DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; National Survey of Child and Adolescent Well-Being-Third Cohort (NSCAW III) (OMB #0970–0202)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), within the U.S. Department of Health and Human Services (HHS), is proposing to collect data on the child welfare workforce as part of the third cohort of children and families for the National Survey of Child and Adolescent Well-Being (NSCAW III). Previous and current data collections for NSCAW have been approved by OMB under OMB #0970–0202. This request is for additional data collection.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: NSCAW is the only source of nationally representative, longitudinal, firsthand information about the functioning and well-being, service needs, and service utilization of children and families who come to the attention of the child welfare system.

OMB previously approved data collection under OMB Control Number 0970–0202 for NSCAW. The Phase I submission, approved November 2016, included recruitment and sampling process data collection activities. The Phase II submission, approved July 2017, included baseline and 18-month follow-up data collection activities.

The proposed new data collection activities will provide national representative data on the characteristics and activities of the workforce in child welfare agencies participating in NSCAW III. Surveys will collect information on workforce characteristics and competencies, training and professional development opportunities, and organizational and agency factors.

Respondents: The respondents are agency directors, supervisors, and caseworkers. All surveys will be conducted in-person.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Agency Director Survey	65	22	1	.42	9
Supervisor Survey	130	43	1	.50	22
Caseworker Survey	390	130	1	.75	98

Estimated Total Annual Burden Hours: 129.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 628b; Continuing Appropriations Act of 2020.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–02075 Filed 2–3–20; 8:45 am]

BILLING CODE 4184–01–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, OMB approval number 0985–NEW

AGENCY: Administration for Community Living, HHS.

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 Proposed New information collection requirements related to the Traumatic Brain Injury (TBI) State Partnership Program.

DATES: Submit written comments on the collection of information by March 5, 2020.

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: Dana Fink, Administration for Community Living, Washington, DC 20201, (202) 795–7604, or *dana.fink@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 a system of services and supports that maximizes the independence, well-being, and health of people with TBIs across the lifespan and all other demographics, their family members, and 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 needs regular information about the grantees' 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.

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 measures assess progress toward surmounting the four commonly recognized barriers to accessing care for people with TBI:

(1) A lack of information about available services and supports with little or no assistance in accessing them (information and referral services);

(2) A shortage of health professionals who may encounter individuals with TBI but lack relevant training to identify or treat the resulting symptoms (professional training);

(3) The absence of a TBI diagnosis or the assignment of an incorrect diagnosis (screening); and (4) Critical TBI services are spread across numerous agencies resulting in services being difficult for individuals and families to identify and navigate (resource facilitation).

The proposed performance measures are designed to account for the varied approaches used across state grantees and are consistent with the TBI State Partnership Program's purpose and ACL's mission.

Comments in Response to the 60–Day Federal Register Notice

ACL published a 60-day **Federal Register** Notice from 11/13/2017–01/12/2018 (Vol. 82, No. 217 pp. 52305–52306). ACL received a large volume of substantive stakeholder comments, causing revisions to the IC based on those public comments. The period in publication between the 60-day FRN and 30-day FRN, allowed ACL to thoughtfully review and apply the significant number of substantive public comments to the proposed new TBI IC.

In response to the original **Federal Register** notice in 2018, twenty-three (23) individuals provided written comments in response to the **Federal Register** notice containing the original proposed TBI Performance Measures, presented in the form of a reporting instrument for future TBI grantees. Commenters provided feedback on specific reporting instrument questions as well as general suggestions and recommendations for ACL about what grantees should report.

- 268 separate comments were made about one or more specific survey questions.
- 102 separate comments asked for a definition, further guidance, or clarification with regard to terminology used.
- 81 comments made a general recommendation, not specific to a particular question.

ACL also received feedback in 2018 through multiple face-to-face interactions with a majority of the current TBI grantees regarding the proposed measures.

ACL revised the instrument in 2019, in order to remain compliant with PRA 5 CFR 1320.8(d), ACL published an abbreviated public comment period prior to publishing the 30-day FRN and submitting to OMB. ACL solicited comments during the abbreviated public comment period regarding: (1) The accuracy of ACL's revised estimate of the burden for the proposed collection of information performance reporting data elements and (2) whether the proposed revisions to the collection of information enhance the quality, utility, and clarity of the information to be collected.

During the abbreviated public comment period published in the 83 FR 53738 received 14 additional comments. These comments have been addressed largely through the addition of definitions and guidance. The tool has been simplified, some questions have been eliminated or simplified because of concern about the burden, and three open-ended narrative questions added. The most prevalent comments and themes emerging from the public comments are summarized below:

Intended scope of the questions: The suggestion that occurred most across all commenters was for ACL to better define the scope of the questions. Many commenters asked whether ACL expected grantees to limit their reporting to their own grant activities, the staff they train with the grant funds, and the people with TBI they interact with using grant funds or if they would be expected to report about activities going on in the state beyond their grant activities. Commenters raised the issue of intended scope in general and specifically about almost all the questions in the instrument. Several commenters noted that the grants were awarded to different types of state agencies in different states and the reporting instrument did not make clear what ACL meant by the term ''TBI System,'' which could be interpreted to mean different things such as: The Medicaid system, the criminal justice system, the educational system, the vocational rehabilitation system, the broader medical system, or all of these together. Many indicated that grantees would have limited or no access to data about activities or people supported outside the grant activities being conducted by their own partnering organizations.

Response and Changes to Instrument: ACL intends for TBI grantees to report only about their own grant activities, the staff they train using grant funds, the partners they work with, and the people affected by TBI they interact with using grant funds. Additional guidance and definitions will be added to the online version of the instrument to clarify this intent and provide more guidance for grantees operating in different systems. For example:

(1) If a grantee is using grant funds to serve people with TBI within the criminal justice system statewide, the

scope of their reporting will be limited to the statewide criminal justice system.

(2) If a grantee is using their grant funds to assist people interacting with the vocational rehabilitation system in one region of the state, the scope of their reporting will be limited to that region's vocational rehabilitation system.

(3) If grant funds are going to several partnering organizations to work with people with TBI, the scope of that grantee's reporting will include the grant-funded activities of all of those partnering organizations (to the extent possible).

In addition, ACL added some new structured and open-ended questions to the instrument to allow grantees to identify their main areas of focus and describe report full or partial data from across their partners depending on what they can access.

Purpose of performance measures and accounting for state and grantee differences: Several commenters indicated they thought the instrument did not adequately account for the differences in how state systems are structured and the different focus areas of different grantees. Several commenters expressed concern that individual grantees would be negatively evaluated. Specific questions were edited to allow for grantees that are not able to provide data about activities and people outside of the scope of their grants or are otherwise not able to respond to every question.

Response and Changes to Instrument: ACL does not intend to use this reporting instrument to score grantees' individual performance or to compare grantees' performance with one another. ACL's intent is to gather a standard set of information from all grantee states, so that it can be aggregated to provide a better picture of the national impact of the grant program. However, ACL understands that states are working within different systems and focusing on different activities and that states' current capacity to collect and report data varies. ACL anticipates that some grantees will not be able to respond to every question on the instrument and this will not negatively affect those grantees. ACL hopes that every question will be applicable and feasible to answer for at least a subset of grantees, therefore providing a more complete (although not perfect) picture of grant activities than is currently available.

ACL revised the instrument questions to account more for state and grantee differences. For example, new structured and open-ended questions have been added at the beginning of the instrument to allow grantees to identify their main areas of focus and describe where the data they report are coming from so that ACL can interpret it appropriately. Using skip patterns programmed into the online tool, additional questions related to these areas of focus will only appear to grantees who indicate they are working in those areas. ACL will program the instrument into the online system so that some grantees may be directed to answer or not to answer some questions depending on how they answer initial questions about their grant activities and scope. Finally, an additional field has been added to most questions to allow grantees who do not respond or who can only respond partially to provide some descriptive notes about the data they submit.

Estimating prevalence and unmet need: Several commenters noted that reporting the prevalence of TBI and estimating the needs of people living with a TBI and their families would be very challenging for many grantees. Some noted that many states do not have registries or good/recent epidemiology data. Others indicated grantees would have no way of estimating the number of people who might need supports but are not accessing them. Several suggested that grantees might be able to respond to these questions if additional funding and/or technical assistance to carry out further study are provided.

Response and Changes to Instrument: These questions have been eliminated from the proposed instrument.

Defining services and supports: Several commenters expressed concern that the instrument asked questions about ''services and supports'' and wondered what ACL means by that term. Noting that grantees are currently focusing on system change work and are not allowed to use grant funds to provide direct in-home hands-on services and supports, some asked whether the funding announcement for new grants will include a different set of objectives and scope than they have in the past. Finally, several commenters interpreted the term to mean Medicaid home and community-based services and noted that not all states have a TBI Medicaid waiver. Those that do not are not likely to be able to access information about participants in other Medicaid waivers who are living with a TBI, so they would not be able to report about people with TBI receiving Medicaid services and supports.

Response and Changes to Instrument: ACL does not intend for grantees to use grant funds to provide direct in-home hands-on services and supports, such as those provided through Medicaid HCBS programs. The instrument's questions were revised to ask more clearly about the specific types of ways grantees may be assisting or supporting people with TBI and their families, such as with information and referral, screening, resource facilitation, service coordination/case management, outreach and education, building stronger partnerships, and other systems change work.

The remaining questions about utilization of home and community-based services and supports are intended to capture information about the extent to which people with TBI who are eligible for these types of services are accessing them, which may be an indicator of long-term systems change that grantees are working towards. These questions will only be applicable to grantees specifically working to increase access to and utilization of home and community-based services in their states.

Medically oriented questions: Several commenters expressed confusion about the instrument including questions they interpreted to be medically oriented, such as questions about technological tools, diagnosis, and treatment. They noted that grant activities might include screening people to identify a history of TBI and/or to better support people with TBI to live more fully in the community—but not diagnosis or medical treatment. They noted these questions would not be applicable to many grantees nor would grantees have access to data about diagnoses and treatment.

Response and Changes to Instrument: The instrument questions have been revised to ask more clearly about the specific ways grantees may be assisting people with TBI and their families, such as by screening for a lifetime history of TBI and facilitating access to community-based services. Questions about diagnosis and treatment have been removed.

Estimated Program Burden: These revisions based on public comments caused a change in the annual reporting burden estimates; there is a program change decrease of −1,008 annual burden hours from the 60-day FRN. In addition, the 60-day FRN respondent estimate was based on the highest number of possible awards anticipated; there is an adjustment decrease of −18 respondents.

Adjusted number of respondents	Number of responses (per respondent)	Average burden hours (per response)	Total burden hours
27	2	8	432

60-day FRN number of respondents	Number of responses (per respondent)	Average burden hours (per response)	Total burden hours
45	2	16	1,440

Dated: January 22, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–02091 Filed 2–3–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5473]

Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers; 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 for industry entitled ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers.'' FDA is issuing this guidance to provide manufacturers, packers, distributors, and their representatives (firms) with information to consider when developing FDA-regulated promotional labeling and advertisements (promotional materials) for prescription reference and biosimilar products licensed under the Public Health Service Act (PHS Act). Although the guidance covers promotional issues involving both reference and biosimilar products, some questions and answers are focused on only biosimilar product promotional materials. The guidance does not discuss considerations unique to promotional materials for interchangeable biosimilars.

DATES: Submit either electronic or written comments on the draft guidance by April 6, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2019–D–5473 for ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the