

help to inform HHS, Exchanges, and health insurance issuers as to the participation of individuals, employers, and employees in the individual Exchange, and SHOP. *Form Number:* CMS–10516 (OMB Control Number: 0938–1277); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 1,915; *Number of Responses:* 1,915; *Total Annual Hours:* 48,732. (For questions regarding this collection, contact Leigha Basini at (301) 492–4380.)

Dated: April 17, 2018.

William N. Parham, III,

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

[FR Doc. 2018–08325 Filed 4–19–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10653]

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

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human 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 (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 May 21, 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*.

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>.

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

2. 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:* Coverage of Certain Preventive Services Under the Affordable Care Act; *Use:* The 2017 interim final regulations titled “Religious Exemptions and

Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” and “Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” 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 interim final rules extend the exemption to health insurance issuers that hold religious or moral objections in certain circumstances. The interim final rules also allow plan participants and enrollees with sincerely held religious or moral objections to request coverage that does not include contraceptive services.

The interim final rules also leave the accommodation process in place as an optional process for objecting entities who wish to use it voluntarily. 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 alternatively submit a notification to HHS as an alternative to submitting the 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 interim final regulations, eligible organizations can revoke at any time the accommodation process if

participants and beneficiaries receive written notice of such revocation from the issuer or third party administrator in accordance with guidance issued by the Secretary, and if the accommodation process is currently being utilized, 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 rules 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 to effectively exempt their plans from the otherwise applicable requirement to cover certain contraceptive services. Previously, this accommodation had been available only to non-profit eligible organizations. These final rules also finalized the 2014 interim final rules 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.

Due to judicial decisions preliminarily enjoining the implementation of the 2017 interim final regulations, the information collection requirements are drafted to be applicable under whichever accommodation rules are in effect (for example, the 2017 interim final rules, or the 2015 final rules if the 2017 interim final rules continue to be enjoined). 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:* 110; *Number of Responses:* 110; *Total Annual Hours:* 181. (For policy questions regarding this collection, contact Usree Bandyopadhyay at 410-786-6650.)

Dated: April 17, 2018.

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-2018-D-1176]

Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients: Questions and Answers; International Council for Harmonisation; 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 final guidance for industry entitled “Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients: Questions and Answers.” The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. This question and answer (Q&A) guidance addresses questions about implementation of FDA’s guidance “Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients” (ICH Q7). The Q&A guidance is intended to clarify uncertainties due to the interpretation of certain sections of ICH Q7 and to help ensure that all active pharmaceutical ingredients (APIs) meet the standards for quality and purity they purport or are represented to possess.

DATES: The announcement of the guidance is published in the **Federal Register** on April 20, 2018.

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 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-1176 for “Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients: Questions and Answers; International Council for Harmonisation; Guidance for Industry; Availability.” 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 submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked