2014–0015, 1600 Clifton Rd. NE., Mailstop A–07, Atlanta, Georgia, 30333.

Instructions: All submissions received must include the agency name and docket number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* All materials submitted will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Standard Time, at 1600 Clifton Road NE., Atlanta, Georgia 30333. Please call ahead to (404) 639–4000 and ask for a representative from Immunization Safety Office to schedule your visit. You should be aware that this office is in a Federal government building; therefore, Federal security measures are applicable. For additional information, please see Roybal Campus Security Guidelines under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Tiffany Suragh; Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality Promotion, Immunization Safety Office, l600 Clifton Road NE., Mailstop D–26; Atlanta, Georgia, 30329–4018; Telephone: (404) 639–4000.

SUPPLEMENTARY INFORMATION: VAERS is an important and critical ''early warning system'' in the federal vaccine safety infrastructure for identifying adverse events after receipt of childhood, adolescent, and adult vaccines licensed for use in the United States (US). Healthcare providers and vaccine manufacturers are required under section 2125(b) of the Public Health Service Act (42 U.S.C. 300aa–25(b)) to file VAERS reports regarding the occurrence of any event set forth in the Vaccine Injury Table which occurs within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table and the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert. VAERS also accepts reports on adverse events following receipt of other vaccines. Patients, parents and others aware of adverse events can also file VAERS reports. Although VAERS is not designed to assess if a vaccine caused an adverse event, VAERS provides CDC and FDA with important early information that might signal a potential problem. If the VAERS data suggest a possible association between an adverse event and vaccination, the relationship will be further assessed. In recent years VAERS has received approximately 30,000 US reports annually.

VAERS is a mandated activity for the U.S. Department of Health and Human Services (HHS) and VAERS data are used by federal agencies, state health officials, health care providers, manufacturers, and the public, therefore it is important to maximize the usefulness of this system. The information collected by the proposed VAERS 2.0 form will be similar to that on the current VAERS–1 form so historical comparisons can be made; however, the changes in the draft VAERS 2.0 form should improve reporting efficiency and data quality. VAERS 2.0 offers standardized responses, clearer instructions and guidance, and improved online reporting. Select questions have been updated, with questions added, removed, and reorganized to decrease response burden and maximize usability. The draft VAERS 2.0 form can be found at *http://www.regulations.gov.*

During the development of the draft VAERS 2.0 form, CDC and FDA sought input from key stakeholders in the federal government, state health officials involved in vaccine safety and vaccine programs, and other public health partners. In addition, the VAERS 2.0 form was presented to three federal advisory committees, the Advisory Commission on Childhood Vaccines (September 5, 2014), the National Vaccine Advisory Committee (September 9, 2014), and the Advisory Committee on Immunization Practices (October, 2014) and was tested with potential reporters (e.g., physicians, nurses, pharmacists, patients, and parents). All public comments will be reviewed and considered prior to finalizing the VAERS 2.0 form.

Roybal Campus Security Guidelines: The Edward R. Roybal Campus is the headquarters of the U.S. Centers for Disease Control and Prevention and is located at 1600 Clifton Road NE., Atlanta, Georgia. The Immunization Safety Office is in a Federal government building; therefore, Federal security measures are applicable.

In planning your arrival time, please take into account the need to park and clear security. All visitors must enter the Roybal Campus through the entrance on Clifton Road; the guard force will direct visitors to the designated parking area. Upon arrival at the facility, visitors must present government issued photo identification (e.g., a valid federal identification badge, state driver's license, state non-driver's identification card, or passport). Non-United States citizens must complete the required security paperwork prior to the visit date and must present a valid passport, visa, Permanent Resident Card, or other type of work authorization document upon arrival at the facility. All persons entering the building must pass through a metal detector. Visitors will be issued a visitor's ID badge at the entrance to Building 19 and will be escorted to a room to view the available materials. All items brought to HHS/CDC are subject to inspection.

Dated: November 18, 2014.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2014–27678 Filed 11–21–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10407 and CMS–R–245]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HSS.

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 January 23, 2015.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). 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–10407 Summary of Benefits and Coverage and Uniform Glossary

CMS–R–245 Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations

Under the Paperwork Reduction Act (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:* Extension of a currently approved collection; *Title of Information Collection:* Summary of Benefits and Coverage and Uniform Glossary; *Use:* Section 2715 of the Public Health Service Act directs the Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (collectively, the Departments), in consultation with the National Association of Insurance Commissioners (NAIC) and a working group comprised of stakeholders, to ''develop standards for use by a group health plan and a health insurance issuer in compiling and providing to applicants, enrollees, and policyholders and certificate holders a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage.'' To implement these disclosure requirements, collection of information requests relate to the provision of the following: Summary of benefits and coverage, which includes coverage examples; a uniform glossary of health coverage and medical terms; and a notice of modifications. *Form Number:* CMS–10407 (OMB control number 0938–1146); *Frequency:* Annual; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 126,500; *Number of Responses:* 41,153,858; *Total Annual Hours:* 322,411. (For policy questions regarding this collection, contact Heather Raeburn at 301–492–4224.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations; *Use:* The Outcome and Assessment Information Set (OASIS) data set is currently mandated for use by Home Health Agencies (HHAs) as a condition of participation (CoP) in the Medicare program. Since 1999, the Medicare CoPs have mandated that HHAs use the OASIS data set when evaluating adult non-maternity patients receiving skilled services. The OASIS is a core standard assessment data set that agencies integrate into their own patient-specific, comprehensive assessment to identify each patient's need for home care that meets the patient's medical, nursing, rehabilitative, social, and discharge planning needs.

The Office of Management and Budget (OMB) approved the OASIS–C1 information collection request on February 6, 2014. We originally planned to use OASIS–C1 to coincide with the original implementation of ICD–10 on October 1, 2014. However, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. This legislation prohibits CMS from adopting ICD–10 coding prior to October 1, 2015. Because OASIS–C1 is based on ICD–10 coding, it is not possible to implement OASIS–C1 prior to October 1, 2015, when ICD–10 is implemented. The passage of the PAMA Act left us with the dilemma of how to collect OASIS data in the interim, until ICD–10 is implemented.

The OASIS–C1/ICD–9 version is an interim version of the OASIS–C1 data item set that was created in response to the legislatively mandated ICD–10 delay. There are five items in OASIS–C1 that require ICD–10 codes. In the OASIS–C1/ICD–9 version, these items have been replaced with the corresponding items from OASIS–C that use ICD–9 coding. The OASIS–C1/ICD–9 version also incorporates updated clinical concepts, modified item wording and response categories and improved item clarity. In addition, the OASIS–C1/ICD–9 version includes a significant decrease in provider burden that was accomplished by the deletion of a number of non-essential data items from the OASIS–C data item set. *Form Number:* CMS–R–245 (OMB control number: 0938–0760); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 12,014; *Total Annual Responses:* 17,268,890; *Total Annual Hours:* 15,305,484. (For policy questions regarding this collection contact Cheryl Wiseman at 410–786–1175).

Dated: November 19, 2014.

Martique Jones,

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

[FR Doc. 2014–27756 Filed 11–21–14; 8:45 am]

BILLING CODE 4120–01–P