

Commission tries to remove individuals' home contact information from comments before placing them on the Commission website.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/altfuelspra>, by following the instructions on the web-based form. When this Notice appears at <http://www.regulations.gov/#/home>, you also may file a comment through that website.

If you file your comment on paper, write "Paperwork Comment: FTC File No. P134200" on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC website at <https://www.ftc.gov/>, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 28, 2019. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

**Heather Hipsley,**

*Deputy General Counsel.*

[FR Doc. 2018-25964 Filed 11-28-18; 8:45 am]

**BILLING CODE 6750-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Common Formats for Patient Safety Data Collection

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

**ACTION:** Notice of availability—New Common Formats.

**SUMMARY:** As authorized by the Secretary of HHS, AHRQ coordinates the development of common definitions and reporting formats (Common Formats or formats) for reporting on health care quality and patient safety. The purpose of this notice is to announce the availability of *Common Formats for Surveillance—Hospital Version 0.2 Beta*.

**DATES:** Ongoing public input.

**ADDRESSES:** The *Common Formats for Surveillance—Hospital Version 0.2 Beta* can be accessed electronically at the following website: [https://www.psoppc.org/psoppc\\_web/publicpages/commonFormatsOverview](https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview).

#### FOR FURTHER INFORMATION CONTACT:

Dr. Hamid Jalal, Center for Quality 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: [psa@ahrq.hhs.gov](mailto:psa@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 299b-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 and analyze confidential and privileged information regarding the quality and safety of health care delivery that meets the definition of patient safety work product. Aggregation of these data enables PSOs and others to identify and address underlying causal factors of patient safety and quality issues.

The Patient Safety Act provides for the development of standardized reporting formats using common language and definitions to ensure that health care quality and patient safety data collected by PSOs and other entities are comparable. The Common Formats facilitate aggregation of comparable data at local, PSO, regional and national levels. In addition, the 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; this is 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 with 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 formats.

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>.

AHRQ announced the availability of the, *Common Formats for Surveillance—Hospital Version 0.2 Beta*, for review and comment on May 9, 2018 in the **Federal Register** (83 FR 21295–21296). After obtaining feedback, the Agency revised and finalized the formats through the development of event descriptions which are definitions of patient safety events, near misses, and unsafe conditions. The *Common Formats for Surveillance—Hospital Version 0.2 Beta* will be posted at the PSOPPC website: [https://www.psoppc.org/psoppc\\_web](https://www.psoppc.org/psoppc_web).

Additional information about the Common Formats can be obtained

through AHRQ's PSO website: <https://psoppc.ahrq.gov/>.

**Francis D. Chesley, Jr.,**  
*Acting Deputy Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers CMS–10137 and CMS–10675]**

#### Agency Information Collection Activities: Submission for OMB Review; 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by December 31, 2018.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 OR, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

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](mailto: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:** Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2020 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application. The information will