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:


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 conduct key informant interviews and focus groups. The surveys were tested during the first week of April 2016, and
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...