Program (VSP) in the 1970s as a cooperative activity with the cruise ship industry. VSP helps the cruise ship industry prevent and control the introduction, transmission, and spread of gastrointestinal illnesses (GI) on cruise ships. VSP operates under the authority of the Public Health Service Act (Section 361 of the Public Health Service Act; *42 U.S.C. 264,* ''Control of Communicable Diseases''). Regulations found at *42 CFR 71.41* state that carriers arriving at U.S. ports from a foreign area are subject to sanitary inspections to determine whether rodent, insect, or other vermin infestations exist, or whether contaminated food or water or other sanitary conditions requiring measures for the prevention of the introduction, transmission, or spread of communicable diseases are present.

VSP established the public health standards found in the current version of the VSP Operations Manual and VSP Construction Guidelines. These standards target the control and prevention of GI illnesses on cruise ships.

VSP is updating the VSP Operations Manual to reflect new technologies, current food science, disease patterns and trends, and emerging pathogens. VSP also is updating the VSP Construction Guidelines as a framework of consistent construction and design guidelines related to public health, including vessel facilities related to food storage, preparation, and service and water bunkering, storage, disinfection, and distribution.

The draft VSP Operations Manual and the draft VSP Construction Guidelines are available online at *www.regulations.gov,* Docket No. CDC–2017–0115, under Supplemental Materials.

Dated: November 27, 2017.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2017–25955 Filed 12–1–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6075–N]

Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2018

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

ACTION: Notice.

SUMMARY: This notice announces a $569.00 calendar year (CY) 2018 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, 2018 and on or before December 31, 2018.

DATES: This notice takes effect on January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Melissa Singer, (410) 786–0365.

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) 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 2017 Fee Amount

In the November 7, 2016 **Federal Register** (81 FR 78159), we published a notice announcing a fee amount for the period of January 1, 2017 through December 31, 2017 of $560.00. 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 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.
- The CPI–U increase for the period of July 1, 2014 through June 30, 2015 was 0.2 percent, based on BLS data. This resulted in an application fee amount for CY 2016 of $554.106 ($553 × 1.002). Rounding this figure to the nearest whole dollar amount resulted in a CY 2016 application fee amount of $554.00.
- The CPI–U increase for the period of July 1, 2015 through June 30, 2016 was 1.0 percent. This resulted in a CY 2017 application fee amount of $559.56 ($554 × 1.01). Rounding this figure to the nearest whole dollar amount resulted in a CY 2017 application fee amount of $560.00.

B. CY 2018 Fee Amount

Using BLS data, the CPI–U increase for the period of July 1, 2015 through June 30, 2016 was 1.6 percent. This results in a CY 2018 application fee amount of $568.96 ($560 × 1.016). As we must round this to the nearest whole dollar amount, the resultant application fee amount for CY 2018 is $569.00.

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 Form 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), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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 2018.

1. Estimates of Number of Affected Institutional Providers in November 7, 2016 Fee Notice

In the November 7, 2016 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 2017.
- 45,000 revalidating Medicare institutional providers would be subject to and pay an application fee in CY 2017.
- 9,000 newly enrolling Medicaid and CHIP providers would be subject to and pay an application fee in CY 2017.
- 21,000 revalidating Medicaid and CHIP providers would be subject to and pay an application fee in CY 2017.

2. CY 2018 Estimates

a. Medicare

Based on CMS data, we estimate that in CY 2018 approximately—

- 3,800 newly enrolling institutional providers will be subject to and pay an application fee; and
- 7.500 revalidating institutional providers will be subject to and pay an application fee.

Using a figure of 11,300 (3,800 newly enrolling + 7,500 revalidating) institutional providers, we estimate an increase in the cost of the Medicare application fee requirement in CY 2018 of $101,700 (or 11,300 × $9 (or $569 minus $560)) from our CY 2017 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 2018. Using this figure, we project an increase in the cost of the Medicaid and CHIP application fee requirement in CY 2018 of $270,000 (or 30,000 × $9 (or $569 minus $560)) from our CY 2017 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 2018 to be $371,700 ($270,000 + $101,700) from our CY 2017 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 2017, that threshold is approximately $148 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.

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

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

Dated: November 28, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–25972 Filed 12–1–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1684–N]

Medicare Program; Town Hall Meeting on the FY 2019 Applications for New Medical Services and Technologies Add-On Payments

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting in accordance with section 1886(d)(5)(K)(viii) of the Social Security Act (the Act) to discuss fiscal year (FY) 2019 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2019 new medical services and technologies applications meet the substantial clinical improvement criterion.

DATES:

Meeting Date: The Town Hall Meeting announced in this notice will be held on Tuesday, February 13, 2018. The Town Hall Meeting will begin at 9:00 a.m. Eastern Standard Time (e.s.t.) and check-in will begin at 8:30 a.m. e.s.t.

Deadline for Registration for Participants (not Presenting) at the Town Hall Meeting: The deadline to register to attend the Town Hall Meeting is 5:00 p.m., e.s.t. on Wednesday, February 7, 2018.

Deadline for Requesting Special Accommodations: The deadline to submit requests for special accommodations is 5:00 p.m., e.s.t. on Tuesday, January 16, 2018.

Deadline for Registration of Presenters at the Town Hall Meeting: The deadline to register to present at the Town Hall Meeting is 5:00 p.m., e.s.t. on Monday, January 29, 2018.

Deadline for Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Written comments and agenda items for discussion at the Town Hall Meeting, including agenda items by presenters, must be received by 5:00 p.m. e.s.t. on Monday, January 29, 2018.

Deadline for Submission of Written Comments after the Town Hall Meeting for consideration in the FY 2019 IPPS proposed rule: Individuals may submit written comments after the Town Hall Meeting, as specified in the **ADDRESSES** section of this notice, on whether the service or technology represents a substantial clinical improvement. These comments must be received by 5:00 p.m. e.s.t. on Friday, February 23, 2018, for consideration in the FY 2019 IPPS proposed rule.

ADDRESSES:

Meeting Location: The Town Hall Meeting will be held in the main Auditorium in the central building of the Centers for Medicare & Medicaid Services located at 7500 Security Boulevard, Baltimore, MD 21244–1850.

In addition, we are providing two alternatives to attending the meeting in person—(1) there will be an open toll-free phone line to call into the Town Hall Meeting; or (2) participants may view and participate in the Town Hall Meeting via live stream technology or webinar. These options are discussed in section II.B. of this notice.

Registration and Special Accommodations: Individuals wishing to participate in the meeting must register by following the on-line registration instructions located in section III. of this notice or by contacting staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individuals who need special accommodations should contact staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Each presenter must submit an agenda item(s) regarding whether a FY 2019 application meets the substantial clinical improvement criterion. Agenda items, written comments, questions or other statements must not exceed three single-spaced typed pages and may be sent via email to *newtech@cms.hhs.gov*.

FOR FURTHER INFORMATION CONTACT:

Michelle Joshua, (410) 786–6050, *michelle.joshua@cms.hhs.gov;* or Michael Treitel, (410) 786–4552, *michael.treitel@cms.hhs.gov*.

Alternatively, you may forward your requests via email to *newtech@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the Add-On Payments for New Medical Services and Technologies Under the IPPS

Sections 1886(d)(5)(K) and (L) of the Social Security Act (the Act) require the Secretary to establish a process of identifying and ensuring adequate payments to acute care hospitals for new medical services and technologies under Medicare. Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the hospital inpatient prospective payment system (IPPS). In addition, section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered ''new'' if it meets criteria established by the Secretary (after notice and opportunity for public comment). (See the fiscal year (FY) 2002 IPPS proposed rule (66 FR 22693, May 4, 2001) and final rule (66 FR 46912, September 7, 2001) for a more detailed discussion.)

In the September 7, 2001 final rule (66 FR 46914), we noted that we evaluated a request for special payment for a new medical service or technology against