

eligibility inquiries (270) and responses (271) on a real-time basis. In creating the HETS application, federal law requires that CMS take precautions to minimize the security risk to federal information systems. Accordingly, CMS is requiring that trading partners who wish to connect to the HETS 270/271 application via the CMS Extranet and/or internet agree to specific trading partner terms as a condition of receiving access to Medicare eligibility information. Applicants will complete the entire Trading Partner Agreement form to indicate agreement with CMS trading partner terms and provide sufficient information to establish connectivity to the service and assure that those entities that access the Medicare eligibility information are aware of applicable provisions and penalties for the misuse of information.

CMS uses the Trading Partner Agreement Form to capture certain information whereby a person certifies that they are fully aware of any and all penalties related to the use of PHI and their access to this data from the HETS application. The information is an attestation by the authorized representative of an entity that wishes to access the Medicare eligibility information to conduct real-time eligibility transactions. The authorized representative is a person responsible for business decisions on behalf of the Organization who is submitting the access request. The data captured includes the authorized representative's name, title contact number and the name of the submitting entity. Other data captured is the submitter's National Provider Identifier (NPI), business name, billing address, physical address, and telephone number. *Form Number:* CMS-10157 (OMB control number: 0938-0960); *Frequency:* Annually; *Affected Public:* Private Sector, Businesses or other for-profits; *Number of Respondents:* 1,000; *Total Annual Responses:* 1,000; *Total Annual Hours:* 250. (For policy questions regarding this collection contact Rupinder Singh at 410-786-7484.)

Dated: November 16, 2021.

William N. Parham, III,

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

[FR Doc. 2021-25318 Filed 11-18-21; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10341 and CMS-10653]

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

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 20, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

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 website address at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

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:* Extension of a currently approved collection; *Title of Information Collection:* Section 1115 Demonstration Projects Regulations at 42 CFR 431.408, 431.412, 431.420, 431.424, and 431.428; *Use:* This collection is necessary to ensure that states comply with regulatory and statutory requirements related to the development, implementation and evaluation of demonstration projects. States seeking waiver authority under Section 1115 are required to meet certain requirements for public notice, the evaluation of demonstration projects, and reports to the Secretary on the implementation of approved demonstrations. *Form Number:* CMS-10341 (OMB control number: 0938-1162); *Frequency:* Yearly and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 48; *Total Annual Responses:* 403; *Total Annual Hours:* 41,847. (For policy questions regarding this collection contact Tonya Moore at 410-786-0019.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Coverage of Certain Preventive Services Under the Affordable Care Act; *Use:* The 2018 final regulations titled "Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act" (83 FR 57536) and "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the

Affordable Care Act” (83 FR 57592) expand exemptions for religious beliefs and moral convictions for certain entities or individuals whose health plans may otherwise be subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. The final regulations extend the exemption to health insurance issuers that hold religious or moral objections in certain circumstances, as well as to additional categories of group health plan sponsors.

The 2018 final regulations also leave the accommodation process in place as an optional process for objecting entities who wish to use it, and expand the categories of group health plan sponsors that may avail themselves of the accommodation. To avoid contracting, arranging, paying, or referring for contraceptive coverage, an organization seeking to be treated as an eligible organization may self-certify (by using EBSA Form 700), prior to the beginning of the first plan year to which an accommodation is to apply, that it meets the definition of an eligible organization. The eligible organization must provide a copy of its self-certification to each health insurance issuer that would otherwise provide such coverage in connection with the health plan (for insured group health plans or student health insurance coverage). The issuer that receives the self-certification must provide separate payments for contraceptive services for plan participants and beneficiaries (or students and dependents). For a self-insured group health plan, the self-certification must be provided to its third party administrator. An eligible organization may submit a notification to HHS as an alternative to submitting EBSA Form 700 to the eligible organization’s health insurance issuer or third party administrator. A health insurance issuer or third party administrator providing or arranging payments for contraceptive services for participants and beneficiaries in plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations must provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments.

Under the 2018 final regulations, eligible organizations can revoke the accommodation process if participants and beneficiaries (or student enrollees and covered dependents) receive written notice of such revocation from the issuer or third party administrator, and such revocation will be effective on

the first day of the first plan year that begins on or after thirty days after the date of revocation. Final regulations were published in the **Federal Register** on July 14, 2015 (80 FR 41318) under which qualifying closely held, for-profit entities may avail themselves of the accommodation. Previously, this accommodation had been available only to non-profit eligible organizations. The 2015 final regulations also finalized the 2014 interim final regulations that permit an eligible organization to notify HHS directly that it will not contract, arrange, pay, or refer for all or a subset of contraceptive services. These information collection requirements (ICRs) are intended for use under whichever accommodation process is in effect at the time an entity avails of it (for example, the 2018 final regulations, or the 2015 final regulations). HHS will only implement the ICRs under regulations that are legally in effect at the time the ICRs are used. *Form Number:* CMS–10653 (OMB Control number 0938–1344); *Frequency:* On Occasion; *Affected Public:* Private Sector; *Number of Respondents:* 60; *Number of Responses:* 595,312; *Total Annual Hours:* 72. (For policy questions regarding this collection, contact Usree Bandyopadhyay at 410–786–6650.)

Dated: November 16, 2021.

William N. Parham, III,

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

[FR Doc. 2021–25316 Filed 11–18–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0268]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the

collection of information by December 20, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0728. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 the Federal Food, Drug, and Cosmetic Act (FD&C Act (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. 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 dissemination and enforcement of regulations with respect to the labeling of distilled spirits, certain wines, and malt beverages issued in the Federal Alcohol Administration Act (the FAA Act). In TTB Ruling 2008–3, dated July 7, 2008, TTB clarified that certain beers, which are not made from both malted