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 2017.

1. Estimates of Number of Affected Institutional Providers in December 3, 2015 Fee Notice

In the December 3, 2015 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 2016.
- 45,000 revalidating Medicare institutional providers would be subject to and pay an application fee in CY 2016.
- 9,000 newly enrolling Medicaid and CHIP providers would be subject to and pay an application fee in CY 2016.
- 21,000 revalidating Medicaid and CHIP providers would be subject to and pay an application fee in CY 2016.

2. CY 2017 Estimates

a. Medicare

Based on CMS data, we estimate that in CY 2017 approximately—

- 10,000 newly enrolling institutional providers will be subject to and pay an application fee; and
- 43,792 revalidating institutional providers will be subject to and pay an application fee.

Using a figure of 53,792 (10,000 newly enrolling + 43,792 revalidating) institutional providers, we estimate an increase in the cost of the Medicare application fee requirement in CY 2017 of $322,752 (or 53,792 × $6 (or $560 minus $554)) from our CY 2016 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 2017. Using this figure, we project an increase in the cost of the Medicaid and CHIP application fee requirement in CY 2017 of $180,000 (or 30,000 × $6 (or $560 minus $554)) from our CY 2016 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 2017 to be $502,752 ($180,000 + $322,752) from our CY 2016 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 2016, that threshold is approximately $146 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: September 22, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–26828 Filed 11–4–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970–0445]

Proposed Information Collection Activity; Comment Request

Title: Implementation Grants to Develop a Model Intervention for Youth/Young Adults with Child Welfare Involvement at Risk of Homelessness: Phase II.

Description: The Administration for Children and Familes (ACF) at the U.S.

Department of Health and Human Services (HHS) intends to collect data for an evaluation of the initiative, Implementation Grants to Develop a Model Intervention for Youth/Young Adults with Child Welfare Involvement at Risk of Homelessness: Phase II. This builds on the previously approved ''Planning Grants to Develop a Model Intervention for Youth/Young Adults with Child Welfare Involvement at Risk of Homelessness'' (Phase I). Phase II is an initiative, funded by the Children's Bureau (CB) within ACF, that will support implementation grants for interventions designed to intervene with youth who have experienced time in foster care and are most likely to have a challenging transition into adulthood, including homelessness and unstable housing experiences. CB awarded six implementation grants (Phase II) in September 2015. During the implementation phase, organizations will conduct a range of activities to fine-tune their comprehensive service model, determine whether their model is being implemented as intended, and develop plans to evaluate the model under a potential future funding opportunity (Phase III). During Phase II, ACF will engage a contractor to: Conduct a cross-site process evaluation. Data collected for the process evaluation will be used to assess grantees' organizational capacity to implement and evaluate the model interventions and to monitor each grantee's progress toward achieving the goals of the implementation period.

Data for the process evaluation will be collected through: Interviews during site visits.

Respondents: Grantee agency directors and staff; partner agency directors and staff. Partner agencies may vary by site, but are expected to include child welfare, mental health, and youth housing/homelessness agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Total/annual burden hours
Call to coordinate site visit	6	1	1	6
Grantee Site Visit-Semi-Structured Interview Topic Guide	60	1	1.5	90
Estimated Total Annual Burden Hours				96

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2016–26806 Filed 11–4–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3586]

Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups About Drug Products as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection resulting from focus groups about drug products as used by FDA.

DATES: Submit either electronic or written comments on the collection of information by January 6, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').