DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10102 and CMS–10377]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by February 11, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10102 National Implementation of the Hospital CAHPS Survey

CMS–10377 Student Health Insurance Coverage

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* National Implementation of the Hospital CAHPS Survey; *Use:* The HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey, also known as the CAHPS® Hospital Survey or Hospital CAHPS®, is a standardized survey instrument and data collection methodology that has been in use since 2006 to measure patients' perspectives of hospital care. While many hospitals collect information on patient satisfaction, HCAHPS created a national standard for the collection and public reporting of information that enables valid comparisons to be made across all hospitals to support consumer choice.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 through 38342), out of an abundance of caution, in the face of a nationwide epidemic of opioid over prescription, we finalized a refinement to the HCAHPS Survey measure as used in the Hospital Inpatient Quality Reporting Program by removing the previously adopted Pain Management questions and incorporating new Communication About Pain questions beginning with patients discharged in January 2018. As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37218), since finalization of the Communication About Pain questions, we have received feedback that some stakeholders are concerned that, although the revised questions focus on communications with patients about their pain and treatment of that pain, rather than how well their pain was controlled, the questions still could potentially impose pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the HCAHPS Survey.

In response to stakeholder feedback, recommendations from the *President's Commission on Combatting Drug Addiction and the Opioid Crisis,* to comply with the requirements of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115–271), and to avoid any potential unintended consequences under the Hospital Inpatient Quality Reporting (IQR) Program, CMS is revising the HCAHPS survey by removing the three recently revised pain communication questions. The removal of these questions is effective with October 2019 discharges. At that point, the HCAHPS Survey will consist of 29 questions which will decrease the burden hours. *Form Number:* CMS–10102 (OMB control number 0938–0981); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 4,200; *Total Annual Responses:* 3,104,200; *Total Annual Hours:* 379,290. (For policy questions regarding this collection contact William Lehrman at 410–786–1037.)

2. *Type of Information Collection Request:* Extension; *Title of Information Collection:* Student Health Insurance Coverage; *Use:* Under the Student

Health Insurance Coverage Final Rule published March 21, 2012 (77 FR 16453), student health insurance coverage is a type of individual health insurance coverage provided pursuant to a written agreement between an institution of higher education (as defined in the Higher Education Act of 1965) and a health insurance issuer, and provided to students who are enrolled in that institution and their dependents. The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule provided that, for policy years beginning on or after July 1, 2016, student health insurance coverage is exempt from the actuarial value (AV) requirements under section 1302(d) of the Affordable Care Act, but must provide coverage with an AV of at least 60 percent. This provision also requires issuers of student health insurance coverage to specify in any plan materials summarizing the terms of the coverage the AV of the coverage and the metal level (or the next lowest metal level) the coverage would otherwise satisfy under § 156.140. This disclosure will provide students with information that allows them to compare the student health coverage with other available coverage options. *Form Number:* CMS–10377 (OMB control number 0938–1157); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 52; *Total Annual Responses:* 1,176,235; *Total Annual Hours:* 52. (For policy questions regarding this collection contact Russell Tipps at 301–492–4371.)

Dated: December 6, 2018.

William N. Parham, III,

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

[FR Doc. 2018–26790 Filed 12–10–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4087]

The Food and Drug Administration's Proposed Current Good Manufacturing Practice Policies for Outsourcing Facilities: Considerations Regarding Access to Office Stock; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled ''FDA's Proposed Current Good Manufacturing Practice Policies for Outsourcing Facilities: Considerations Regarding Access to Office Stock.'' Stakeholders, including healthcare providers (HCPs) and medical specialty groups, have expressed concerns regarding the availability of certain compounded drug products from outsourcing facilities that they would like to have on-hand as in-office supplies of non-patient-specific compounded drugs (''office stock''). The purpose of the public meeting is to provide HCPs, outsourcing facilities, entities considering becoming outsourcing facilities, and other interested parties with an opportunity to present to FDA their perspectives concerning access to office stock from outsourcing facilities in light of FDA's enforcement policies as proposed in the revised draft guidance on current good manufacturing practice (CGMP) for human drug compounding outsourcing facilities.

DATES: The public meeting will be held on May 21, 2019, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by June 21, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 21, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 21, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 Docket No. FDA–2018–N–4087 for ''FDA's Proposed Current Good Manufacturing Practice Policies for Outsourcing Facilities: Considerations Regarding Access to Office Stock.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' are publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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