qualifications of the candidate 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 HHS.

Nominations should be submitted (postmarked or received) by August 15, 2016.

Electronic submissions: You may submit nominations, including attachments, electronically to *hicpac@cdc.gov*.

Regular, Express or Overnight Mail: Written nominations may be submitted to the following addressee only: Erin Stone, M.S., HICPAC, Division of Healthcare Quality Promotion, NCEZID, CDC, l600 Clifton Road NE., Mailstop A–07, Atlanta, Georgia 30333.

Telephone and facsimile submissions cannot be accepted. Nominations may be submitted by the candidate 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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

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

[FR Doc. 2016–10423 Filed 5–3–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10615]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 an information collection concerning CMS' Healthy Indiana Program (HIP) 2.0 Beneficiaries Survey. We are also announcing that the proposed information collection had been submitted to OMB and was approved under control number 0938–1300 through September 30, 2016. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA) we requested emergency review under 5 CFR 1320.13(a)(2)(i) because public harm is reasonably likely to result if the regular clearance procedures were followed.

More specifically, the regular PRA clearance process would jeopardize the timely completion of CMS' evaluation of the State's upcoming non-emergency medical transportation (NEMT) waiver and other important waivers. Most importantly, it would potentially cause significant harm by depriving Medicaid beneficiaries—especially those affected by the NEMT waiver—of appropriate medical services and needed care.

Although we have already received OMB approval to test/develop the survey instruments, we are now soliciting public comment for 30-days prior to implementing the survey in order to meet the conditions of OMB's Terms of Clearance that were issued on March 21, 2016.

Under the PRA, federal agencies are required to publish notice in the **Federal Register** concerning each proposed information collection request (ICR). Interested persons are invited to send comments regarding our burden estimates or any other aspect of this ICR, including any of the following subjects: (1) The necessity and utility of the proposed ICR 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 must be received by June 3, 2016.

ADDRESSES: When commenting, please reference the document identifier (CMS–10615) or OMB control number (0938–1300). 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: CMS–10615/OMB Control Number 0938–1300, 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: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following ICR. More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10615 Healthy Indiana Program (HIP) 2.0 Beneficiaries Survey

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. In compliance with the requirement of section 3506(c)(2)(A) of the PRA, we submitted to OMB our request for emergency processing of this information collection. OMB approved the emergency ICR for testing/developing the survey on March 21, 2016. This iteration seeks emergency approval for fielding the survey and for conducting interviews and focus groups.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Healthy Indiana Program (HIP) 2.0 Beneficiaries Survey; *Use:* This is a request for emergency approval to field the surveys and to conduct key informant interviews and focus groups. The surveys were tested during the first week of April 2016, and

there was a week-long public comment period that was announced in the **Federal Register** on March 29, 2016 (81 FR 17460). This ICR contains the revised surveys based on testing and public comments provided during the survey testing period.

Emergency OMB approval is being sought, as permitted under 5 CPR 1320.13(a)(2)(i), since public harm is reasonably likely to occur if the regular nonemergency PRA clearance procedures are followed. Potential harm may result due to insufficient information to adequately support decision making that is required in November 2016. The clearance is particularly important for decisions about the renewal of precedent-setting waivers of Medicaid policy that assure important beneficiary protections regarding coverage and access to care; *e.g.,* the NEMT waiver. That waiver ends or will be extended by no later than December 1, 2016. The survey effort is critical to supply more detail and information on HIP 2.0 beneficiary understanding and experiences (current and new enrollees as well as disenrollees/lockouts). Other information on other key policies under the Indiana HIP 2.0 demonstration, such as the 60 day beneficiary lock-out period, is also included in this information collection. Including this other information, as well as the interviews and focus groups, with the NEMT related information allows all this information to be collected during the same period of time; this will improve the efficiency of resources when compared to fielding separate surveys, interviews and focus groups at a later time which would be needed under the regular PRA process. *Form Number:* CMS–10615 (OMB control number: 0938–1300); *Frequency:* Once; *Affected Public:* Individuals and households, Private sector (Business or other for-profits and Not-for-profits institutions), and State, Local, or Tribal Governments; *Number of Respondents:* 5,240; *Total Annual Responses:* 5,240; *Total Annual Hours:* 1,442. (For policy questions regarding this collection contact Teresa DeCaro at 202–384–6309).

Written comments and recommendations will be considered from the public if received by the date and address noted above.

Dated: April 29, 2016.

William N. Parham, III,

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

[FR Doc. 2016–10448 Filed 5–3–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1174]

Special Protocol Assessment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Special Protocol Assessment.'' This draft guidance provides information about the procedures and general policies adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for special protocol assessment (SPA). This draft guidance is intended to improve the quality of Requests for SPAs and accompanying submission materials, and the quality of the resulting interaction between sponsors and FDA. This draft guidance revises the guidance for industry entitled ''Special Protocol Assessment'' issued May 17, 2002.

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 guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 5, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–1174 for ''Special Protocol Assessment; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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 as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR