#### ICD-10-PCS Topics

- 1. Administration of Lovotibeglogene autotemcel (lovo-cel) \*
- 2. Administration of Exagamglogene autotemcel (exa-cel),
- 3. External Support Device for AV Fistula Creation
- 4. Implantation of Polymethyl Methacrylate Cranioplasty Plates \*
- 5. Insertion of Transcatheter Bicaval Valve System \*
- 6. Implantation of Bioprosthetic Femoral Venous Valve
- 7. Intubated Prone Positioning
- 8. Section X Updates
- 9. Addenda and Key Updates

\* Requestor intends to submit a new technology add-on payment (NTAP) application for FY 2024.

\* Request is for an April 1, 2023, implementation date, and the requestor intends to submit an NTAP application for FY 2024 consideration.

Presentations for procedure code requests are conducted by both the requestor and CMS during the C&M Committee meeting. Discussion from the requestor generally focuses on the clinical issues for the procedure or technology, followed by the proposed coding options from a CMS analyst. Topics presented may also include requests for new procedure codes that relate to a new technology add-on payment (NTAP) policy request.

CMS is continuing to modify the approach for presenting the new NTAPrelated ICD-10-PCS procedure code requests that involve the administration of a therapeutic agent for the September 13-14, 2022, ICD-10 Coordination and Maintenance Committee meeting. Consistent with the requirements of section  $1886(d)(5)(K)(i\bar{i}i)$  of the Social Security Act, applicants submitted requests to create a unique procedure code to describe the administration of a therapeutic agent, such as the option to create a new code in Section X within the ICD-10-PCS procedure code classification. CMS will initially display only those meeting materials associated with the NTAP-related ICD-10-PCS procedure code requests that involve the administration of a therapeutic agent on the CMS website in early August 2022 at: https://www.cms.gov/Medicare/ Coding/ICD10/C-and-M-Meeting-Materials.

The two NTAP-related ICD-10-PCS procedure code requests that involve the administration of a therapeutic agent

- 1. Administration of Lovotibeglogene autotemcel (lovo-cel) \*
- 2. Administration of Exagamglogene autotemcel (exa-cel) \*\*

These topics will not be presented during the September 13-14, 2022,

meeting. CMS will solicit public comments regarding any clinical questions or coding options included for these two procedure code topics in advance of the meeting continuing through the end of the respective public comment periods. Members of the public should send any questions or comments to the CMS mailbox at: ICDProcedureCodeRequest@ cms.hhs.gov.

CMS intends to post a question-andanswer document in advance of the meeting to address any clinical or coding questions that members of the public may have submitted. Following the conclusion of the meeting, CMS will post an updated question-and-answer document to address any additional clinical or coding questions that members of the public may have submitted during the meeting that CMS was not able to address or that were submitted after the meeting.

The NTAP-related ICD-10-PCS procedure code requests that do not involve the administration of a therapeutic agent and all non-NTAPrelated procedure code requests will continue to be presented during the virtual meeting on September 13, 2022, consistent with the standard meeting process.

CMS will make all meeting materials and related documents available at: https://www.cms.gov/Medicare/Coding/ ICD10/C-and-M-Meeting-Materials. Any inquiries related to the procedure code topics scheduled for the September 13-14, 2022, ICD-10 Coordination and Maintenance Committee meeting that are under consideration for April 1, 2023, or October 1, 2023, implementation should be sent to the CMS mailbox at: ICDProcedureCodeRequest@

cms.hhs.gov.

#### ICD-10-CM Topics

- 1. Extraocular Muscle Entrapment
- 2. IGAN
- 3. Inappropriate Sinus Tachycardia
- 4. Insulin Resistance Syndrome
- 5. Leukodystrophies
- 6. Nontraumatic Coma Not Elsewhere Classified
- 7. Sickle Cell Retinopathy
- 8. Addenda

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

#### Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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BILLING CODE 4163-18-P

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### Centers for Disease Control and Prevention

[30Day-22-0856]

### **Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "National Quitline Data Warehouse (NQDW)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on July 7, 2021 to obtain comments from the public and affected agencies. CDC received three comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments

- (a) 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;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected:
- (d) 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 submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/ do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

#### **Proposed Project**

National Quitline Data Warehouse (NQDW) (OMB Control No. 0920–0856, Exp. 10/31/2022)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Since 2010, the National Ouitline Data Warehouse (NQDW) has collected a core set of information from the 50 U.S. states, the District of Columbia, Guam, and Puerto Rico regarding what services telephone quitlines offer to tobacco users as well as the number and type of tobacco users who receive services from telephone quitlines. The data collection was modified in 2015 to collect data from the Asian Smokers' Quitline (ASQ) in addition to the other 53 states/territories that provide data and included five new questions to the NQDW Intake Questionnaire to help CDC and states tailor quitline services to the needs of its callers. Additionally, collection of the NQDW Services Survey was changed from quarterly to semiannually in 2019.

The NQDW provides data on the general smoking population who contact their state quitlines, but also allows for collections of information about key subgroups of tobacco users who contact state quitlines to better support cessation services. Data is collected on tobacco users who received service from state telephone quitlines from all funded U.S. states, territories, and the Asian Smokers' Quitline (ASQ) through the NQDW Intake Questionnaire. The NQDW Seven-Month Follow-up Questionnaire is administered to tobacco users who received services from the ASQ only. Data on the quitline call volume, number of tobacco users served, and the services offered by state quitlines will be provided by state health department personnel who manage the quitline, or their designee, such as contracted quitline service providers, using the NQDW Quitline Services Survey. Data collected from the NQDW is analyzed with simple descriptive data tabulations, and trends are currently reported online through the CDC State Tobacco Activities Tracking and Evaluation (STATE) System website. More complex statistical analyses, including multivariate regression techniques will be utilized to assess quitline outcomes such as quitline reach, service utilization, how callers reported hearing about the quitline, and the effectiveness of quitline promotions and the CDC Tips From Former Smokers national tobacco education media campaigns on state quitline call volume and tobacco users receiving services from state quitlines. CDC uses the information collected by the NQDW for ongoing monitoring, reporting, and evaluation related to state quitlines. Select data from the NQDW are reported online through the CDC's STATE System website (https://www.cdc.gov/ statesystem).

CDC requests OMB approval to continue the NODW information collection for three years. Fifty states, the District of Columbia, Guam, and Puerto Rico continue to receive funding to participate. This Revision reflects inclusion of additional measures, including those related to e-cigarette use and online quitline services, that reflect the impact of new technologies. Adding these measures to the NQDW survey instruments will impose minimal additional burden on states but will substantially improve the utility of the NQDW data to identify use of state quitlines by key tobacco use populations and through modalities other than telephone calls.

Participation in the Caller Intake and Follow-Up Interviews is voluntary for quitline callers. The estimated burden is 10 minutes for a complete intake call conducted with an individual who calls on their own behalf. The estimated burden is one minute for a caller who requests information for someone else, as these callers complete only a subset of questions on the Intake Questionnaire.

As a condition of funding (CDC-RFA-DP20-2001), the 54 cooperative agreement awardees are required to submit NQDW intake data quarterly, and services survey data semiannually. CDC recognizes that awardees incur additional burden for preparing and transmitting summary files with their de-identified caller intake and follow-up data. This burden is acknowledged in the instructions for transmitting the electronic data files. There is a net decrease in burden hours, primarily due to decreases in the overall number of telephone calls to the quitlines, which is estimated to be only partially offset by the use of other quitline modalities.

CDC requests OMB approval for an estimated 68,089 annual burden hours. There is no cost to respondents other than their time to participate.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Quitline participants who contact the quitline for help for themselves.	NQDW Intake Questionnaire (English-complete).	405,053	1	10/60
	ASQ Intake Questionnaire (Chinese, Korean, or Vietnamese-complete).	1,686	1	10/60
	ASQ Seven-Month Follow-up Questionnaire	236	1	7/60
Participants who contact the quitline on behalf of someone else.	NQDW Intake Questionnaire (English-subset).	819	1	1/60
	ASQ Intake Questionnaire (Chinese, Korean, or Vietnamese-subset).	249	1	1/60
Tobacco Control Manager or their Designee/ quitline Service Provider.	Submission of NQDW Intake Questionnaire Electronic Data File to CDC.	54	4	1

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
	Submission of NQDW (ASQ) Seven-Month Follow-up Electronic Data File to CDC.	1	1	1
	NQDW Quitline Services Survey	54	2	20/60

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

### Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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BILLING CODE 4163-18-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# Centers for Disease Control and Prevention

[60Day-22-22HN; Docket No. CDC-2022-0089]

#### 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 information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled School-Based Active Surveillance (SBAS) of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Among Schoolchildren: Phase-2 of the National Roll-Out. This project will expand on the work from the pilot phase and increase the number of local schools, school districts, states and subsequently school nurses involved in active surveillance of chronic conditions, including ME/CFS, using an electronic data collection platform.

**DATES:** CDC must receive written comments on or before September 20, 2022.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2022-0089 by either of the following methods:

• Federal eRulemaking Portal: www.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 H21–8, Atlanta, Georgia 30329.

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

Please note: Submit all comments through the Federal eRulemaking portal (www.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 H21–8, Atlanta, Georgia 30329; Telephone: 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:
- 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; and
  - 5. Assess information collection costs.

#### **Proposed Project**

School-Based Active Surveillance (SBAS) of Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome Among Schoolchildren: Phase-2 of the National Roll-Out—New—National Center for Emerging Zoonotic and Infectious Disease (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), a complex, chronic, debilitating multi-system disease, affects an estimated 836,000 to 2.5 million persons in the United States. However, about 90% of people with ME/CFS have not received an official diagnosis from a healthcare professional. ME/CFS affects up to two in 100 children and adolescents, which often goes undiagnosed by healthcare professionals.

Data on chronic conditions among schoolchildren, such as asthma, has been collected over the years, but there has been little to no emphasis on ME/ CFS in the United States. Chronic conditions among school-aged children likely account for a high proportion of chronic school absenteeism and school withdrawal. Conducting active surveillance among students using school nurses could expedite the diagnosis and management of children who present with symptoms commonly seen in ME/CFS. This involves educating school nurses about ME/CFS and its related syndromes, how to best approach parents and guardians when suggesting the diagnosis, and how to