

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 29, 2017.

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 Web site 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.

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:

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Conditions of Participation for Critical Access Hospitals (CAH) and Supporting

Regulations; *Use:* At the outset of the critical access hospital (CAH) program, the information collection requirements for all CAHs were addressed together under the following information collection request: CMS-R-48 (OCN: 0938-0328). As the CAH program has grown in both scope of services and the number of providers, the burden associated with CAHs with distinct part units (DPUs) was separated from the CAHs without DPUs. Section 1820(c)(2)(E)(i) of the Social Security Act provides that a CAH may establish and operate a psychiatric or rehabilitation DPU. Each DPU may maintain up to 10 beds and must comply with the hospital requirements specified in 42 CFR Subparts A, B, C, and D of part 482. Presently, 105 CAHs have rehabilitation or psychiatric DPUs. The burden associated with CAHs that have DPUs continues to be reported under CMS-R-48, along with the burden for all 4,890 accredited and non-accredited hospitals.

The CAH conditions of participation and accompanying information collection requirements specified in the regulations are used by surveyors as a basis for determining whether a CAH meets the requirements to participate in the Medicare program. We, along with the healthcare industry, believe that the availability to the facility of the type of records and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. *Form Number:* CMS-10239 (OMB Control number: 0938-1043); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profit; *Number of Respondents:* 1,215; *Total Annual Responses:* 144,585; *Total Annual Hours:* 24,183. (For policy questions regarding this collection contact Mary Collins at 410-786-3189.)

Dated: August 24, 2017.

Martique Jones,

*Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2017-18275 Filed 8-29-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: National and Tribal Evaluation of the 2nd Generation of the Health Profession Opportunity Grants.
OMB No.: 0970-0462.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing data collection activities as part of the Health Profession Opportunity Grants (HPOG) to Serve TANF and Other Low Income Individuals. ACF has developed a multi-pronged research and evaluation approach for the HPOG program to better understand and assess the activities conducted and their results. Two rounds of HPOG grants have been awarded—the first in 2010 (HPOG 1.0) and the second in 2015 (HPOG 2.0). There are federal evaluations associated with each round of grants. HPOG grants provide funding to government agencies, community-based organizations, post-secondary educational institutions, and tribal-affiliated organizations to provide education and training services to Temporary Assistance for Needy Families (TANF) recipients and other low-income individuals, including tribal members. Under HPOG 2.0, ACF provided grants to five tribal-affiliated organizations and 27 non-tribal entities.

OMB previously approved data collection under OMB Control Number 0970-0462 for: The HPOG 2.0 National and Tribal Evaluation (Approved August 2015); and the National Evaluation impact study, the National Evaluation descriptive study, and the Tribal Evaluation (All approved June 2017). The proposed data collection activities described in this **Federal Register** Notice will provide data for the impact and cost benefit studies of the 27 non-tribal grantees participating in the National Evaluation of HPOG 2.0.

National Evaluation: The National Evaluation pertains only to the 27 non-tribal grantees that received HPOG 2.0 funding. The design for the National Evaluation features an implementation study, a systems change analysis, and cost benefit analysis. In addition, the National Evaluation is using an experimental design to measure and analyze key participant outcomes including completion of education and training, receipt of certificates and/or degrees, earnings, and employment in a

healthcare career. The impact evaluation will assess the outcomes for study participants that were offered HPOG 2.0 training, financial assistance, and support services, compared to what their outcomes would have been if they had not been offered HPOG 2.0 services.

This Notice provides the opportunity to comment on a proposed new information collection activity for the HPOG 2.0 National Evaluation's impact study—the HPOG 2.0 Impact Evaluation first follow-up survey. The first follow-up survey of both treatment and control group members will be administered approximately 15 months after baseline data collection and random assignment. The survey will collect data about key outcomes of interest, including

participants' tenure and experience in HPOG programming, certifications and educational achievements, job placement, and benefits. These are the key outcomes of interest for which data are not otherwise available through existing data sources. Previously approved collection activities under 0970-0462 will continue under this new request for the National Evaluation of the non-tribal grantees.

In subsequent requests for clearance, we will submit (1) additional data collection instruments to support the descriptive study of the 27 non-tribal grantees participating in the HPOG 2.0 National Evaluation, including grantee interview guides and participant interview guides; and (2) the second

follow-up survey for the HPOG 2.0 National Evaluation impact study. The second follow-up survey is for collecting data from both treatment and control group members at the 27 non-tribal grantees, approximately 36 months after baseline data collection and random assignment. This submission will also include data collection necessary for the National Evaluation's cost benefit analysis.

Respondents: For the National Evaluation impact study: HPOG 2.0 study participants at the 27 non-tribal grantees.

Annual Response Burden Estimates: (This information collection request is for 3 years):

| Instrument | Total number of respondents | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Annual burden hours |
|---|-----------------------------|------------------------------|------------------------------------|-----------------------------------|---------------------|
| HPOG 2.0 National Evaluation: 15-month Follow-up Survey | 10,400 | 3,467 | 1 | 1 | 3,467 |

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families (ACF), Department of Health and Human Services, is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded in writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to

comments and suggestions submitted within 60 days of this publication.

Mary Jones,
ACF/OPRE Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidance for Digoxin; Draft Revised Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft revised guidance for industry on generic digoxin tablets entitled "Draft Guidance on Digoxin." The guidance, once finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for digoxin tablets.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft revised guidance before it begins work on the final version of the guidance, submit either electronic or written

comments on the draft revised guidance by October 30, 2017.

ADDRESSES: You may submit comments 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: