Demonstration and Prior Authorization Demonstration

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 without change of a previously approved collection; *Title of Information Collection:* Hospital Conditions of Participation and Supporting Regulations; *Use:* The information collection requirements described in this information collection request are needed to implement the Medicare and Medicaid conditions of participation (CoP) for 4,890 accredited and non-accredited hospitals and an additional 101 critical access hospitals (CAHs) that have distinct part psychiatric or rehabilitation units (DPUs). CAHs that have DPUs must comply with all of the hospital CoPs on these units. Thus, this package reflects the burden for a total of 4,991 hospitals (that is, 4,890 accredited/non-accredited hospitals and 101 CAHs which include 81 CAHs that have psychiatric DPUs and 20 CAHs that have rehabilitation DPUs). The information collection requirements for the remaining 1,183 CAHs have been approved in a separate package under CMS–10239 (OMB control number: 0938–1043).

The CoPs and accompanying regulatory requirements are used by our surveyors as a basis for determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid. CMS and the health care industry believe that the availability to the facility of the type of records and general content of records is standard medical practice and is necessary to ensure the well-being and safety of patients and professional treatment accountability. *Form Number:* CMS–R–48 (OMB control number: 0938–0328); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profit); *Number of Respondents:* 4,991; *Total Annual Responses:* 1,342,424; *Total Annual Hours:* 18,840,617. (For policy questions regarding this collection contact Scott Cooper at 410–786–9465.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Fee-for-Service Recovery Audit Prepayment Review Demonstration and Prior Authorization Demonstration; *Use:* OMB approved the collections required for two demonstrations of prepayment review and prior authorization. The first demonstration allows Medicare Recovery Auditors to review claims on a pre-payment basis in certain States. The second demonstration established a prior authorization program for Power Mobility Device claims in certain States. The first demonstration has ended, so we are only extending the collection of information for the second demonstration, prior authorization of power mobility devices.

For the Prior Authorization of Power Mobility Devices (PMDs) Demonstration, we are piloting prior authorization for PMDs. Prior authorization will allow the applicable documentation that supports a claim to be submitted before the item is delivered. For prior authorization, relevant documentation for review is submitted before the item is delivered or the service is rendered. CMS will conduct this demonstration in California, Florida, Illinois, Michigan, New York, North Carolina, Texas, Pennsylvania, Ohio, Louisiana, Missouri, Maryland, New Jersey, Indiana, Kentucky, Georgia, Tennessee, Washington, and Arizona based on beneficiary address as reported to the Social Security Administration and recorded in the Common Working File (CWF). For the demonstration, a prior authorization request can be completed by the (ordering) physician or treating practitioner and submitted to the appropriate Durable Medical Equipment Medicare Administrative Contractor (DME MAC) for an initial decision. The supplier may also submit the request on behalf of the physician or treating practitioner. The physician, treating practitioner or supplier who submits the request on behalf of the physician or treating practitioner, is referred to as the ''submitter.'' Under this demonstration, the submitter will submit to the DME MAC a request for prior authorization and all relevant documentation to support Medicare coverage of the PMD item.

Form Number: CMS–10421 (OMB control number: 0938–1169); *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 50,500; *Total Annual Responses:* 50,500; *Total Annual Hours:* 25,125. (For policy questions regarding this collection contact Daniel Schwartz at 410–786–4197.)

Dated: November 7, 2017.

Martique Jones,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Public Comment Request; Semiannual Performance Measures for the ACL Traumatic Brain Injury State Partnership Program (ICR New)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This notice solicits comments on proposed semiannual performance measures for the ACL Traumatic Brain Injury State Partnership program as reauthorized under the Traumatic Brain Injury Reauthorization Act of 2014.

DATES: Submit written or electronic comments on the collection of information by January 12, 2018.

ADDRESSES: Submit electronic comments on the collection of information to: *TBI@acl.gov.* Submit written comments to: U.S. Department of Health and Human Services, Administration for Community Living, Washington, DC 20201, Attention: Thom Campbell.

FOR FURTHER INFORMATION CONTACT: Thom Campbell by telephone: (202) 795–7263 or by email: *TBI@acl.gov.*

SUPPLEMENTARY INFORMATION: 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. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval.

To comply with the above requirement, ACL is publishing a notice of a new collection of information as set forth in this document. With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility and/or help ACL illustrate the program's return on investment; (2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate and other forms of information technology.

Purpose

The purpose of the Traumatic Brain Injury (TBI) State Partnership program is to increase access to rehabilitation and other services for individuals with traumatic brain injury. Under the Traumatic Brain Injury Reauthorization Act of 2014 (Pub. L. 113–196), the Traumatic Brain Injury State Partnership program transitioned from the Health Resources and Services Administration (HRSA) to the Administration for Community Living (ACL). Under this law, the Secretary, acting through ACL, was authorized to ''make grants to States and American Indian consortia for the purpose of carrying out projects to improve access to rehabilitation and other services regarding traumatic brain injury.'' ACL seeks to collect performance measure data from state grantees consistent with the TBI State Partnership program's purpose and ACL's mission to ''Maximize the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers.''

ACL seeks data on a semi-annual basis on the types of practices, protocols, and activities performed by each grantee, as well as the cost of each activity and the number and types of people they served. ACL also seeks information about the number and types of individuals who receive TBI-related home and community based services. Finally, ACL seeks information regarding the involvement of people with TBI in advisory and program support roles.

The data collected will allow ACL to determine the extent to which the grant program is meeting its goals of expanding and improving services, generating sustainable funding streams, and enriching service systems to better serve individuals with TBI and their families. The data will also help ACL develop and expand baseline information around the nature and scope of the incidence of TBI. Additionally, this data collection will help ACL illustrate the return on investment of the TBI funds in terms of system change (*i.e.,* changes in policies and practices and the development of networks). By matching the project dollars spent against measurable improvements in state systems for delivering services and supports to people living with TBI, ACL will have a strong indicator of the effect of the TBI program on the quality of services which ultimately impact the lives of people across the country living with TBI. The proposed data collection forms may be found on the ACL Web site for review at: *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: The annual reporting burden estimates are shown below.

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
States	State Performance Report	*45	2	16	1,440

*This is the highest number of awards anticipated, but it is possible that there will be less. If less than 45 grants are awarded, the total burden hours will be adjusted proportionally.

Dated: November 7, 2017.

Mary Lazare,

Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5138]

S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals; International Council for Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled ''S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance replaces the existing guidance entitled ''S5(R2) Detection of Toxicity to Reproduction for Human Pharmaceuticals.'' The draft guidance is intended to align with other ICH guidances, elaborate on concepts to consider when designing studies, and identify potential circumstances in which a risk assessment can be made based on preliminary studies. It also clarifies the qualification and potential use of alternative assays.