DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6051–N]

Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2014

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

ACTION: Notice.

SUMMARY: This notice announces a $542.00 calendar year (CY) 2014 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, 2014 and on or before December 31, 2014.

DATES: *Effective Date:* This notice is effective on January 1, 2014.

FOR FURTHER INFORMATION CONTACT: Frank Whelan, (410) 786–1302 for Medicare enrollment issues. Alvin Anderson, (410) 786–2188 for Medicaid and CHIP enrollment issues.

SUPPLEMENTARY INFORMATION:

I. Background

In the February 2, 2011 **Federal Register** (76 FR 5862), we published a final rule with comment period entitled ''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 rule finalized, among other things, provisions related to the submission of application fees as part of the Medicare, Medicaid, and CHIP provider enrollment processes. As stated in 42 CFR 424.514, ''institutional providers'' that are initially enrolling in the Medicare, Medicaid or CHIP program, revalidating their enrollment, or adding a new Medicare practice location are required to submit a fee with their enrollment application. An ''institutional provider'' is defined at 42 CFR 424.502 as ''(a)ny 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 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 include nursing facilities, intermediate care facilities for persons with mental retardation (ICF/MR), psychiatric residential treatment facilities, and may include other institutional provider types designated by a State in accordance with their approved State plan.''.

As indicated in 42 CFR 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 re-enrolling Medicaid or CHIP provider—

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

++ That is enrolled 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

A. CY 2013 Fee Amount

In the November 30, 2012 **Federal Register** (77 FR 71423), we published a notice announcing a fee amount for the period of January 1, 2013 through December 31, 2013 of $532.00. This figure was calculated as follows:

- Section 1866(j)(2)(C)(i)(I) of the Social Security Act (the Act) established a $500 application fee for institutional providers in CY 2010.
- Consistent with section 1866(j)(2)(C)(i)(II) of the Act, 42 CFR 424.514(d)(2) states that for CY 2011 and subsequent years, the 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 in June of the previous year.
- The CPI–U increase for CY 2011 was 1.0 percent, based on data obtained from the Bureau of Labor Statistics (BLS). This resulted in an application fee amount for CY 2011 of $505 (or $500 × 1.01).
- The CPI–U increase for the period of July 1, 2010 through June 30, 2011 was 3.54 percent, based on BLS data. This resulted in an application fee amount for CY 2012 of $522.87 (or $505 × 1.0354). In the aforementioned February 2, 2011 final rule, we stated that if the adjustment sets the fee at an uneven dollar amount, we would round the fee to the nearest whole dollar amount. Accordingly, the application fee amount for CY 2012 was rounded to the nearest whole dollar amount, or $523.00.
- The CPI–U increase for the period of July 1, 2011 through June 30, 2012 was 1.664 percent, based on BLS data. This resulted in an application fee amount for CY 2013 of $531.70 ($523 × 1.01664). Rounding this figure to the nearest whole dollar amount resulted in a CY 2013 application fee amount of $532.00.

B. CY 2014 Fee Amount

Using BLS data, the CPI–U increase for the period of July 1, 2012 through June 30, 2013 was 1.8 percent. This results in a CY 2014 application fee amount of $541.576 ($532 × 1.018). As we must round this to the nearest whole dollar amount, the resultant application fee amount for CY 2014 is $542.00. This represents a $6.00 difference from the $536 application fee amount that we had originally projected for CY 2014 in the February 2, 2011 final rule.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). However, it does reference currently approved information collections. Form CMS–855A, and CMS–855I are approved under OMB control number 0938–0685. Form CMS–855B is approved under OMB control number 0938–1198. Form CMS–855S is approved under OMB control number 0938–1056.

IV. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), 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 regulatory approaches that maximize net benefits, including potential economic,

environmental, public health and safety effects, distributive impacts, and equity. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). As explained in this section of the notice (section IV.), we estimate that the total cost of the increase in the application fee will not exceed $100 million. This notice therefore does not reach the $100 million economic threshold and is not considered a major notice.

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 $7.0 million to $35.5 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 with comment period (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 2013, that threshold is approximately $141 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.

The costs associated with this notice involve the increase in the application fee that certain providers and suppliers must pay in CY 2014. As indicated earlier, in the RIA for the February 2, 2011 final rule, we estimated the total amount of application fees for CYs 2011 through 2015. For CY 2014, and based on a $536 application fee amount, we projected in Tables 11 and 12 (76 FR 5955 and 5956) a total cost in fees of $62,189,400 ($16,723,200 + $45,466,200) for 116,025 affected Medicare institutional providers (31,200 newly enrolling + 84,825 re-enrolling). We also projected in Tables 13 and 14 (76 FR 5957 and 5958) a total cost in CY 2014 application fees of $13,471,824 ($4,522,768 + $8,949,056) for 25,134 affected Medicaid and CHIP providers (8,438 newly enrolling + 16,696 re-enrolling).

In the November 30, 2012 application fee notice, we stated in part that we were—

- Increasing the estimated number of affected Medicaid and CHIP providers in CY 2013 from 25,134 to 27,859, based on CY 2009 and CY 2010 data furnished by State Medicaid agencies through the annual State Program Integrity Assessment; and

- Reducing the estimated number of affected Medicare institutional providers from 116,025 to 84,120. This was due to a much-lower-than-expected number of affected newly-enrolling institutional providers. We had projected in the February 2, 2011 final rule that 31,200 newly-enrolling institutional providers would be subject to an application fee in CY 2013. We reduced this figure to 4,120 based on CMS data.

Our statistics indicate that roughly the same number of Medicaid and CHIP providers that we projected in the November 30, 2012 fee notice would be subject to an application fee in CY 2013 will be similarly affected in CY 2014. We will therefore use the CY 2013 figures in our calculations of the fee costs for CY 2014. However, as explained later in this section, we project that the number of affected Medicare institutional providers in CY 2014 will be higher than the CY 2013 projection we used in the November 30, 2012 fee notice.

1. Medicare

a. Newly-Enrolling Institutional Providers

Based on CMS statistics for the final quarter of CY 2012, we estimate that 4,800 newly-enrolling institutional providers will be subject to an application fee in CY 2014. This represents an increase of 670 from the CY 2013 projection we used in the November 30, 2012 fee notice.

b. Revalidating Institutional Providers

Again based on CMS data, we estimate that approximately 580,000 Medicare providers and suppliers will be subject to revalidation in CY 2014. (This represents an increase of 180,000 from the CY 2013 projection we used in the November 30, 2012 fee notice.) Of this total, and based on our experience, we believe that roughly 80 percent of them will be exempt from the application fee requirement because the provider or supplier: (1) Is of a type (for example, a physician) that is exempt from the requirement; or (2) qualifies for a hardship exception under 42 CFR 424.514(c). This leaves 116,000 revalidating institutional providers that will have to pay the fee. Using a figure of 120,800 (116,000 revalidating + 4,800 newly-enrolling) institutional providers, we estimate an increase in the cost of the Medicare application fee requirement in CY 2014 of $ 724,800 (or 120,800 x $6.00) from the CY 2014 projections we had made in the February 2, 2011 final rule.

2. Medicaid and CHIP

We estimate that 27,859 (8,438 newly enrolling + 19,421 re-enrolling) Medicaid and CHIP providers would be subject to an application fee in CY 2014. Using this figure, we estimate an increase in the cost of the Medicaid and CHIP application fee requirements in CY 2014 of $167,154 (27,859 x $6.00) from the CY 2014 projections we had made in the February 2, 2011 final rule.

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 2014 to be $891,954 ($724,800 + $167,154) from the CY 2014 projections we had made in the February 2, 2011 final rule.

In accordance with the provisions of Executive Order 12866, this notice was/was not reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital

Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 7, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0719]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 2, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0675. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products—(OMB Control Number 0910–0675)—Extension

The guidance recommends that manufacturers of drug and therapeutic biological products and manufacturers of raw materials and components used in those products develop a written Emergency Plan (Plan) for maintaining an adequate supply of medically necessary drug products (MNPs) during an emergency that results in high employee absenteeism. The guidance discusses the issues that should be covered by the Plan, such as: (1) Identifying a person or position title (as well as two designated alternates) with the authority to activate and deactivate the Plan and make decisions during the emergency; (2) prioritizing the manufacturer's drug products based on medical necessity; (3) identifying actions that should be taken prior to an anticipated period of high absenteeism; (4) identifying criteria for activating the Plan; (5) performing quality risk assessments to determine which manufacturing activities may be reduced to enable the company to meet a demand for MNPs; (6) returning to normal operations and conducting a post-execution assessment of the execution outcomes; and (7) testing the Plan. The guidance recommends developing a Plan for each individual manufacturing facility as well as a broader Plan that addresses multiple sites within the organization. For purposes of this information collection analysis, we consider the Plan for an individual manufacturing facility as well as the broader Plan to comprise one Plan for each manufacturer. Based on FDA's data on the number of manufacturers that would be covered by the guidance, we estimate that approximately 70 manufacturers will develop a Plan as recommended by the guidance (i.e., one Plan per manufacturer to include all manufacturing facilities, sites, and drug products), and that each Plan will take approximately 500 hours to develop, maintain, and update.

The guidance also encourages manufacturers to include a procedure in their Plan for notifying the Center for Drug Evaluation and Research (CDER) when the Plan is activated and when returning to normal operations. The guidance recommends that these notifications occur within 1 day of a Plan's activation and within 1 day of a Plan's deactivation. The guidance specifies the information that should be included in these notifications, such as which drug products will be manufactured under altered procedures, which products will have manufacturing temporarily delayed, and any anticipated or potential drug shortages. We expect that approximately 2 notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be sent to CDER by approximately 2 manufacturers each year, and that each notification will take approximately 16 hours to prepare and submit.

The guidance also refers to previously approved collections of information found in FDA regulations. Under the guidance, if a manufacturer obtains information after releasing an MNP under its Plan, leading to suspicion that the product might be defective, CDER should be contacted immediately at *drugshortages@fda.hhs.gov* in adherence to existing recall reporting regulations (21 CFR 7.40; OMB control number 0910–0249), or defect reporting requirements for drug application products (21 CFR 314.81(b)(1)) and therapeutic biological products regulated by CDER (21 CFR 600.14) (OMB control numbers 0910–0001 and 0910–0458, respectively).

In addition, the following collections of information found in FDA current good manufacturing practice (CGMP) regulations in part 211 (21 CFR part 211) are approved under OMB control number 0910–0139. The guidance encourages manufacturers to maintain records, in accordance with the CGMP requirements (*see,* e.g., § 211.180) that support decisions to carry out changes to approved procedures for manufacturing and release of products under the Plan. The guidance states that a Plan should be developed, written, reviewed, and approved within the site's change control quality system in accordance with the requirements in §§ 211.100(a) and 211.160(a); execution of the Plan should be documented in accordance with the requirements described in § 211.100(b); and standard operating procedures should be reviewed and revised or supplementary procedures developed and approved to enable execution of the Plan.

In the **Federal Register** of June 21, 2013 (78 FR 37548), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this information collection as follows: