

Background and Brief Description

Due to defunding and as part of a revision in 2014 of the information collection entitled *National Disease Surveillance Program II: Disease Summaries* (OMB Control Number 0920–0004), CDC discontinued its data collection of harmful algal bloom-related illnesses through its Harmful Algal Bloom-related Illness Surveillance System (HABISS). However, in part to the Great Lakes Restorative Initiative, the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) now considers harmful algal bloom-related illness surveillance as a priority and will seek a three-year OMB approval for HABISS.

The goal of harmful algal bloom-related illness surveillance is to collect data on harmful algal blooms (HABs), human illnesses, and animal illnesses related to HAB exposures and use the data to better define and prevent HAB-related illnesses. HABs are the fast growth of aquatic organisms including algae, cyanobacteria, phytoplankton, and similar organisms. HABs can produce potent natural toxins that can contaminate surface water used for recreation, drinking water, or food

sources. Contaminated water and food can cause illness when people or animals have exposures to them. HABs are an emerging public health concern with several outbreaks related to HAB exposures through contact, inhalation, and ingestion of contaminated fish, shellfish, and water. In humans and animals, illnesses related to HAB exposures have ranged from dermatologic, respiratory, gastrointestinal, neurological illness, and even death. HABs might be identified through the reporting of single cases of human or animal illness as indicators.

HABISS data will be reported by states and territories in a web-based electronic reporting system. The National Outbreak Reporting System (NORS) (OMB Control Number 0920–0004) is an existing password-protected web-based surveillance platform for national reporting of foodborne, waterborne, and other enteric outbreaks. HAB-related outbreaks can already be reported by state and territorial health departments in NORS; however, there is currently no national surveillance for single cases of human or animal illnesses. State and territorial staff with access to NORS will be able to use a

hyperlink on the NORS main user page to report individual human and animal case information related to HAB exposures. State agencies will voluntarily report single human and animal illnesses related to HAB exposures, as well as environmental data about HABs.

HABISS data will include the date of the HAB, the type of exposure that the person or animal had, the length of the exposure, signs and symptoms, and laboratory testing. No Personally Identifiable Information (PII) will be reported or collected. CDC will use the data to better characterize human and animal illnesses related to HAB exposures and to inform future prevention efforts, health departments, federal partners and other stakeholders.

There are no costs to respondents other than their time.

CDC will analyze and present the collected data through summaries and reports.

It is estimated that epidemiologists will report illnesses and HAB events three times during the year with a burden of 20 minutes. An estimated total burden for HABISS data reporting is 57 hours per year.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State Epidemiologists	Harmful Algal Bloom Illness Surveillance System (HABISS) data elements (electronic, year-round).	57	3	20/60	57
Total	57

Leroy A. Richardson,
 Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: **CMS–10387, CMS–10110 and CMS–10393**]

Agency Information Collection Activities: Proposed Collection; 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 (the

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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection 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 *September 21, 2015*.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. 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: Document Identifier/OMB Control Number ____, 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 information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10387 Skilled Nursing Facility (SNF) Prospective Payment System and Consolidated

Billing

CMS-10110 Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B

Drugs and Biologicals

CMS-10393 Medicare Beneficiary and Family-Centered Satisfaction 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. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Skilled Nursing Facility (SNF) Prospective Payment System and Consolidated Billing; *Use:* We are requesting approval of a reinstatement of a Change of Therapy OMRA for Skilled Nursing Facilities (SNFs). As described in CMS-1351-F, we finalized the assessment effective October 1, 2011. SNFs are required to submit this assessment. The COT OMRA is comprised of a subset of resident assessment information developed for use by SNFs to satisfy a Medicare payment requirement. The burden associated with this is the SNF staff time required to complete the COT OMRA, SNF staff time to encode the data, and SNF staff time spent in transmitting the data. SNFs are required to complete a COT OMRA when a SNF resident was receiving a sufficient level of rehabilitation therapy to qualify for an Ultra High, Very High, High, Medium, or Low Rehabilitation category and when the intensity of therapy (as indicated by the total reimbursable therapy minutes (RTM) delivered, and other therapy qualifiers such as number of therapy days and disciplines providing therapy) changes to such a degree that it would no longer reflect the RUG-IV classification and payment assigned for a given SNF resident based on the most recent assessment used for Medicare payment. The COT OMRA is a type of required PPS assessment which uses the same item set as the End of Therapy (EOT) OMRA. *Form Number:* CMS-10387 (OMB Control Number: 0938-1140); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits and Not-for-profit institutions); *Number of Respondents:* 15,421; *Total Annual Responses:* 678,524; *Total Annual Hours:* 701,119. (For policy questions

regarding this collection contact Penny Gershman at 410-786-6643).

2. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals; *Use:* In accordance with section 1847A of the Social Security Act (the Act), Medicare Part B covered drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) of the drug or biological, beginning in Calendar Year (CY) 2005. The ASP data reporting requirements are specified in section 1927 of the Act. The reported ASP data are used to establish the Medicare payment amounts. The reporting template was revised in CY 2011 in order to facilitate accurate collection of ASP data. An accompanying user guide with instructions on the template's use was also created and included an explanation of the data elements in the template. *Form Number:* CMS-10110 (OMB Control Number: 0938-0921); *Frequency:* Quarterly; *Affected Public:* Private sector (Business or other For-profits); *Number of Respondents:* 180; *Total Annual Responses:* 720; *Total Annual Hours:* 34,560. (For policy questions regarding this collection contact Amy Gruber at 410-786-1542).

3. *Type of Information Collection Request:* Extension of a previously approved collection; *Title of Information Collection:* Medicare Beneficiary and Family-Centered Satisfaction Survey; *Use:* The data collection methodology used to determine Beneficiary Satisfaction flows from the proposed sampling approach. Based on recent literature on survey methodology and response rates by mode, we recommend using a data collection that is done primarily by mail. A mail-based methodology will achieve the goals of being efficient, effective, and minimally burdensome for beneficiary respondents. We anticipate that a mail-based methodology could yield a response rate of approximately 60 percent. In order to achieve this response rate, we would recommend a 3 staged approach to data collection:

(1) Mailout of a covering letter, the paper survey questionnaire, and a postage-paid return envelope.

(2) Mailout of a post card that thanks respondents and reminds the non-respondents to please return their survey.

(3) Mailout of a follow-up covering letter, the paper survey questionnaire, and a postage-paid return envelope.

Through the pilot test, we will determine the response rate that can be achieved using this approach. If it is deemed necessary, a prenotification letter, additional mailout reminders and a telephone non-response step can be added to the protocol to achieve desired response rate. *Form Number:* CMS–10393 (OMB Control number: 0938–1177); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 16,010; *Number of Responses:* 16,010; *Total Annual Hours:* 4,002. (For policy questions regarding this collection, contact Coles Mercier at 410–786–2112.)

Dated: July 16, 2015.

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

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Form CB–496, “Title IV–E Programs Quarterly Financial Report”
OMB No.: 0970–0205

Description: This is a financial report submitted following the end of each fiscal quarter by each State or Tribe with an approved title IV–E plan administering any of three title IV–E entitlement grant programs—Foster Care, Adoption Assistance or Guardianship Assistance.

The purpose of this form is to enable each State or Tribe to meet its statutory and regulatory requirement to report program expenditures made in the preceding fiscal quarter and to estimate program expenditures to be made in the upcoming fiscal quarter. This form also allows States and Tribes to report the actual and estimated average monthly number of children assisted in each of the three IV–E entitlement grant programs in the preceding and upcoming fiscal quarters, respectively.

The Administration for Children and Families provides Federal funding at the rate of 50 percent for nearly all allowable and legitimate administrative costs of these programs and at other funding rates for other specific categories of costs as detailed in Federal statute and regulations. The information collected in this report is used by this agency to calculate quarterly Federal grant awards and to enable oversight of the financial management of the programs. Legislation enacted in 2014 through Public Law 113–183, the “Preventing Sex Trafficking and Strengthening Families Act” added a requirement that title IV–E grantees

annually report on the methodology used to calculate adoption savings due to the application of differing title IV–E Adoption Assistance eligibility criteria for children designated as an “applicable child” along with an accounting of the amount of and the expenditure of any such savings.

To accommodate this change in the law, we have added additional data entry lines in part 4 of Form CB–496, “Annual Adoption Savings Calculation and Accounting Report” which will be submitted annually by grantees.

In addition, the same law adds additional requirements that title IV–E grantees develop and implement policies and procedures to identify, document, and determine appropriate services for any child or youth in the placement, care or supervision of the title IV–E agency who is at-risk of becoming a sex trafficking victim or who is determined as a sex trafficking victim.

To accommodate this change in the law we have added additional reporting lines and prior quarter reporting odes for expenditure reporting and child counts and in parts 1 and 2 of Form CB–496.

Respondents: States (including Puerto Rico and the District of Columbia) and Tribes* with approved title IV–E plans. (*An estimated 15 Tribes have or will have approved title IV–E plans within the next 3-year period.)

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Form CB–496: Title IV–E Programs Quarterly Financial Report	67	4	21	5,628

Estimated Total Annual Burden Hours: 5,628.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L’Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of

publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0067]

Medical Device Patient Labeling; Request for Comments; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration is announcing the following public workshop entitled “Medical Device Patient Labeling”. The purpose of the public workshop is to discuss issues associated with the development and use of medical device