ensure continuity of supply of a critical input, the Order requires that the parties supply Spectranetics with PTA balloon catheters for up to three years while Spectranetics transitions to independent manufacturing. This provision ensures that drug-coated balloon catheters will continue to be available for ongoing clinical trials while Spectranetics works to obtain FDA approval to manufacture the PTA balloon catheters independently.

To ensure that the divestiture is successful, the Order requires the parties to enter into a transitional services agreement with Spectranetics to assist the company in establishing its manufacturing capabilities and securing all necessary FDA approvals. Further, the Order requires that the parties transfer all confidential business information to Spectranetics, as well as provide access to employees who possess or are able to identify such information. Spectranetics also will have the right to interview and offer employment to employees associated with Covidien's drug-coated balloon catheter business.

The parties must accomplish the divestiture no later than ten days after the consummation of the Proposed Acquisition. If the Commission determines that Spectranetics is not an acceptable acquirer, or that the manner of the divestiture is not acceptable, the Order requires the parties to unwind the sale and accomplish the divestiture within 180 days of the date the Order becomes final to another Commission-approved acquirer.

To ensure compliance with the Order, the Commission has agreed to appoint an Interim Monitor to ensure that Medtronic and Covidien comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to Spectranetics. Further, the Order allows the Commission to appoint a Divestiture Trustee to accomplish the divestiture should the parties fail to comply with their divestiture obligations. Lastly, the Order terminates after ten years.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2014–28609 Filed 12–4–14; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6056–N]

Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2015

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

ACTION: Notice.

SUMMARY: This notice announces a $553.00 calendar year (CY) 2015 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, 2015 and on or before December 31, 2015.

DATES: This notice is effective on January 1, 2015.

FOR FURTHER INFORMATION: 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 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 (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, 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'' 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 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 §§ 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 2014 Fee Amount

In the December 2, 2013 **Federal Register** (78 FR 72089), we published a notice announcing a fee amount for the period of January 1, 2014 through December 31, 2014 of $542.00. 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.

B. CY 2015 Fee Amount

Using BLS data, the CPI–U increase for the period of July 1, 2013 through June 30, 2014 was 2.1 percent. This results in a CY 2015 application fee amount of $553.382 ($542 × 1.021). As we must round this to the nearest whole dollar amount, the resultant application fee amount for CY 2015 is $553.00. This represents a $6.00 difference from the $547 application fee amount that we had originally projected for CY 2015 in the February 2, 2011 final rule.

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 2015.

1. Initial Estimates in February 2011 Final Rule

In the RIA for the February 2, 2011 final rule, as indicated earlier, we estimated the total amount of application fees for CYs 2011 through 2015. For CY 2015, and based on a projected $547 application fee amount, we estimated in Tables 11 and 12 (76 FR 5955 and 5956) a total cost in fees of $63,465,675 ($17,066,400 + $46,399,275) for 116,025 affected Medicare institutional providers (31,200 newly enrolling + 84,825 revalidating). We also projected in Tables 13 and 14 (76 FR 5957 and 5958) a total cost in CY 2015 application fees of $13,748,298 ($4,615,586 + $9,132,712) for 25,134 affected Medicaid and CHIP providers (8,438 newly enrolling + 16,696 revalidating).

2. Estimates of Number of Affected Institutional Providers in December 2, 2013 Fee Notice

In the December 2, 2013 application fee notice, we estimated that—

- 4,800 newly enrolling Medicare institutional providers would be subject to an application fee in CY 2014. This was based on CMS statistics for the final quarter of CY 2012 and represented a substantial decrease from our estimate in the February 2, 2011 final rule of 31,200 affected, newly enrolling institutional providers for CY 2014.
- 580,000 Medicare providers and suppliers would be subject to revalidation in CY 2014, of which 116,000 would be institutional providers required to pay a fee.
- 27,859 Medicaid and CHIP providers (8,438 newly enrolling + 19,421 revalidating) would be subject to an application fee in CY 2014.

3. CY 2015 Estimates

a. Medicare

Based on CMS data, we estimate that in CY 2015 approximately—

- 10,000 newly enrolling institutional providers will pay an application fee; and
- 35,000 institutional providers will be subject to revalidation and will pay an application fee.

Using a figure of 45,000 (10,000 newly enrolling + 35,000 revalidating) institutional providers, we estimate an increase in the cost of the Medicare application fee requirement in CY 2015 of $270,000 (or 45,000 x $6.00) from the CY 2015 projections we had made in the February 2, 2011 final rule.

b. Medicaid and CHIP

As we did for CY 2014, we continue to estimate that 27,859 (8,438 newly enrolling + 19,421 revalidating) Medicaid and CHIP providers would be subject to an application fee in CY 2015. Using this figure, we project an increase in the cost of the Medicaid and CHIP application fee requirement in CY 2015 of $167,154 (27,859 x $6.00) from the CY 2014 projections we had made in the February 2, 2011 final rule.

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 2015 to be $437,154 ($270,000 + $167,154) from the CY 2015 projections we had made in the February 2, 2011 final rule.

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 2014, 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.

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

Dated: October 22, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–28503 Filed 12–2–14; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1891]

How To Obtain a Letter From the Food and Drug Administration Stating That Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable Risk Evaluation and Mitigation Strategies for Reference Listed Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD.'' This draft guidance describes how a prospective abbreviated new drug application (ANDA) applicant may request a letter stating that FDA has determined the following: The potential applicant's bioequivalence (BE) study protocol contains safety protections comparable to those in the risk evaluation and mitigation strategy (REMS) with elements to assure safe use (ETASU) applicable to the reference listed drug (RLD) and FDA will not consider it a violation of the REMS for the RLD sponsor to provide a sufficient quantity of the RLD to the interested generic firm or its agent to allow the firm to perform the testing necessary to support its ANDA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 3, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993, 240–402–7930, *Elizabeth.Giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD.'' Section 505–1(a)(1) of the FD&C Act authorizes FDA to require applicants to submit a proposed REMS as a part of the relevant application [1] if FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh its risks (21 U.S.C. 355–1(a)(1)). A REMS is a required risk management plan that uses tools beyond routine professional labeling (such as a medication guide, a patient package insert, and/or a communication plan) to ensure that the benefits of a drug outweigh its risks (section 505–1(f) of the FD&C Act). In addition, FDA may require ETASU in some circumstances when such elements are necessary to mitigate the risks associated with the drug. ETASU may include, for example, requirements that health care providers who prescribe or administer the drug have particular training or certification; that patients using the drug be monitored and/or enrolled in a registry; or that pharmacies, practitioners, or health care settings that dispense the drug be specially certified.

FDA is aware of instances in which an RLD sponsor has refused to sell drug products to a prospective ANDA applicant seeking to conduct the testing needed to obtain approval, and the RLD sponsor has cited the REMS ETASU as justification. In the interest of facilitating prospective generic applicants' access to RLD products to conduct the testing necessary to support ANDA approval, FDA has, on request, reviewed the BE study protocols proposed by a prospective ANDA

[1] Section 505–1 of the FD&C Act applies to any application for approval of a prescription drug submitted under section 505(b) or (j) of the FD&C Act (including both NDAs submitted under section 505(b)(2) and ANDAs submitted under section 505(j)), as well as applications submitted under section 351 of the Public Health Service Act (42 U.S.C. 262).