selection of their providers. It also allows advocacy organizations, researchers, and other interested parties access to information on the quality of care provided to Medicaid beneficiaries enrolled in Medicaid/CHIP MCOs. States use the information during their oversight of these organizations. *Form Number:* CMS–R–305 (OMB control number 0938–0786); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 629; *Total Annual Responses:* 4,869; *Total Annual Hours:* 426,492. (For policy questions regarding this collection contact Jennifer Sheer at 410–786–1769.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Report of a Hospital Death Associated with Restraint or Seclusion; *Use:* The final rule, which finalized the regulations at 42 CFR 482.13(g), published on May, 16, 2012 (77 FR 29074) included a reduction in the reporting requirements related to hospital deaths associated with the use of restraint or seclusion. Section § 482.13(g) requires that hospitals must use form CMS–10455 to report those deaths associated with restraint and/or seclusion directly to the Centers for Medicare & Medicaid Services (CMS) Regional Office (RO). This requirement also applies to rehabilitation or psychiatric distinct part units (DPUs) in Critical Access Hospitals (CAHs). Currently, the hospital, CAH, or psychiatric DPU must submit the form CMS–10455 to the CMS RO via fax or email, based on RO's preference. Beginning on May 9, 2014, hospitals were no longer required to report to CMS, those deaths that were not associated with the use of seclusion and where the only restraints used were 2-point soft wrist restraints. This reporting requirement change resulted in no necessary edits to the form CMS–10455. It was estimated that this would reduce the volume of reports that must be submitted by 90 percent for hospitals. In addition, the final rule replaced the previous requirement for reporting via telephone to CMS, which proved to be cumbersome for both CMS and hospitals, with a requirement that allows the submission of reports on the form CMS–10455 via facsimile or electronically, as determined by CMS. In this PRA package, CMS is seeking OMB approval for an electronically submitted version of the currently approved paper version of form CMS–10455. *Form Number:* CMS–10455 (OMB control number: 0938–1210); *Frequency:* Occasionally; *Affected Public:* Private Sector; *Number of Respondents:* 6,389; *Number of Responses:* 6,389; *Total Annual Hours:* 6,389. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

4. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of*

Information Collection: Marketplace Quality Standards; *Use:* The Patient Protection and Affordable Care Act establishes requirements to support the delivery of quality health care coverage for health insurance issuers offering Qualified Health Plans (QHPs) in Exchanges. Section 1311(c)(3) of the Patient Protection and Affordable Care Act directs the Secretary to develop a system to rate QHPs on the basis of quality and price and requires Exchanges to display this quality rating information on their respective websites. Section 1311(c)(4) of the Patient Protection and Affordable Care Act requires the Secretary to develop an enrollee satisfaction survey system to assess enrollee experience with each QHP (with more than 500 enrollees in the previous year) offered through an Exchange. Section 1311(h) requires QHPs to contract with certain hospitals that meet specific patient safety and health care quality standards.

This collection of information is necessary to provide adequate and timely health care quality information for consumers, regulators, and Exchanges as well as to collect information to appropriately monitor and provide a process for a survey vendor to appeal HHS' decision to not approve a QHP Enrollee Survey vendor application. *Form Number:* CMS–10520 (OMB control number: 0938–1249) *Frequency:* Annually. *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions). *Number of Respondents:* 264. *Total Annual Responses:* 264. *Total Annual Hours:* 348,764. (For policy questions regarding this collection contact Nidhi Singh Shah at 301–492–5110.)

Dated: February 8, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–02231 Filed 2–13–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4417]

Center for Drug Evaluation and Research's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality.'' This guidance describes a proposed program at FDA's Center for Drug Evaluation and Research (CDER) to make public a comprehensive listing of informally recognized voluntary consensus standards related to pharmaceutical quality. This program, once established, will facilitate submissions by external stakeholders and CDER staff proposing voluntary consensus standards related to pharmaceutical quality for informal recognition. CDER believes that this informal program, which is different than the formal recognition standards program in FDA's Center for Devices and Radiological Health, will help promote innovation in pharmaceutical development and manufacturing and streamline the compilation and assessment of marketing applications for products regulated by CDER. CDER is issuing this draft guidance to obtain public comments on the proposed program.

DATES: Submit either electronic or written comments on the draft guidance by April 15, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by April 15, 2019.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to *https://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 *https://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'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–4417 for ''CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Colleen Thomas, Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4334, Silver Spring, MD 20993–0002, 301–796–4853.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality.'' This program, once established, will facilitate submissions by external stakeholders and CDER staff proposing voluntary consensus standards related to pharmaceutical quality for informal recognition.

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) and Circular A–119 by the Office of Management and Budget (OMB) have established Federal Government policies to improve the internal management of the executive branch by directing agencies to use voluntary consensus standards developed or adopted by a standards developing organization—rather than Government-unique standards—except where these standards are inconsistent with applicable law or otherwise impractical. FDA's development and use of standards have been integral to the execution of FDA's mission.

CDER believes that this informal program, which is different than the formal recognition standards program in FDA's Center for Devices and Radiological Health, will help promote innovation in pharmaceutical development and manufacturing and streamline the compilation and review of marketing applications for products regulated by CDER. CDER also believes that this program will: (1) Allow CDER to communicate to external stakeholders that its relevant expert(s) have evaluated a consensus standard and determined if that standard is potentially useful both to industry and CDER staff and (2) provide transparency to industry regarding CDER's thinking about a method or approach.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality. It does not establish any rights for any person and 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this

requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Request for Recognition of a Voluntary Consensus Standard

OMB Control Number 0910–NEW

The draft guidance for industry entitled ''CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality'' provides guidance to industry about the procedures the Center for Drug Evaluation and Research follows when a request for recognition of a voluntary consensus standard is received. The guidance outlines justifications for why a standard may be recognized wholly, partly, or not at all. The guidance also provides that any interested party may request recognition of a standard. Specifically, this process will allow CDER to:

- Receive a candidate consensus standard, with relevant information (*e.g.,* the scope of the standard and the purpose), from internal or external parties for informal recognition.
- Determine whether to informally recognize a standard in whole or in part following an internal scientific evaluation.
- List the informally recognized standards in a publicly searchable database on CDER's website, accompanied by an information sheet describing the scope and the extent of CDER's informal recognition of that standard and any other relevant information about it.

Request for Recognition of a Voluntary Consensus Standard

We estimate that FDA will receive nine requests annually. We estimate that each request will take less than 1 hour to prepare.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for recognition of a voluntary consensus standard	9	1	9	1	9

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: February 11, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02326 Filed 2–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Council on Graduate Medical Education

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

ACTION: Notice.

SUMMARY: The Council on Graduate Medical Education (COGME) has scheduled a public meeting. Information about COGME and the agenda for this meeting can be found on the COGME website at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/index.html.*

DATES: June 5, 2019, 8:30 a.m.–5:00 p.m. and June 6, 2019, 8:30 a.m.–2:00 p.m. ET.

ADDRESSES: This meeting will be held in-person and through teleconference and webinar. The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857.

- Conference call-in number is: 1–888–455–0640.
- Passcode is: HRSA COUNCIL (voice response).
- Webinar link is: *https://hrsa.connectsolutions.com/cogme.*

FOR FURTHER INFORMATION CONTACT: Kennita R. Carter, MD, Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, 15N–116, Rockville, Maryland 20857; 301–945–3505; or *KCarter@hrsa.gov.*

SUPPLEMENTARY INFORMATION: COGME makes recommendations to the Secretary of HHS (Secretary) and Congress on policy, program development, and other matters of significance as specified by section 762 of Title VII of the Public Health Service (PHS) Act. Issues addressed by COGME include (1) the nature and financing of medical education training; (2) the development of performance measures and longitudinal evaluation methods of medical education programs; (3) foreign medical school graduates; (4) the supply and distribution of the physician workforce in the United States, including any projected shortages or excesses; (5) deficiencies in databases of the supply and distribution of the physician workforce and postgraduate programs for training physicians; and (6) appropriation levels for certain programs under Title VII of the PHS Act. Additionally, COGME encourages entities providing graduate medical education to conduct activities to voluntarily achieve the recommendations of the council. COGME submits reports to the Secretary of HHS, the Senate Committee on Health, Education, Labor and Pensions, and the House of Representatives Committee on Energy and Commerce.

During the June 2019, meeting, COGME will discuss the topic of rural health in relation to workforce development and graduate medical education financing. Agenda items are subject to change as priorities dictate. Refer to the COGME website for any updated information concerning the meeting. The meeting agenda will be available on the COGME website at least 14 calendar days prior to the meeting.