

largely extends the transparency reporting provisions set forth in section 1311(e)(3) to non-grandfathered group health plans (including large group and self-insured health plans) and health insurance issuers offering group and individual health insurance coverage (non-QHP issuers), the Departments intend to propose other transparency reporting requirements at a later time, through a separate rulemaking conducted by the Departments, for non-QHP issuers and non-grandfathered group health plans. Those proposed reporting requirements may differ from those prescribed in the HHS proposal under section 1311(e)(3), and will take into account differences in markets, reporting requirements already in existence for non-QHPs (including group health plans), and other relevant factors. The Departments also intend to streamline reporting under multiple reporting provisions and reduce unnecessary duplication. The Departments intend to implement any transparency reporting requirements applicable to non-QHP issuers and non-grandfathered group health plans only after notice and comment, and after giving those issuers and plans sufficient time, following the publication of final rules, to come into compliance with those requirements. *Form Number:* CMS-10572 (OMB control number: 0938-New); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other For-profit and Not-for-profit institutions); *Number of Respondents:* 475; *Total Annual Responses:* 475; *Total Annual Hours:* 16,150. (For policy questions regarding this collection contact Valisha Price at 301-492-4343).

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Home Health Face-to-Face Encounter Clinical Templates; *Use:* The Centers for Medicare & Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval of the collection of data required to support the eligibility of Medicare home health services. Home health services are covered under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. It consists of part-time, medically necessary skilled care (nursing, physical therapy, occupational therapy, and speech-language therapy) that is ordered by a physician. The CMS has developed a list of clinical elements within a suggested electronic clinical template that would allow electronic health record vendors to create prompts to assist physicians when documenting

the HH face-to-face encounter for Medicare purposes. Once completed by the physician, the resulting progress note or clinic note would be part of the medical record. The primary users of these new clinical templates will be physicians and/or allowed non-physician practitioners (NPPs). The templates will help users to capture the necessary information needed to complete the face-to-face encounter documentation. This will help physicians and/or allowed NPPs comply with Medicare policy requirements, thereby reducing the possibility of a home health claim not being paid because of failure to meet Medicare requirements. *Form Number:* CMS-10564 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other For-profit and Not-for-profit institutions); *Number of Respondents:* 2,926,420; *Total Annual Responses:* 2,926,420; *Total Annual Hours:* 1,220,317. (For policy questions regarding this collection contact Kristal Vines at 410-786-0119).

Dated: August 7, 2015.

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

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-2540-10]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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 any of the following subjects: (1) The necessity and

utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) 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 September 11, 2015.

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.

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: Reports Clearance Office at (410) 786-1326.

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:* Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report Form; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Form CMS-2540-10 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. The revisions made to the SNF cost report are in accordance with the statutory requirement for hospice payment reform in § 3132 of the Patient Protection and Affordable Care Act (ACA). *Form Number:* CMS-2540-10 (OMB control number 0938-0463); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 14,398; *Total Annual Responses:* 14,398; *Total Annual Hours:* 2,908,396. (For policy questions regarding this collection contact Amelia Citerone at 410-786-8008).

Dated: August 7, 2015.

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-2009-D-0268]

Agency Information Collection Activities; Proposed Collection; Comment Request; Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public

comment on our proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments on the information collection provisions of the recommended labeling of certain beers subject to our labeling jurisdiction.

DATES: Submit either electronic or written comments on the collection of information by October 13, 2015.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: 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. "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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our 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.

Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration—(OMB Control Number 0910-0728)—Extension

The definition of "food" under section 201(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) See 21 U.S.C. 321(f), includes "articles used for food or drink" and thus includes alcoholic beverages. As such, alcoholic beverages are subject to the FD&C Act's adulteration and misbranding provisions, and implementing regulations, related to food. For example, manufacturers of alcoholic beverages are responsible for adhering to the registration of food facilities requirements in 21 CFR part 1 and to the good manufacturing practice regulations in 21 CFR part 110. There are also certain requirements for nutrition labeling on menus, menu boards, and other written materials for alcohol beverages served in restaurants or similar retail food establishments in 21 CFR part 101 (79 FR 71156, December 1, 2014). However, as reflected in a 1987 Memorandum of Understanding between FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB), TTB is responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, certain wines, and malt beverages pursuant to the Federal Alcohol Administration Act (FAA Act). In TTB Ruling 2008-3, dated July 7, 2008, TTB clarified that certain beers, which are not made from both malted barley and hops but are instead made from substitutes for malted barley (such as sorghum, rice, or wheat) or are made without hops, do not meet the definition of a "malt beverage" under the FAA Act. Accordingly, TTB stated in its ruling that such products (other than sake, which is classified as a wine under the FAA Act), are not subject to the labeling, advertising, or other provisions of the TTB regulations promulgated under the FAA Act.

In cases where an alcoholic beverage is not covered by the labeling provisions of the FAA Act, the product is subject to ingredient and other labeling requirements under the FD&C Act and the implementing regulations that we administer. In addition, as provided for