Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## Background on Common Formats Development

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70731–70814, provide for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The collection of patient safety work product allows for the aggregation of data that help to identify and address underlying causal factors of patient safety and quality issues.

The Patient Safety Act provides for AHRQ to develop standardized reporting formats using common language and definitions (Common Formats) for reporting on health care quality and patient safety that will ensure that data collected by PSOs and other entities have comparable clinical meaning. The Common Formats facilitate aggregation of comparable data at local, PSO, regional and national levels. In addition, the Common Formats are intended to enhance the reporting of information that is standardized both clinically and electronically.

AHRQ has developed Common Formats for three settings of care—acute care hospitals, skilled nursing facilities, and community pharmacies—for use by health care providers and PSOs. AHRQ-listed PSOs are required to collect patient safety work product in a standardized manner to the extent practical and appropriate; a requirement the PSO can meet by collecting such information using Common Formats. Additionally, providers and other organizations not working with an AHRQ-listed PSO can use the Common Formats in their work to improve quality and safety; however, they cannot benefit from the federal confidentiality and privilege protections of the Patient Safety Act.

Since February 2005, AHRQ has convened the Federal Patient Safety Work Group (PSWG) to assist AHRQ in developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS as well as the Departments of Defense and Veterans Affairs. The PSWG helps assure the consistency of definitions/formats with those of relevant government agencies. In addition, AHRQ has solicited comments from the private and public sectors regarding proposed versions of the Common Formats through a contract, since 2008, with the National Quality Forum (NQF), which is a non-profit organization focused on health care quality. After receiving comments, the NQF solicits review of the formats by its Common Formats Expert Panel. Subsequently, NQF provides this input to AHRQ who then uses it to refine the Common Formats before issuing as a production version.

Previously, AHRQ's primary focus with the Common Formats has been to support traditional event reporting. For the Common Formats, it should be noted that AHRQ uses the term ''surveillance'' to refer to the improved detection of events and calculation of adverse event rates in populations reviewed that will allow for collection of comparable performance data over time and across settings. These formats are designed to provide, through retrospective review of medical records, information that is complementary to that derived from event reporting systems. For more information on AHRQ's efforts measuring patient safety in this area, please go to: *https://www.ahrq.gov/news/blog/ahrqviews/new-system-aims-to-improve-patient-safety-monitoring.html.*

## Commenting on Common Formats: Common Formats for Surveillance—Hospital Version 0.2 Beta

AHRQ is specifically interested in receiving feedback in order to guide the improvement of the Common Formats. Information on how to comment on the *Common Formats for Surveillance—Hospital Version 0.2 Beta* is available at: *http://www.qualityforum.org/Project_Pages/Common_Formats_for_Patient_Safety_Data.aspx.*

Additional information about the Common Formats can be obtained through AHRQ's PSO website: *https://pso.ahrq.gov/.*

**Francis D. Chesley, Jr.,**

*Acting Deputy Director.*

[FR Doc. 2018–09870 Filed 5–8–18; 8:45 am]

**BILLING CODE 4160–90–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–10102]**

### 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 *July 9, 2018.*

**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' 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:** William Parham 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**

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:* Extension 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. *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:* 3,100,000; *Total Annual Hours:* 413,230. (For policy questions regarding this collection contact William Lehrman at 410–786–1037.)

Dated: May 2, 2018.

**William N. Parham, III,**

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

[FR Doc. 2018–09686 Filed 5–8–18; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–D–1434]**

### Waivers, Exceptions, and Exemptions From the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act; 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 ''Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act.'' When finalized, this draft guidance will describe the process that trading partners and stakeholders should use to request a waiver, exception, or exemption from certain requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and describe how FDA intends to review and decide such requests and determine FDA-initiated exceptions and exemptions. Additionally, when finalized, this draft guidance will describe how FDA intends to biennially review and renew waivers, exceptions, and exemptions.

**DATES:** Submit either electronic or written comments on the draft guidance by July 9, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**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–1434 for ''Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry.'' 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 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