

services and technology applications for fiscal year (FY) 2014. In addition, they will help us to evaluate our policy on the IPPS new technology add-on payment process before the publication of the FY 2014 IPPS proposed rule.

## II. Town Hall Meeting and Conference Calling/Live Streaming Information

### A. Format of the Town Hall Meeting

As noted in section I. of this notice, we are required to provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS concerning whether the service or technology represents a substantial clinical improvement. This meeting will allow for a discussion of the substantial clinical improvement criteria on each of the FY 2014 new medical services and technology add-on payment applications. Information regarding the applications can be found on our Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>.

The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter's comments will be approximately 10 to 15 minutes and will be based on the number of registered presenters. Presenters will be scheduled to speak in the order in which they register and grouped by new technology applicant. Therefore, individuals who would like to present must register and submit their agenda item(s) via email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov) by the date specified in the **DATES** section of this notice.

In addition, written comments will also be accepted and presented at the meeting if they are received via email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov) by the date specified in the **DATES** section of this notice. Written comments may also be submitted after the meeting for our consideration. If the comments are to be considered before the publication of the proposed rule, the comments must be received via email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov) by the date specified in the **DATES** section of this notice.

### B. Conference Call, Live Streaming, and Webinar Information

For participants who cannot attend the Town Hall Meeting in person, an open toll-free phone line, (877) 267-1577, has been made available. The conference code is "7702."

Also, there will be an option to view and participate in the Town Hall Meeting via live streaming technology and/or a webinar. Information on the option to participate via live streaming technology and/or a webinar will be provided through an upcoming listserv notice and posted on the New Technology Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>. Continue to check the Web site for updates.

*Disclaimer:* Because this is the first year that we are providing an option for live streaming technology and/or a webinar, we cannot guarantee the reliability of these technologies.

## III. Registration Instructions

The Division of Acute Care in CMS is coordinating the meeting registration for the Town Hall Meeting on substantial clinical improvement. While there is no registration fee, individuals planning to attend the Town Hall Meeting in person must register to attend.

Registration may be completed online at the following web address: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>. Select the link at the bottom of the page "Register to Attend the New Technology Town Hall Meeting". After completing the registration, on-line registrants should print the confirmation page(s) and bring it with them to the meeting(s).

If you are unable to register on-line, you may register by sending an email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov). Please include your name, address, telephone number, email address and fax number. If seating capacity has been reached, you will be notified that the meeting has reached capacity.

## IV. Security, Building, and Parking Guidelines

Because these meetings will be located on Federal property, for security reasons, any persons wishing to attend these meetings must register by the date specified in the **DATES** section of this notice. Please allow sufficient time to get through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 8:30 a.m. e.s.t. if you are attending the Town Hall Meeting so that you will be able to arrive promptly for the meeting.

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Interior and exterior inspection of vehicles (this includes engine and trunk

inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.

- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

*Note:* Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting in person. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting(s).

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building. Seating capacity is limited to the first 250 registrants.

**Authority:** Section 503 of Public Law 108-173.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 14, 2012.

**Marilyn Tavenner,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

##### Proposed Projects

*Title:* Form CB-496: Title IV-E Programs Quarterly Financial Report.  
*OMB No.:* 0970-0205.

*Description:* This is a financial report submitted following the end of each fiscal quarter by each State or Tribe with an approved title IV-E plan administering any of three title IV-E entitlement grant programs—Foster Care, Adoption Assistance or Guardianship Assistance.

The purpose of this form is to enable each State or Tribe to meet its statutory and regulatory requirement to report program expenditures made in the

preceding fiscal quarter and to estimate program expenditures to be made in the upcoming fiscal quarter. This form also allows States and Tribes to report the actual and estimated average monthly number of children assisted in each of the three IV–E entitlement grant programs in the preceding and upcoming fiscal quarters, respectively.

The Administration for Children and Families provides Federal funding at the rate of 50 percent for nearly all allowable and legitimate administrative costs of these programs and at other funding rates for other specific categories of costs as detailed in Federal statute and regulations. The information collected in this report is used by this agency to calculate quarterly Federal

grant awards and to enable oversight of the financial management of the programs.

*Respondents:* States (including Puerto Rico and the District of Columbia) and Tribes\* with approved title IV–E plans. (\*An estimated 10 Tribes will have approved title IV–E plans within the next 3-year period.)

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Form CB–496: Title IV–E Programs Quarterly Financial Report .....	62	4	20	4,960

Estimated Total Annual Burden Hours: 4,960.

In compliance with the requirements of Section 506(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, 370 L’Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@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.

**Robert Sargis,**  
*Reports Clearance Officer.*  
 [FR Doc. 2012–28340 Filed 11–21–12; 8:45 am]  
**BILLING CODE 4184–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
**[Docket No. FDA–2012–N–1090]**

**Provisions of the Food and Drug Administration Safety and Innovation Act Related to Medical Gases; Establishment of a Public Docket**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is establishing a public docket for information pertaining to FDA’s implementation of the provisions of the Food and Drug Administration Safety and Innovation Act (FDASIA) related to medical gases. This action is intended to ensure that information submitted to FDA on the implementation of the medical gas provisions of FDASIA is available to all interested persons in a timely fashion.

**DATES:** Submit electronic or written comments by November 25, 2013.  
**ADDRESSES:** Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6368, Silver Spring, MD 20993–0002, 301–796–3522, [patrick.raulerson@fda.hhs.gov](mailto:patrick.raulerson@fda.hhs.gov); or Germaine Connolly, Center for Veterinary Medicine, Food and Drug

Administration, 7500 Standish Pl., MPN2, Rockville, MD 20855, 240–276–8331, [germaine.connolly@fda.hhs.gov](mailto:germaine.connolly@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On July 9, 2012, President Obama signed into law FDASIA (Pub. L. 112–144, 126 Stat. 993). Title XI, Subtitle B, section 1111 of FDASIA added new sections 575, 576, and 577 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) regarding medical gases. Among other things, these new sections define the terms “designated medical gas” and “medical gas” and establish the process for the certification of a medical gas as a designated medical gas. (See sections 575(1) and (2) of the FD&C Act.) The sections describe the process for filing a request for certification and describe the information that should be included in the request for certification. (See section 576(a) of the FD&C Act.) Under section 576(a)(3) of the FD&C Act, if a certification is granted for a designated medical gas, the designated medical gas will be deemed to have in effect an approved new human drug application under section 505 (21 U.S.C. 355) or an approved new animal drug application under section 512 (21 U.S.C. 360b) of the FD&C Act for certain specified indications and subject to all applicable postapproval requirements. Under section 576(a)(1) of the FD&C Act, requests for certification may be submitted to FDA beginning 180 days after the enactment of FDASIA, or January 5, 2013.

FDA is establishing a public docket for information pertaining to FDA’s implementation of these new medical gas provisions. This action is intended to ensure that information submitted to FDA on the implementation of the medical gas provisions of FDASIA is available to all interested persons in a timely fashion. The Compressed Gas