information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box, and follow the prompts; and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg. 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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.

**FOR FURTHER INFORMATION CONTACT:** Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance for industry entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' The guidance addresses provisions in the FD&C Act, as amended by the DSCSA (Pub. L. 113–54). Section 202 of the DSCSA adds section 582(h)(2) to the FD&C Act (21 U.S.C. 360eee–1(h)(2)), which requires FDA to issue guidance to aid certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) in identifying a suspect product and terminating notifications. The guidance identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain, and provides recommendations on how trading partners can identify such product and determine whether the product is a suspect product as soon as practicable.

Beginning January 1, 2015, section 582 of the FD&C Act required trading partners, upon determining that a product in their possession or control is illegitimate, to notify: (1) FDA and (2) all immediate trading partners that they have reason to believe may have received the illegitimate product, not later than 24 hours after making the determination. Manufacturers are additionally required under section 582(b)(4)(B)(ii)(II) of the FD&C Act to notify FDA and any immediate trading partners that the manufacturer has reason to believe may possess a product manufactured by (or purported to be manufactured by) the manufacturer, not later than 24 hours after the manufacturer determines or is notified by FDA or a trading partner that there is a high risk that a product is illegitimate. Section III.C of this guidance, entitled ''For Manufacturers: High Risk of Illegitimacy Notification'' and highlighted in grey, describes notifications related to products that pose a high risk of illegitimacy, and is marked ''for comment purposes only'' to provide an opportunity for comment before it is finalized. The guidance also addresses how trading partners should notify FDA using Form FDA 3911. In addition, in accordance with section 582(h)(2) of the FD&C Act, the guidance sets forth the process by which trading partners must terminate the notifications using Form FDA 3911, in consultation with FDA, regarding illegitimate product and, for a manufacturer, a product with a high risk of illegitimacy, under section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) of the FD&C Act.

In the **Federal Register** of June 11, 2014 (79 FR 33564), FDA announced the availability of a draft guidance entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' FDA has carefully considered the comments received and made the following changes in response to the comments: Section C, ''For Manufacturers: High Risk of Illegitimacy Notifications,'' on pgs. 8–11 of the guidance, is a new section added in response to comments and questions received. In addition, FDA made minor changes to the Form FDA 3911 and to the instructions for completing the form.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' It does not establish any rights for any person and, with the exception of section IV.B, is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

## III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0806.

Dated: December 5, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–29588 Filed 12–8–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Council on Graduate Medical Education

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice of charter renewal.

**SUMMARY:** HHS is hereby giving notice that the Council on Graduate Medical Education (COGME) has been renewed. The effective date of the renewed charter is September 30, 2016.

**FOR FURTHER INFORMATION CONTACT:** Dr. Kennita Carter, Senior Advisor and Designated Federal Official, Division of Medicine and Dentistry, HRSA, HHS, 15M116, 5600 Fishers Lane, Rockville, MD 20857. Phone: (301) 945–3505; email: *kcarter@hrsa.gov.*

**SUPPLEMENTARY INFORMATION:** COGME is authorized by section 762 (42 U.S.C. 294o) of the Public Health Service Act,

as amended. Except where otherwise indicated, COGME is governed by provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2), as amended, which sets forth standards for the formation and use of advisory committees. In accordance with the Federal Advisory Committee Act (FACA), COGME was initially chartered on September 30, 1996, and has been renewed at appropriate intervals.

COGME provides advice to the Secretary of HHS (Secretary) on a range of issues including: The supply and distribution of physicians in the United States; current and future physician shortages or excesses; issues relating to foreign medical school graduates; Federal policies related to the previously listed topics, including policies concerning changes in the financing of medical education training; and the development of performance measures and longitudinal evaluation of medical education programs. COGME's reports are submitted to the Secretary and Chairmen and Ranking Members of the Senate Committee on Health, Education, Labor, and Pensions and the House of Representatives Committee on Energy and Commerce.

Renewal of the COGME charter authorizes the Committee to operate until September 30, 2018.

A copy of the COGME charter is available on the COGME Web site at *http://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/index.html*. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is *http://www.facadatabase.gov/*.

**Jason E. Bennett,**

*Director, Division of the Executive Secretariat.*

[FR Doc. 2016–29499 Filed 12–8–16; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Public Comment Request; Children's Hospitals Graduate Medical Education Payment Program Application and Full-Time Equivalent Resident Assessment Forms

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than January 9, 2017.

**ADDRESSES:** Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N–39, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Children's Hospitals Graduate Medical Education Payment Program Application and Full-Time Equivalent Resident Assessment Forms OMB No. 0915–0247 Revision.

*Abstract:* The Children's Hospitals Graduate Medical Education (CHGME) Payment Program was enacted by Public Law 106–129, and reauthorized by the CHGME Support Reauthorization Act of 2013 (Pub. L. 113–98) to provide Federal support for graduate medical education (GME) to freestanding children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. The CHGME Payment Program application and full-time equivalent (FTE) resident assessment forms received OMB clearance on June 30, 2014.

The CHGME Support Reauthorization Act of 2013 included a provision to allow certain newly qualified children's hospitals to apply for CHGME Payment Program funding. The CHGME Payment Program application forms have been revised to accommodate the new statute. In addition, a payment question included in the CHGME Payment Program application forms has been removed, since the participating children's hospitals are now required to electronically communicate their financial information to the Payment Management System through the Electronic Handbook.

The form changes are only applicable to the HRSA 99–1 (also known as Exhibit O (2)) and HRSA 99–5 forms. All other hospital and auditor forms are the same as currently approved. The changes to the HRSA 99–1 and HRSA 99–5 forms require OMB approval and are as follows:

*1. HRSA 99–1:* Add additional description to Line 4.06 (both Page 2 and Page 2 Supplemental), 5.06 and 6.06. The current description is ''FTE adjusted cap.'' The new description will be ''FTE adjusted cap or 2013 CHGME Reauthorization cap due to Public Law 113–98.''

*2. HRSA 99–5:* Remove Payment Information question and check boxes, applicable only to: (1) Hospitals which have not previously participated in the CHGME Payment Program, and (2) hospitals in which financial institution information has changed since submission of its last application.

*Need and Proposed Use of the Information:* Data on the number of FTE residents trained are collected from children's hospitals applying for CHGME Payment Program funding. These data are used to determine the amount of direct and indirect medical education payments to be distributed to participating children's hospitals. Indirect medical education payments are derived from a formula that requires the reporting of discharges, beds, and case mix index information from participating children's hospitals. As required by statute, the FTE resident assessment shall determine any changes to the FTE resident counts initially reported to the CHGME Payment Program.

*Likely Respondents:* The likely respondents include the estimated 60 children's hospitals that apply and receive CHGME Payment Program funding, as well as the 30 auditors contracted by HRSA to perform the FTE resident assessments of the children's hospitals participating in the CHGME Payment Program. Children's hospitals applying for CHGME Payment Program funding are required by the CHGME Payment Program statute to submit data on the number of FTE residents trained in an annual application. Once funded by the CHGME Payment Program, these same children's hospitals are required to submit audited data on the number of FTE residents trained during the federal fiscal year to participate in the reconciliation payment process. Contracted auditors are requested by