reporting requirements are effective in ensuring grantees data, there is no consistency or uniformity in how individual grantees submit their data.

For example, SHIP profiles currently exist; these profiles are accessible to the SHIP grantee network via the program's technical assistance center, and they can be updated directly by grantee states. SMP and MIPPA profiles have yet to be developed. The goal of this data collection effort is to obtain consistent data elements for the three programs that will allow ACL to reimagine the existing profiles into a comparable set of data elements across programs.

These data will allow RTI International, a contractor to ACL, to develop an updated set of grantee profiles that are accessible, visually appealing, and consistent across programs. Specifically, the purpose of this data collection effort is to update the SHIP grantee profiles, which were last updated in 2016, and develop similar profiles for SMP and MIPPA. These profiles will be internal to ACL and will only be shared with grantees.

A web-based questionnaire will be emailed to all 125 grant managers (representing 54 states and territories) electronically via Smartsheet. The collected data will be imported into a dataset and will be used to create program profiles accessible to ACL and grantees.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** 87 FR 65068–65069 on October 27, 2022. Zero public comments were received during the 60-day FRN. ACL's responses to these comments are included below.

Estimated Program Burden

ACL estimates the burden of this collection of information as follows:

A maximum of 125 grantees are expected to respond to the web-based data collection instrument. The approximate burden for pre-data collection preparation is 30 minutes per respondent and approximate burden for form completion is 20 minutes per respondent for a total annual estimate of 103.75 hours. The estimated completion burden includes time to review the instructions, read the questions and complete and responses.

IC BURDEN CHART

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Pre-data collection preparation	125	1	0.5	62.5
Web-based data collection	125	1	0.33	41.25
Total	125	1	0.83	103.75

Dated: February 3, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–02673 Filed 2–7–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Traumatic Brain Injury (TBI) State Partnership Program Performance Progress Reporting; OMB Control Number 0985–0066

AGENCY: Administration for Community Living, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under the Paperwork Reduction Act of 1995. This 30-day notice collects comments on the information collection requirements related to an extension of an existing collection of information related to the Traumatic Brain Injury (TBI) State Partnership Program.

DATES: Submit written comments on the collection of information by March 10, 2023d.

ADDRESSES: Submit electronic comments on the collection of information by:

(a) Email to *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL;

(b) fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or

(c) by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Elizabeth Leef, (202) 475–2482 or *Elizabeth.Leef@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with the Paperwork Reduction Act, ACL has submitted the following proposed new information collection to OMB for review and clearance.

The purpose of the federal Traumatic Brain Injury (TBI) State Partnership Program is to create and strengthen person-centered, culturally competent systems of services and supports that maximize the independence and overall health and well-being of all people with TBI across the lifespan, their family members, and their support networks. The TBI State Partnership Program funds the development and implementation of statewide systems that ensure access to TBI related services, including transitional services, rehabilitation, education and employment, and long-term community support. To best monitor, guide, and support TBI State Partnership Program grantees, ACL requires grantees to report about their activities and outcomes. The simplest, least burdensome and most useful way to accomplish this goal is to require grantees to submit information as part of their required semiannual reports via the proposed electronic data submission instrument (appendix A).

In 1996, the Public Health Service Act was amended ''to provide for the conduct of expanded studies and the establishment of innovative programs with respect to traumatic brain injury, and for other purposes'' (Pub. L. 104–166). This legislation allowed for the implementation of ''grants to States for the purpose of carrying out demonstration projects to improve access to health and other services regarding traumatic brain injury.'' The TBI Reauthorization Act of 2014 (Pub. L. 113–196) allowed the Department of Health and Human Services Secretary to review oversight of the federal TBI

programs (TBI State Partnership Grant program and the TBI Protection and Advocacy program) and reconsider which operating division should lead them. With avid support from TBI stakeholders, the Secretary found that the goals of the federal TBI programs closely align with ACL's mission to advance policy and implement programs that support the rights of older Americans and people with disabilities to live in their communities. As a result, on Oct. 1, 2015, the federal TBI programs moved from the Health Resources and Services Administration to ACL. These programs were reauthorized again by the Traumatic Brain Injury Reauthorization Act of 2018 (Pub. L. 115–377).

The proposed performance progress reporting (PPR) tool is consistent with both the TBI State Partnership Program's purpose and also ACL's mission. The 2010 Government Performance Results Modernization Act requires federal agencies to develop annual and long-term performance outcome measures and to report on these measures annually. ACL sees the GPRA Modernization Act as an opportunity to document annually the results that are produced through the programs it administers under the authority for the TBI State Partnership Program.

It is the intent and commitment of ACL, in concert with grantees, to use the performance progress reporting tool of GPRAMA to continuously improve its programs and services.

The TBI State Partnership Program grantees have been submitting data using a PRA approved tool since 2000; that tool was revised to create the current proposed PPR tool. Revisions were made to eliminate questions that the majority of grantees could not respond to or created undue burden, make questions clearer, and add questions that were seen valuable to collect.

Comments in Response to the 60-Day Federal Register Notice

ACL published a 60-day **Federal Register** Notice from 9/30/2022–11/29/2022 (87 FR 59439–59441). ACL received no comments.

The PPR is an extension of a currently approved data collection. Changes were done during the Summer of 2022. Revisions were made to eliminate questions that the majority of grantees could not respond to or created undue burden, make questions clearer, and add questions that were seen valuable to collect.

In August 2022, ACL received feedback through an online meeting with a majority of the TBI State Partnership Program grantees regarding the proposed PPR. Some grantees also provided written feedback. Additional revisions were made to the PPR tool to incorporate feedback received from the grantees.

The questions that were eliminated because grantees could not respond to or created undue burden were regarding: estimated number of people in the states who have experienced a TBI and are getting some kind of Medicaid Home and Community Based services or supports; the types of settings the people were living in when they were screened for a TBI or receiving resource facilitation; how many people were in competitive, integrated employment and/or in school at the time of screening or receiving resource facilitation; and how many people who received resource facilitation were supported through a transition from an institution setting (*e.g.,* criminal justice system, nursing facility) into the community.

The following questions were removed because comparable information is available from other sources: program funds spent on activities; whether grantees are involved in mentoring and workgroup activities; and use of and satisfaction with the services of the technical assistance resource center.

Questions were added to collect more information regarding the advisory boards/councils that are an important component of the TBI SPP grants. The questions added are: characteristics of the advisory board/how structured within a state, regarding what supports are provided to people with TBI that are involved in the advisory boards/councils; how the advisory boards/councils are involved with the grant program; and what it means and the efforts or actions being taken to ensure that the advisory boards/councils are representative (*e.g.,* of the state's demographics, types of brain injury, severity of brain injury, etc.).

Estimated Program Burden

The annual burden estimates are shown below.

Instrument	Number of respondents	Number of responses (per respondent)	Average burden hours (per response)	Total burden hours
Semiannual Performance Progress Reporting	29	2	8	464
Estimated Total Annual Burden Hours:				464

Dated: February 3, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–02672 Filed 2–7–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–5846]

Determination of Regulatory Review Period for Purposes of Patent Extension; REMEDE SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for REMEDE SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by April 10, 2023.