Patient Protection and Affordable Care Act (ACA, Pub. L. 111–148, 124 Stat, 119, Mar. 23, 2010). Included in HIPAA is the statutory reporting requirement that the Committee submit to Congress and make public, a report regarding the implementation of part C of title XI of the Social Security Act.

Purpose: The National Committee on Vital and Health Statistics shall assist and advise the Secretary on health data, statistics, privacy, national health information policy, and the Department's strategy to best address those issues. The Committee also shall assist and advise the Department in the implementation of the Administrative Simplification provisions of HIPAA and shall inform decision making about data policy by HHS, states, local governments and the private sector.

Matters to be Considered: The agenda will include drafting of the annual Report to Congress and a review of potential future topics. The Committee will reserve time on the agenda for public comment. Agenda items are subject to change as priorities dictate. Summaries of meetings and a roster of Committee members are available on the NCVHS website: *https://www.cdc.gov/faca/committees/ncvhs.html,* where further information including an agenda and instructions to access the broadcast of the meeting will be posted.

Should you require reasonable accommodation due to a disability, please contact Naomi Michaelis at *ncvhsmail@cdc.gov* (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2026–23954 Filed 11–24–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6100–N]

RIN 0938–ZC03

Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2027

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

ACTION: Notice.

SUMMARY: This notice announces a $776.00 calendar year 2027 application fee for institutional providers that are initially enrolling in the Medicare or Medicaid program or the Children's Health Insurance Program (CHIP); revalidating their Medicare, Medicaid, or CHIP enrollment; or adding a new Medicare practice location. This fee is required with any enrollment application submitted on or after January 1, 2027, and on or before December 31, 2027.

DATES: The application fee announced in this notice is effective on January 1, 2027.

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

SUPPLEMENTARY INFORMATION:

I. Background

In the February 2, 2011, **Federal Register** (76 FR 5862), we 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''. This final rule finalized, among other things, provisions related to the submission of application fees as part of the Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) provider enrollment processes.

As provided in section 1866(j)(2)(C)(i) of the Social Security Act (the Act) and in 42 CFR 424.514, ''institutional providers'' that are initially enrolling in the Medicare or Medicaid programs or CHIP, revalidating their enrollment, or adding a new Medicare practice location are required to submit a fee with their enrollment application. An ''institutional provider'' for purposes of Medicare is defined at § 424.502 as ''any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and non-physician practitioner organizations), CMS–855S, or associated internet-based PECOS enrollment application.'' As we explained in the February 2, 2011, final rule (76 FR 5914), in addition to the providers and suppliers subject to the application fee under Medicare, Medicaid-only and CHIP-only institutional providers would include nursing facilities, intermediate care facilities for persons with intellectual disabilities (ICF/IID), and psychiatric residential treatment facilities; they may also include other institutional provider types designated by a State in accordance with their approved State plan.

As indicated in §§ 424.514 and 455.460, the application fee is not required for either of the following:

- A Medicare physician or non-physician practitioner submitting a CMS–855I.
- A prospective or revalidating Medicaid or CHIP provider—

++ Who is an individual physician or non-physician practitioner; or

++ That is enrolled as an institutional provider in Title XVIII of the Act or another State's Title XIX or XXI plan and has paid the application fee to a Medicare contractor or another State.

II. Provisions of the Notice

Section 1866(j)(2)(C)(i)(I) of the Act established a $500 application fee for institutional providers in calendar year (CY) 2010. Consistent with section 1866(j)(2)(C)(i)(II) of the Act, § 424.514(d)(2) states that for CY 2011 and subsequent years, the preceding year's fee will be adjusted by the percentage change in the consumer price index (CPI) for all urban consumers (all items; United States city average, CPI–U) for the 12-month period ending on June 30 of the previous year. Consequently, each year since 2011 we have published in the **Federal Register** an announcement of the application fee amount for the forthcoming CY based on this formula. Most recently, in the December 3, 2025, **Federal Register** (90 FR 55738), we published a notice announcing a fee amount for the period of January 1, 2026, through December 31, 2026, of $750.00. The $750.00 fee amount for CY 2026 was used to calculate the fee amount for CY 2027 as specified in § 424.514(d)(2).

According to Bureau of Labor Statistics (BLS) data, the CPI–U increase for the period of July 1, 2025, through June 30, 2026, was 3.5 percent. (See *https://www.bls.gov/news.release/archives/cpi_07142026.htm*). As required by § 424.514(d)(2), the preceding year's fee of $750 will be

adjusted by 3.5 percent. This results in a CY 2027 application fee amount of $776.25 ($750 × 1.035). As we must round this to the nearest whole dollar amount, the resultant application fee amount for CY 2027 is $776.

III. 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.*). However, it does reference previously approved information collections. The CMS–855A, CMS–855B, CMS–855I, and CMS–855S applications are approved under, respectively, OMB control numbers 0938–0685, 0938–1377, 0938–1355, and 0938–1056.

IV. Regulatory Impact Statement

A. Background and Review Requirements

We have examined the impacts of this 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; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4); and the Congressional Review Act (5 U.S.C. 804(2)).

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.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. As explained in this section of the notice, we estimate that the total cost of the increase in the application fee will not exceed $100 million. Therefore, this notice does not reach the $100 million economic threshold and is not considered a major notice.

B. Costs

The costs associated with this notice involve an increase in the application fee amount that certain providers and suppliers must pay in CY 2027. The CY 2027 cost estimates are as follows:

1. Medicare

Based on CMS data, we estimate that in CY2027 approximately:

- 8,392 newly enrolling institutional providers will be subject to and pay an application fee; and
- 35,148 revalidating institutional providers will be subject to and pay an application fee.

Using a figure of 43,540 (8,392 newly enrolling + 35,148 revalidating) institutional providers, we estimate an increase in the cost of the Medicare application fee requirement in CY 2027 of $1,132,040 (or 43,540 × $26 (or $776 minus $750)) from our CY 2026 projections.

2. Medicaid and CHIP

Based on CMS and State statistics, we estimate that approximately 30,000 (9,000 newly enrolling + 21,000 revalidating) Medicaid and CHIP institutional providers will be subject to an application fee in CY 2027. Using this figure, we project an increase in the cost of the Medicaid and CHIP application fee requirement in CY 2027 of $780,000 (or 30,000 × $26 (or $776 minus $750)) from our CY 2026 projections.

3. Total

Based on the foregoing, we estimate the total increase in the cost of the application fee requirement for Medicare, Medicaid, and CHIP providers and suppliers in CY 2027 to be $1,912,040 ($1,132,040 + $780,000) from our CY2026 projections.

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 hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $9 million to $47. million in any 1 year. Individuals and States are not included in the definition of a small entity. As we stated in the RIA for the February 2, 2011, final rule (76 FR 5952), we do not believe that the application fee will have a significant impact on small entities.

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 604 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 a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this notice would not have a significant impact on the operations of a substantial number of small rural hospitals.

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 was approximately $193 million. The Agency has determined that there will be minimal impact from the costs of this notice, as the threshold is not met under the UMRA.

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. Since this notice does not impose substantial direct 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 Chyana Woodyard, who is the Federal Register Liaison, to electronically sign

this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2026–24000 Filed 11–24–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0446]

Proposed Information Collection Activity; Temporary Assistance for Needy Families Expenditure Report, Form ACF–196R

AGENCY: Office of Family Assistance, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families' (ACF) Office of Family Assistance (OFA) is requesting a 3-year extension of the Temporary Assistance for Needy Families (TANF) Expenditure Report, Form ACF–196R (Office of Management and Budget #: 0970–0446, expiration January 31, 2027). ACF is proposing revisions to streamline instructions, improve organization and flow, and remove redundant reporting requirements.

DATES: Comments due January 25, 2027.

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Form ACF–196R is used by states administering the TANF program to report quarterly expenditure data and to request quarterly grant funds. Failure to collect the data would seriously compromise OFA's and ACF's ability to monitor TANF expenditures and compliance with statutory requirements. These data are also needed to estimate outlays and to prepare reports and budget submissions for Congress. Since its last approval, the instructions have been streamlined in plain language and reorganized with formatting and clear section headers. Specifically, ACF has made the following updates to the form and instructions: Updated dates and references to more current status; simplified examples and explanations to support comprehension of reporting expectations; added table of contents and introduced plain language edits to improve clarity and the presentation of the document; and grayed out form fields where input is no longer required.

Respondents: State agencies administering the TANF program (50 states and the District of Columbia).

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Form ACF–196R	51	4	9	1,836

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 609.

Samantha L. Illangasekare,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–23967 Filed 11–24–26; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1188]

Over-the-Counter Monograph Order Requests: Format and Content; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry titled ''Over-the-Counter Monograph Order Requests: Format and Content.'' This guidance provides recommendations on the format and content of the information that a requestor should provide in an over-the-counter (OTC) monograph order request (OMOR) and identifies relevant guidance documents to assist requestors in preparing their OMORs. This guidance finalizes the draft guidance titled ''Over-the-Counter Monograph Order Requests (OMORs): Format and Content'' issued on April 13, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on November 25, 2026.

ADDRESSES: You may submit either electronic or written comments on any Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*