☐ One was from a commenter who did not provide an affiliation. The commenter shared concerns regarding how the level of evidence was graded.

☐ One was from a healthcare provider who shared citations for consideration.

☐ One was from an advocacy group that provided a comment outside the scope of the docket.

A summary of the revisions made to the final Systematic Review and Guideline based on external peer reviewer comments are posted in the Supporting Documents section of the docket (document titled ''Ped mTBI Guideline Response to Peer Reviewer Comments'').

CDC also revised the document based on public comments. For example, a few commenters expressed concern regarding recommendations not being applicable in the emergency care setting. As the clinical recommendations in the guideline were created for both the acute care and primary care setting, CDC added language to emphasize that the recommendations were drafted to be relevant for both settings. As another example, multiple comments were received regarding the content in the systematic review on the use of CT imaging. Commenters explained that current evidence that provides the basis for CT imaging focus on ruling out clinically-important traumatic brain injury among pediatric patients presenting with a TBI. In response, CDC revised the conclusion to specify that the recommendations are for children presenting with mTBI versus TBI of all severity levels in the acute care setting. All public and peer reviewer comments were carefully reviewed and considered to strengthen and improve the quality of the Systematic Review and Guideline. The final Systematic Review and Guideline on the Diagnosis and Management of Mild Traumatic Brain Injury Among Children can be found at *https://jamanetwork.com/journals/jamapediatrics/fullarticle/2698456?guestAccessKey=80a9ecdc-ea57-447d-a1b3-b4a87cadd40d* (Guideline) and *https://jamanetwork.com/journals/jamapediatrics/fullarticle/2698455?guestAccessKey=24b78e3d-571f-49fb-9daf-499d2b3e2cc1* (Systematic Review).

Dated: September 5, 2018.

Lauren Hoffmann,

Acting Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2018–19536 Filed 9–7–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Performance Reporting Form.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), Office of Child Care, in collaboration with the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau, administers the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, as authorized by Title V, Section 511 of the Social Security Act. The Administration for Children and Families administers the Tribal MIECHV Program while HRSA administers the State/Territory MIECHV Program. Tribal MIECHV discretionary grants support cooperative agreements to conduct community needs assessments; plan for and implement high-quality, culturally-relevant, evidence-based home visiting programs in at-risk tribal communities; establish, measure, and report on progress toward meeting performance measures in six legislatively-mandated benchmark areas; and conduct rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

The proposed data collection form is as follows: In order to continuously monitor, provide grant oversight, quality improvement guidance, and technical assistance to Tribal MIECHV grantees, ACF is seeking to collect services utilization data on a quarterly basis. The Tribal MIECHV Quarterly Data Performance Reporting Form, is made up of five categories of data—program capacity, place-based services, family engagement, staff recruitment and retention and staff vacancies. This form will be used by Tribal MIECHV grantees that receive grants under the Tribal MIECHV Program to collect data in order to determine the caseload capacity grantees are achieving, where services are being delivered, the retention and attrition of enrolled families, and the retention and attrition of program staff on a quarterly basis.

Respondents: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Managers. The information collection does not include direct interaction with individuals or families that receive the services.

ANNUAL BURDEN ESTIMATES

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Tribal MIECHV Grantees	Tribal MIECHV Quarterly Reporting Form.	25	4	24	2,400
Total					2,400

Estimated Total Annual Burden Hours: 2,400.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

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.

Robert A. Sargis,

Reports Clearance Officer.

[FR Doc. 2018–19561 Filed 9–7–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3065]

Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the States and the Food and Drug Administration; Revised Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability for public comment of a revised draft standard memorandum of understanding (MOU) entitled ''Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration'' (revised draft standard MOU). The revised draft standard MOU describes the responsibilities of a State that chooses to sign the MOU in investigating and responding to complaints related to compounded drug products compounded in the State and distributed outside the State and in addressing the interstate distribution of inordinate amounts of compounded drug products.

FDA is also announcing the withdrawal of an earlier draft standard MOU entitled ''Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration,'' which was issued in February 2015 (2015 draft standard MOU). The 2015 draft standard MOU is superseded by the revised draft standard MOU.

DATES: FDA is withdrawing its draft standard MOU that published on February 19, 2015 (80 FR 8874), as of September 10, 2018. Submit either electronic or written comments on the revised draft standard MOU by December 10, 2018, to ensure that the Agency considers your comment on this draft MOU before it begins work on the final version of the MOU. Submit either electronic or written comments on information collection issues under the Paperwork Reduction Act of 1995 by December 10, 2018 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments on the MOU 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–2018–N–3065 for ''Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the States and the Food and Drug Administration; Revised Draft; Availability.'' 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 heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft MOU to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft document.