

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–18AFX; Docket No. CDC–2018–0052]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Traumatic Brain Injury Disparities in Rural Areas (TBIDRA). This study will conduct a formative research to understand the challenges that rural healthcare providers face when diagnosing, treating, and managing traumatic brain injury (TBI) and develop a knowledge base to address gaps in services to improve clinical care and TBI outcomes in rural communities.

DATES: CDC must receive written comments on or before August 6, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0052 by any of the following methods:

- *Federal eRulemaking Portal:* Regulations.gov. Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and

instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Traumatic Brain Injury Disparities in Rural Areas (TBIDRA)—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Traumatic Brain Injury (TBI) is a significant public health concern in the United States, research indicates that residents of rural areas have both higher

incidence and higher mortality rates from TBI than do residents of urban areas, and that the prevalence of TBI-related disability in rural geographical areas is higher than in urban and suburban areas. The obstacles healthcare providers and patients face in rural areas are vastly different than those in urban areas. There is little published research specifically related to the challenges rural providers face in TBI diagnosis and treatment, and even less examination into effective ways to address gaps in service and improve TBI outcomes. The National Center for Injury Prevention and Control at the CDC, in a 2015 “Report to Congress on TBI in the United States,” determined that certain population groups, including residents of rural geographic areas, require special consideration when it comes to researching TBI.

This is a new Information Collection Request for 2 years to collect information on challenges that rural healthcare providers face in diagnosing, treating, and managing TBI of all severities and develop a knowledge base upon which we can begin to address gaps in services to improve clinical care and TBI outcomes in rural communities. The target population for the data collection effort includes physicians, nurse practitioners (NPs), and physician assistants (PAs) in selected specialties (general or family practice, emergency medicine, pediatrics) working in direct patient care in rural and urban areas. The focus of the study is rural healthcare providers; urban healthcare providers will be included in this study to allow for comparison in identifying the distinct challenges and opportunities for rural healthcare providers. This study has two data collection methods. A web survey to gather quantitative data on the unique challenges faced by rural clinicians, and focus groups to gain deeper insight into the context supporting and/or inhibiting access to comprehensive TBI evaluation and treatment, the study will collect qualitative data through focus groups with rural clinicians.

The proposed information collection is authorized by the Public Health Services Act (PHS Act) which provides the legislative means for states to advance public health across the lifespan and to reduce health disparities.

The total estimated annualized burden hours is 200. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Health care providers (Primary Care Physician, Emergency Physician, Nurse Practitioner and Physician Assistant).	TBI Provider Survey	600	1	15/60	150
	Focus group screener	36	1	5/60	3
	Focus group questionnaire	31	1	5/60	3
	Focus group discussion guide	31	1	85/60	44
Total	200

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 049

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled “Modifications to the List of Recognized Standards, Recognition List Number: 049” (Recognition List Number: 049), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: These modifications to the list of recognized standards are applicable June 7, 2018.

ADDRESSES: You may submit comments 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-2004-N-0451 for “Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 049.” 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. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 049.

- **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