

toxins that have the potential to pose a severe threat to human health and that may be used for or adapted for bioterrorist attacks. There are special reporting requirements for Select Agents, as detailed in 42 CFR part 73. Those agents included on the HHS Select Agents List that are routinely transmitted person to person and for which natural transmission remains a significant concern are categorized in the "List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May be Exposed," Part I above, according to their modes of transmission. The remaining agents on the Select Agent List would not typically exhibit human-to-human transmission or be considered contemporary contagious threats. However, in the setting of potential intentional modification to artificially increase transmissibility and/or lethality ("weaponization") and deployment as bio-weapons (potentially in quantities far greater than would naturally be encountered), atypical pathways of transmission may occur. In this case, EREs may be exposed by entering contaminated environments to care for victims and by exposure to contaminated individuals from those environments.

Part III. Guidelines Describing the Manner in Which Medical Facilities Should Make Determinations for Purposes of Section 2695B(d) [42 U.S.C. 300ff-133(d)]

Section 2695B(d) [42 U.S.C. 300ff-133(d)] specifies that medical facilities must respond to appropriate requests by making determinations about whether EREs have been exposed to infectious diseases included on the list issued pursuant to sec. 2695(a)(1) [42 U.S.C. 300ff-131(a)(1)]. A medical facility has access to two types of information related to a potential exposure incident to use in making a determination. First, the request submitted to the medical facility contains a "statement of the facts collected" about the ERE's potential exposure incident.²⁵ Information about infectious disease transmission provided in relevant CDC guidance documents²⁶ or in current

medical literature should be considered in assessing whether there is a realistic possibility that the exposure incident described in the statement of the facts could potentially transmit an infectious disease included on the list issued pursuant to sec. 2695(a)(1) [42 U.S.C. 300ff-131(a)(1)].

Second, the medical facility possesses medical information about the victim of an emergency transported and/or treated by the ERE. This is the medical information that the medical facility would normally obtain according to its usual standards of care to diagnose or treat the victim, since the Act does not require special testing in response to a request for a determination. As stated in sec. 2695G(b) [42 U.S.C. 300ff-138(b)], "this part may not, with respect to victims of emergencies, be construed to authorize or require a medical facility to test any such victim for any infectious disease."

Information about the potential exposure incident and medical information about the victim should be used in the following manner to make one of the four possible determinations as required by sec. 2695B(d) [42 U.S.C. 300ff-133(d)]:

- (1) The ERE involved has been exposed to an infectious disease included on the list:
 - Facts provided in the request document a realistic possibility that an exposure incident occurred with potential for transmitting a listed infectious disease from the victim of an emergency to the involved ERE; and
 - The medical facility possesses sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved ERE had a listed infectious disease that was possibly contagious at the time of the potential exposure incident.
- (2) The ERE involved has not been exposed to an infectious disease included on the list:
 - Facts provided in the request rule out a realistic possibility that an exposure incident occurred with potential for transmitting a listed infectious disease from the victim of an emergency to the involved ERE; or
 - The medical facility possesses sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved ERE did not have a listed infectious disease that was possibly contagious at the

time of the potential exposure incident.

(3) The medical facility possesses no information on whether the victim involved has an infectious disease included on the list:

- The medical facility lacks sufficient medical information allowing it to determine whether the victim of an emergency treated and/or transported by the involved ERE had, or did not have, a listed infectious disease at the time of the potential exposure incident.
- If the medical facility subsequently acquires sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved ERE had a listed infectious disease that was possibly contagious at the time of the potential exposure incident, then it should revise its determination to reflect the new information.

(4) The facts submitted in the request are insufficient to make the determination about whether the ERE was exposed to an infectious disease included on the list:

- Facts provided in the request insufficiently document the exposure incident, making it impossible to determine if there was a realistic possibility that an exposure incident occurred with potential for transmitting an infectious disease included on the list issued pursuant to Section 2695(a)(1) [42 U.S.C. 300ff-131(a)(1)] from the victim of an emergency to the involved ERE.

Dated: October 26, 2011.

James W. Stephens,

Director, Office of Science Quality, Office of the Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2011-28234 Filed 11-1-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6049-N]

Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2012

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

ACTION: Notice.

SUMMARY: This notice announces the \$523 calendar year (CY) 2012

pseudomallei (formerly *Pseudomonas pseudomallei*); Hendra virus; Nipah virus; Rift Valley fever virus; Venezuelan Equine Encephalitis virus.

²⁵ Section 2695B [42 U.S.C. 300ff-133].

²⁶ For example:

Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational

Exposures to HIV and Recommendations for Postexposure Prophylaxis. MMWR 2005;54 (No. RR-9):1-17.

application fee for institutional providers that are initially enrolling in the Medicare or Medicaid programs or 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, 2012 and on or before December 31, 2012.

DATES: *Effective Date:* This notice is effective on December 2, 2011.

FOR FURTHER INFORMATION CONTACT: Frank Whelan, (410) 786-1302 for Medicare enrollment issues. Claudia Simonson, (312) 353-2115 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 Children's Health Insurance Program (CHIP) provider enrollment processes. Specifically, and as indicated 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 an enrollment application submitted on or after March 25, 2011. An "institutional provider" is defined at 42 CFR 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 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.

In the March 23, 2011 **Federal Register** (76 FR 16422), we published a notice announcing—

- A \$505 calendar year (CY) 2011 application fee for institutional providers that are initially enrolling in the Medicare, Medicaid, or CHIP program; revalidating their enrollment; or adding a new Medicare practice location;
- That institutional providers are required to submit the \$505 fee with enrollment applications submitted on or after March 25, 2011 and on or before December 31, 2011; and
- That prospective or re-enrolling Medicaid or CHIP providers must submit the application fee unless: (1) The provider is an individual physician or non-physician practitioner; or (2) the provider 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. Current Fee Amount

As noted in section I. of this notice, the fee amount for the period of March 25, 2011 through December 31, 2011 is \$505. 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) for the 12-month period ending with June of the previous year.
- The CPI increase for CY 2011, which was calculated to be 1.0 percent, was based on data obtained from the Bureau of Labor Statistics. This resulted in an application fee for CY 2011 of \$505 (or $\$500 \times 1.01$). For more detailed information on the CPI and the calculation of the application fee, see the February 2, 2011 final rule with comment period (76 FR 5955) and the March 23, 2011 notice (76 FR 16423).

B. Fee Amount for Calendar Year 2012

The CPI increase for the period of July 2010 through June 2011 was 3.54 percent, based on data obtained from the Bureau of Labor Statistics. (This percentage is higher than the 2.0 percent CPI increase that we estimated for CY 2012 in the February 2, 2011 final rule with comment period (76 FR 5955).) This results in a projected application fee amount for the period of January 1,

2012 through December 31, 2012 of \$522.87 (or $\$505 \times 1.0354$). However, in the preamble to the February 2, 2011 final rule with comment period (76 FR 5907), we stated that "(t)o ease the administration of the fee, if the adjustment sets the fee at an uneven dollar amount, we will round the fee to the nearest whole dollar amount." Therefore, the projected application fee amount for CY 2012 will be rounded to the "nearest whole dollar amount," which is \$523.00. This represents an \$8.00 difference from the \$515 fee that we had originally projected for CY 2012.

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 previously approved information collections. As stated in section I. of this notice, 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

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 (February 2, 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 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 \$7.0 million to \$34.5 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) and the regulatory impact statement of the March 23, 2011 notice (76 FR 16423), 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 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 2011, that threshold is approximately \$136 million. This notice does not mandate such expenditures by States and local governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed 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 2012. In the RIA for the February 2, 2011 final rule with comment period (76 FR 5955 through 5958), we estimated the total amount of application fees for CYs 2011 through 2015. For 2012, and based on a \$515 application fee, we projected in Tables 11 and 12 (76 FR 5955 and 5956) a total cost in fees of \$71,803,875 for Medicare institutional providers (or 139,425 providers $\times$ \$515). In the February 2, 2011 final rule with comment period (76 FR 5957 and 5958), we estimated the total cost in CY 2012 for Medicaid providers to be \$12,944,010 (or 25,134 providers $\times$ \$515), as indicated in Tables 13 and 14.

We are retaining the figure of 25,134 Medicaid providers for purposes of this notice. However, we are changing the Medicare provider estimate based on our plan to revalidate all Medicare providers and suppliers— even if the revalidation is considered “off-cycle” per 42 CFR 424.515(e).

1. Medicare

For purposes of this notice only, we estimate that approximately 840,000 Medicare providers and suppliers will be subject to revalidation in CY 2012. Of this total, we believe that roughly 80 percent 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 168,000 revalidating providers and suppliers that will have to pay the fee.

In the February 2, 2011 final rule with comment period (76 FR 5955), we estimated that 31,200 newly-enrolling institutional providers would be subject to the application fee in CY 2012. We stand by this projection for purposes of this notice. Using a figure of 199,200 providers and suppliers (168,000 + 31,200), we estimate an increase in the cost of the Medicare application fee requirement in CY 2012 of \$1,593,600 (or 199,200 $\times$ \$8.00).

2. Medicaid and CHIP

In the February 2, 2011 final rule with comment period (76 FR 5957 and 5958), we estimated that 25,134 (8,438 newly enrolling + 16,696 re-enrolling) Medicaid and CHIP providers would be subject to an application fee in CY 2012.

This results in an increase in the cost of the Medicaid and CHIP application fee requirement in CY 2012 of \$201,072 (or 25,134 $\times$ \$8.00).

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 2012 to be \$1,794,672.

In accordance with the provisions of Executive Order 12866, this notice 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: September 30, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–28424 Filed 11–1–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Descriptive Study of Tribal Temporary Assistance for Needy Families (TANF) Programs.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF) is proposing an information collection activity as part of the Descriptive Study of Tribal TANF Programs. The proposed information collection consists of semi-structured interviews and focus groups with key Tribal TANF respondents on questions of Tribal TANF administration, policies, service delivery, and program context. Through this information collection, ACF seeks to gain an in-depth, systematic understanding of program implementation, operations, outputs and outcomes in selected sites, and identify promising practices and other areas for further study.

Respondents: Tribal TANF administrators, staff and participants, and staff of related programs.