

the accomplishments of the committee's objectives. The Administrator is seeking nominations for members fulfilling the following categories:

- Environmental medicine or environmental health specialist;
- Epidemiologist;
- Occupational physician who has experience treating WTC rescue and recovery workers;
- Occupational physician;
- Representative of WTC responders; and
- Toxicologist.

Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address);

- The category of membership (environmental medicine or environmental health specialist, occupational physician, pulmonary physician, representative of WTC responders, certified-eligible WTC survivor representative, industrial hygienist, toxicologist, epidemiologist, or mental health professional) that the candidate is qualified to represent);

- A summary of the background, experience, and qualifications that demonstrates the nominee's suitability for the nominated membership category; and

- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. (Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (e.g., CDC, NIH, FDA, etc.).

Nominations may be submitted by the candidate him- or herself, or by the person/organization recommending the candidate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10656 and CMS-10455]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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 January 8, 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' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

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-10656 Evaluation of the Partnership for Patients (PfP) 3.0
 CMS-10455 Report of a Hospital Death Associated with Restraint or Seclusion

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:* New collection of information request; *Title of Information Collection:* Evaluation of the Partnership for Patients (PfP) 3.0; *Use:* In the summer of 2015, the Centers for Medicare & Medicaid Services (CMS) Administrator approved the plans for integration of the Partnership for Patients (PfP) Hospital Engagement Network (HEN) model test with the Quality Improvement Network-Quality Improvement Organization (QIN-QIO) program. This is consistent

with the Agency's intention for further integration to maximize the strengths of the QIO program and PfP HENs to sustain and expand current national reductions in in-patient harm and 30-day readmissions. The alignment of the two programs permits the systematic use of innovative patient safety practices at a national scale.

Under this initiative, CMS has awarded multiple contracts to Hospital Improvement Innovation Networks (HIINs), formerly known as HENs, to engage the hospital, provider, and broader caregiver communities to implement well-tested and measured best practices. The end result of the overall initiative is the anticipated reduction in preventable hospital-based harm and readmissions for patients.

The PfP initiative is a public-private partnership dedicated to the improvement of health care quality, safety, and affordability. CMS, working with hospitals, providers, and the broader caregiver community, aims to implement and disseminate best practices on a national scale to reduce hospital acquired conditions (HACs) and all-cause readmissions. Through the PfP model, which was initiated in April 2011, CMS fostered rapid learning among a nationwide community of practice, resulting in major strides in patient safety and engagement by patients and families.

A mixed methods approach to answering the PfP HIIN evaluation questions includes three primary data collection activities, as follows: Hospital Survey on Prevention of Adverse Events and Reduction of Readmissions, HIIN Data Quality Assurance (QA) Survey and Qualitative Discussions with HIIN leaders and Other Support Contractors. The data collected will provide us feedback to focus efforts to improve the effectiveness and efficiency of the HIIN initiative. As we draft future HIIN and QIO contracts, information from hospitals about HIIN influence on their care processes will be used together with follow-up input from stakeholders about the survey results. *Form Number:* CMS-10656 (OMB Control Number: 0938-NEW); *Frequency:* Annually; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 835; *Total Annual Responses:* 854; *Total Annual Hours:* 392. (For policy questions regarding this collection contact Israel Cross at 410-786-0619.)

2. *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

regulation that was published on May, 16, 2012 (77 FR 29074) included a reduction in the reporting requirement related to hospital deaths associated with the use of restraint or seclusion, § 482.13(g). 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). The RO must provide hospitals with instructions for submitting the form fax and/or email, based on RO preference. Hospitals are no longer required to report to CMS those deaths where there was no use of seclusion and the only restraint was 2-point soft wrist restraints beginning in May 9, 2014. This reporting requirement change resulted in no necessary edits to the form CMS-10455 as soft wrist restraints may be used in combination with other types of restraints. 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 submission of reports via telephone, facsimile or electronically, as determined by CMS.

Form CMS-10455 is being revised in order to obtain the necessary information for the ROs to make a determination whether or not to authorize an on-site investigation related to the details surrounding the death of individuals associated with restraint and/or seclusion. *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:* 2,619. (For policy questions regarding this collection contact Karina Meushaw at 410-786-1000.)

Dated: November 1, 2017.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0529]

Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery; 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 guidance for industry entitled "Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery." The guidance is intended to promote the safe use of nonprescription (also referred to as over-the-counter or OTC) aspirin drug products by encouraging drug manufacturers, packagers, and labelers marketing aspirin drug products with cardiovascular-related imagery to include a statement that reminds consumers to talk to their health care provider before using aspirin for their heart.

DATES: The announcement of the guidance is published in the **Federal Register** on November 7, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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