provider or supplier information, such as phone number or address.
- Changes in ownership (except changes in majority ownership (CIMOs) of home health agencies (HHAs), hospices, and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that would require an initial enrollment).

Also, in accordance with § 424.570(a)(1)(iv), a temporary moratorium does not apply to any enrollment application that has been received by the Medicare contractor prior to the date the moratorium is imposed.

B. CMS' Previous Temporary Enrollment Moratoria

We first used our moratorium authority to prevent enrollment of new HHAs, subunits, and branch locations in Miami-Dade County, Florida and Cook County, Illinois, as well as surrounding counties, and Part B ambulance suppliers in Harris County, Texas and surrounding counties, in a notice issued on July 31, 2013 (78 FR 46339). We extended and expanded these moratoria several times, with the last in this series of moratoria expiring in 2019.

In the February 27, 2026, **Federal Register** (91 FR 9855), we published a notice announcing a 6-month nationwide enrollment moratorium on DMEPOS medical supply companies.[1] Said moratorium expired on August 27, 2026. It was not extended.

C. May 2026 Hospice Moratorium

In weighing the need to establish an enrollment moratorium, CMS considers whether a significant risk of fraud, waste, or abuse exists. CMS also relies on its own and law enforcement's longstanding experience with ongoing and emerging fraud trends and activities gained through civil, criminal, and administrative investigations and prosecutions. Having analyzed this risk with respect to hospices, we published in the **Federal Register** on May 15, 2026, a notice announcing a 6-month nationwide temporary moratorium on the Medicare enrollment of new hospices and hospice practice locations (91 FR 27946).[2] The moratorium took effect on May 13, 2026.

We explained in detail the rationale for our temporary moratorium. We noted in part the HHS–OIG's concerns about fraud, waste, and abuse in this sector; the HHS–OIG had stated in early 2026: ''[T]here are significant problems with the [hospice] program. Our reports and investigations have revealed several

[1] ''Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Nationwide Temporary Moratoria on Enrollment of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Medical Supply Companies'', 91 FR 9855.

[2] ''Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Nationwide Temporary Moratorium on Enrollment of Hospices'', published in the **Federal Register** on May 15, 2026.

concerning issues, including poor—sometimes harmful—quality of care, fraud schemes that involve enrolling beneficiaries without their consent, inappropriate billing practices, limited transparency for patients and their families, a payment system that creates incentives to minimize services, and a rapid growth in the number of new hospices, often to take advantage of these conditions.'' [3] Along with citing a number of criminal convictions involving hospices, we furnished examples of improper hospice-related activities we had seen. These included—

- Instances of hospices certifying patients for hospice care when they were not terminally ill and providing little to no services to beneficiaries.[4] This included telling patients that they were terminally ill when they were not; in such circumstances, beneficiaries who are inappropriately deemed terminally ill may be denied coverage for other care because they are receiving the hospice benefit.
- The rapid growth in potentially fraudulent hospices, particularly in Arizona, California, Nevada, and Texas. Nevada, for instance, saw a 151 percent increase in the number of enrolled hospices between CY 2019 and CY 2023. In Los Angeles County, numerous hospices were simultaneously operating out of a single building or otherwise were massed in large numbers within a very small geographic area or neighborhood. Too, some of the addresses for these hospices appeared to be non-operational.[5]
- ''Churn and burn'' schemes whereby a new hospice opens and starts billing but once that hospice is audited or reaches its statutory yearly payment limit, it shuts down, keeps the money, and buys a new Medicare billing number; it then transfers its patients over to the new Medicare billing number, and starts billing again.[6]
- Hospices paying: (1) recruiters to target beneficiaries who are not eligible for hospice care, sometimes without the beneficiary's knowledge; and (2) kickbacks to physicians for the latter to falsely certify a patient's terminal status (or falsely certifying even without receiving renumeration).[7]
- Parties establishing hospices for the exclusive purpose of selling them for a profit and/or after committing fraud but before they can be revoked from Medicare. Furnishing quality patient care was not a priority—or even a consideration—for these parties.[8]

We also noted our continued hospice program integrity efforts, such as our 2023 inclusion of hospices in § 424.518's highest screening category, our 2023 expansion of § 424.550(b) to include hospice CIMOs, and our establishment of a provisional period of enhanced oversight (PPEO) in 2023 for hospices in Arizona, California, Nevada, and Texas.[9]

Besides outlining the significant program integrity risks that hospices pose, we also stressed in the May 15, 2026, **Federal Register** notice that CMS must be aggressive in halting fraud before it begins; proactivity is a far better anti-fraud approach than a reactive, ''pay-and-chase'' one, whereby we do not take action until after the enrolled provider engages in fraud, waste, and abuse.[10] This was a critical consideration in our hospice moratorium.

D. Extension of Moratorium

1. Reasons

As already noted, § 424.570(b) permits CMS to extend a temporary moratorium in 6-month increments. Under this authority, CMS is extending the hospice moratorium for another 6-month period as described in this section I.D.1. of this notice. This notice fulfills § 424.570(b)'s requirement that CMS will publish a document in the **Federal Register** when it extends a moratorium.

There are several reasons for our extension. First, we remain deeply concerned about hospice fraud, waste, and abuse. The hospice program integrity problems previously cited have not dissipated, the payment safeguard risks associated with hospices are still high, and criminal activity in the hospice sphere continues to occur. Several criminal cases this year highlight the ongoing problem:

- In August 2026, a California woman pleaded guilty to submitting more than $2.2 million in fraudulent claims to Medicare for hospice services for beneficiaries. As a hospice owner—and according to her plea agreement—she knowingly and willfully submitted (and caused the submission) to Medicare for payment of hospice services for beneficiaries who did not have a terminal illness with a life expectancy of six months or less if the illness ran its normal course. In submitting the false claims to Medicare, she either knew the beneficiaries did not qualify for hospice or knew that they did not have sufficient medical records supporting a diagnosis and prognosis that qualified them for hospice benefits. She did not routinely coordinate with the beneficiaries' primary care physicians about their purported conditions or terminal prognoses.[11]
- A California woman in March 2026 was sentenced to 35 months in federal prison for defrauding Medicare out of more than $14 million by submitting fraudulent claims for hospice care and diagnostic testing services that were either unnecessary or not provided at all. The defendant and others—often using aliases—used multiple fictitious hospice providers enrolled with Medicare and submitted fraudulent claims on behalf of companies she owned. They used the information of Medicare beneficiaries and checked beneficiaries' Medicare eligibility to knowingly and willfully submit fraudulent claims to Medicare on behalf of beneficiaries who: (1) did not need the services; (2) had never received the services; and (3) were not familiar with the fraudulent hospice and diagnostic testing providers—all with the intent to defraud Medicare into reimbursing the sham providers for those claimed services.[12]

In fact, hospice fraud, waste, and abuse remains such a serious problem that the Federal Bureau of Investigation on June 3, 2026, issued a Public Service Announcement titled ''Emerging Hospice Fraud Targeting Medicare Recipients'' (Alert Number: I–060326–

[3] *https://oig.hhs.gov/reports/featured/hospice/.*

[4] *https://www.cms.gov/blog/cms-taking-action-address-benefit-integrity-issues-related-hospice-care.*

[5] Ibid.

[6] Ibid.

[7] Ibid.

[8] Ibid.

[9] 91 FR 27946. Section 1866(j)(3) of the Act permits the Secretary to establish a provisional period of enhanced oversight (PPEO) of between 30 days and 1 year during which new providers or suppliers (including categories thereof) would be subject to enhanced oversight, such as prepayment review and payment caps. Consistent therewith, and in light of the payment safeguard threats that hospices posed, we implemented a PPEO in 2023 on new hospices enrolling in Arizona, California, Nevada, and Texas. Under this initiative, as of June 2025 approximately 670 hospices were subject to medical review with 122 of them revoked from Medicare. This 18 percent revocation rate is far more than the average revocation rate of about 1 to 3 percent. (That is—and though it varies depending on, for example, the provider/supplier type in question and the geographic region involved—1 to 3 percent of providers/suppliers are revoked at least once during their enrollment). The much higher percentage of hospices revoked during this initiative compared to general provider/supplier revocation rates helps demonstrate the extent of the hospice program integrity problem.

[10] ''Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Nationwide Temporary Moratorium on Enrollment of Hospices'', published in the **Federal Register** on May 15, 2026.

[11] *https://www.justice.gov/usao-cdca/pr/anaheim-woman-pleads-guilty-submitting-more-22-million-fraudulent-hospice-care-claims.*

[12] *https://www.justice.gov/usao-cdca/pr/larchmont-woman-sentenced-nearly-3-years-federal-prison-her-role-hospice-and.*

PSA).[13] The notice was issued to ''warn the public of an emerging hospice fraud scheme that targets vulnerable Medicare recipients who are not in need of hospice services.'' [14] The FBI explained: ''Scammers are enrolling Medicare patients in hospice care for services they do not need or for services that are not provided. Enrollment can also occur without the patient's knowledge, allowing the scammers to bill Medicare for a patient that is not present in the hospice facility. Some scammers use door-to-door solicitation tactics and offer free home services such as house cleaning and meal delivery, which are conditional on using a specific hospice.'' [15] Among the recent schemes the FBI noted were:

- Enrolling Medicare recipients in hospice care despite patients having no terminal illness or chronic condition.
- Enrolling patients in hospice care without their knowledge.
- Hospice providers billing Medicare without the beneficiary's knowledge for services that were not provided.
- Recruiters paying bonuses for enrolling a specific number of patients in hospice.
- Falsifying diagnosis paperwork for hospice care.
- Pressuring patients to sign up for hospice care when they do not need it.[16]

The circumstances warranting the imposition of the hospice moratorium, in short, have not yet abated. CMS has accordingly determined that the moratorium on new hospice enrollments is still needed as we: (1) monitor the indicators; and (2) continue with administrative actions to combat fraud and abuse, such as payment suspensions and revocations of providers.[17]

We note that we consulted with the HHS–OIG regarding the extension of the moratorium; they agreed there remains a significant potential for fraud, waste, or abuse in the Medicare program with respect to hospices. Based in part on said consultation, we believe the moratorium extension is justified.

We are, though, scaling back the moratorium's scope during the 6-month extension period. The moratorium extension will only apply to initially enrolling hospices (including those initially enrolling pursuant to a non-exempt CIMO under § 424.550(b)). The extension will not apply to additions of hospice practice locations, and the moratorium on the enrollment of new practice locations by currently enrolled hospices will end as of the effective date of this notice. This is primarily due to our greater concern at this current time about new hospices—with whom we may have no experience—than with hospices that are already enrolled but are merely seeking to add a new location to its current enrollment (though the latter are still of concern to us).

2. Medicaid and CHIP

We stated in our May 15, 2026, **Federal Register** notice that, in our view, it is in Medicaid and CHIP beneficiaries' best interests to allow each State to decide whether some form of hospice moratorium is appropriate for their respective Medicaid programs and CHIPs, and the scope of any such moratorium. Each State has greater expertise and experience with their pool of hospices—including the requirements for each type of hospice—than CMS. Yet we encouraged each State to, as appropriate, implement a hospice moratorium tailored to the specifics of their beneficiary population as well as any geographic considerations (in accordance with 42 CFR 455.470(b)). Too, we offered each State and territory the opportunity to consult with CMS on the prospect of implementing a Medicaid- or CHIP-based moratorium in their jurisdictions.

Five States—Louisiana, Nevada, Ohio, Pennsylvania, and Rhode Island—have indeed implemented hospice moratoria in response to our May 15, 2026, notice. Our extension notice is not intended to impact these existing moratoria. As we stated in the May 15, 2026, notice, the decision still rests with the State or territory.

3. Access to Care

We have seen no evidence that the May 15, 2026, hospice moratorium has materially reduced Medicare beneficiary access to hospice services on a nationwide or even a State level. In addition, States and territories have not indicated to CMS that the hospice moratorium has led to access to care problems for Medicaid or CHIP beneficiaries in their jurisdictions. Nonetheless, we will continue to monitor this important issue to ensure that such problems do not arise with our moratorium extension, particularly in rural areas.

III. No Judicial Review of CMS's Decision To Impose an Enrollment Moratorium

In accordance with section 1866(j)(7)(B) of the Act, there is no judicial review under sections 1869 and 1878 of the Act, or otherwise, of the decision to impose a temporary enrollment moratorium. Under §§ 424.530(a)(10) and 424.570(c), CMS denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium. In addition, § 424.514(d)(2)(v)(C) states that if the provider or supplier was required to pay an application fee, the application fee will be refunded if the application was denied because of the imposition of a temporary moratorium.

A provider or supplier that is impacted by a moratorium may use the existing appeal procedures at 42 CFR part 498 to administratively appeal a denial of billing privileges based on the imposition of a temporary moratorium. The scope of any such appeal, though, would be limited solely to assessing whether the temporary moratorium applies to the provider or supplier appealing the denial (see 42 CFR 498.5(l)(4)).

IV. Collection of Information Requirements

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.*).

V. Regulatory Impact Statement

A. Statement of Need

This extension notice is necessary to help reduce the prevalence of Medicare fraud, waste, and abuse among hospices.

B. Overall Impact

We have examined the impacts of this notice 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) (5 U.S.C. 601 through 612); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory

[13] *https://www.ic3.gov/PSA/2026/PSA260603.*

[14] Ibid.

[15] Ibid.

[16] Ibid.

[17] For more information regarding the monitored indicators, see the February 4, 2014, and July 28, 2017, moratoria document (79 FR 6475) and 82 FR 35127, respectively).

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; and 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, the President's priorities, or the Executive Order itself.

An RIA must be prepared for a regulatory action that is significant under section 3(f)(1) of Executive Order 12866. Based on our analysis, the Office of Information and Regulatory Affairs (OIRA) has determined that this notice is not significant pursuant to section 3(f)(1) of Executive Order 12866. Accordingly, we have not prepared a regulatory impact analysis. In accordance with Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this notice does not meet the criteria for a major rule as defined in 5 U.S.C. 804(2).

In addition, section 1102(b) of the Act requires us to prepare an RIA 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 RFA provisions at 5 U.S.C. 604. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This notice is primarily applicable to hospices, not rural hospitals. Therefore, the Secretary has certified that this notice will not have a significant economic impact on the operations of small rural hospitals.

We continue to expect savings for the Medicare program from the reduction in the number of newly enrolled hospices. However, we do not yet have data upon which to base an estimate of the amount of savings.

C. Regulatory Flexibility Analysis (RFA)

1. Small Business Impact

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most entities and most other providers and suppliers are small entities, either by nonprofit status or by having revenue less than $19 million to $41 million in any 1 year. Individuals and States are not included in the definition of a small entity. For reasons stated in the May 15, 2026, notice, we do not believe that our hospice moratorium has a significant economic impact on a substantial number of small businesses. Even conceding the impact on newly enrolled hospices, we believe that the risk that hospice fraud, waste, and abuse poses to the Trust Funds, Medicare beneficiaries, and the taxpayers far exceeds this and thus justifies our measure.

2. Alternatives Considered

There are two principal alternatives we considered in preparing this notice. First, we contemplated allowing the May 15, 2026, moratorium to expire without extension. Yet as already mentioned—and as highlighted by the previously noted FBI alert—fraud schemes remain a significant problem. We believe that permitting new hospices—some of which may, after enrollment, engage in fraud, waste, or abuse—to begin enrolling again without limitation would only exacerbate the dilemma. Second, we contemplated limiting the moratorium to southern California. We believe, though, that the problems the moratorium seeks to address are nationwide—again, as indicated in the FBI alert—rather than restricted to particular geographic areas.

D. Unfunded Mandates Reform Act (UMRA)

Section 202 of the UMRA 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 notice will not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than $193 million in any 1 year. UMRA only applies in situations where an agency engages in notice-and-comment rulemaking. It does not apply to this notice.

E. State and Local Costs

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed regulatory action (and subsequent final action) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this notice does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Dr. 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, Centers for Medicare & Medicaid Services.

[FR Doc. 2026–23242 Filed 11–12–26; 4:15 pm]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services.

Privacy Act of 1974; Matching Program

AGENCY: The Department of Health and Human Services, Centers for Medicare and Medicaid Services.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with subsection (e)(12) of the Privacy Act of 1974, as amended, the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), is providing notice of a new matching program between CMS and the U.S. Department of Education (ED), Federal Student Aid. The matching program supports eligibility determinations for enrollment in applicable State health subsidy programs under the Patient Protection and Affordable Care Act (PPACA), including Qualified Health Plans (QHPs), Medicaid, the Children's Health Insurance Program (CHIP), and Basic Health Programs (BHPs). The matching program also supports implementation of statutory requirements concerning Medicaid community engagement and the prevention of concurrent Medicaid