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Sharon B. Arnold,
AHRQ Deputy Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6066-N]

Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2016

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

ACTION: Notice.

SUMMARY: This notice announces a \$554.00 calendar year (CY) 2016 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, 2016 and on or before December 31, 2016.

DATES: This notice is effective on January 1, 2016.

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 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 provided in section 1866(j)(2)(C)(i) of the Social Security Act (the Act) (as amended by section 6401 of the Affordable Care 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 "(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 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), 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 §§ 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 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 2015 Fee Amount

In the December 5, 2014 **Federal Register** (79 FR 72183), we published a notice announcing a fee amount for the period of January 1, 2015 through December 31, 2015 of \$553.00. This figure was calculated as follows:

- Section 1866(j)(2)(C)(i)(I) of 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, § 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.
- 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.

- The CPI-U increase for the period of July 1, 2012 through June 30, 2013 was 1.8 percent, based on BLS data. This resulted in an application fee amount for CY 2014 of \$541.576 (\$532 × 1.018). Rounding this figure to the nearest whole dollar amount resulted in a CY 2014 application fee amount of \$542.00.

- The CPI-U increase for the period of July 1, 2013 through June 30, 2014 was 2.1 percent, based on BLS data. This resulted in an application fee amount for CY 2015 of \$553.382 (\$542 × 1.021). Rounding this figure to the nearest whole dollar amount resulted in a CY 2015 application fee amount of \$553.00.

B. CY 2016 Fee Amount

Using BLS data, the CPI-U increase for the period of July 1, 2014 through June 30, 2015 was 0.2 percent. This results in a CY 2016 application fee amount of \$554.106 (\$553 × 1.002). As we must round this to the nearest whole dollar amount, the resultant application fee amount for CY 2016 is \$554.00.

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. However, it does reference previously approved information collections. The forms CMS-855A, CMS-855B, and CMS-855I are approved under OMB

control number 0938–0685; the CMS–855S is approved under OMB control number 0938–1056.

IV. Regulatory Impact Statement

A. Background

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, 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 the increase in the application fee amount that certain providers and suppliers must pay in CY 2016.

1. Estimates of Number of Affected Institutional Providers in December 5, 2014 Fee Notice

In the December 5, 2014 application fee notice, we estimated that based on CMS statistics—

- 10,000 newly enrolling Medicare institutional providers would be subject to and pay an application fee in CY 2015.
- 35,000 revalidating Medicare institutional providers would be subject to and pay an application fee in CY 2015.
- 8,438 newly enrolling Medicaid and CHIP providers would be subject to and pay an application fee in CY 2015.
- 19,421 revalidating Medicaid and CHIP providers would be subject to and pay an application fee in CY 2015.

2. CY 2016 Estimates

a. Medicare

Based on CMS data, we estimate that in CY 2016 approximately—

- 10,000 newly enrolling institutional providers will be subject to and pay an application fee; and
- 45,000 revalidating institutional providers will be subject to and pay an application fee.

Using a figure of 55,000 (10,000 newly enrolling + 45,000 revalidating) institutional providers, we estimate an increase in the cost of the Medicare application fee requirement in CY 2016 of \$5,585,000 (or (10,000 additional newly enrolling or revalidating institutional providers × \$554) + (45,000 × \$1.00)) from our CY 2015 projections and as previously described.

b. 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 2016. Using this figure, we project an increase in the cost of the Medicaid and CHIP application fee requirement in CY 2016 of \$1,213,973 ((562 additional newly enrolling institutional providers + 1,579 additional revalidating institutional providers, or 2,141 total additional institutional providers) × \$554) + 27,859 × \$1.00) from our CY 2015 projections and as previously described.

c. 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 2016 to be \$6,798,973 (\$5,585,000 + \$1,213,973) from our CY 2015 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 \$7.5 million to \$38.5 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 2015, that threshold is approximately \$144 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.

Dated: November 14, 2015.

Andrew M. Slavitt,
Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2175]

Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.