

studies are entirely behavioral but most often they are cycles of interviews and focus groups designed to inform the development of a product.

Products from these formative research studies will be used for prevention of disease. Findings from these studies may also be presented as evidence to disease-specific National Advisory Committees, to support revisions to recommended prevention and intervention methods, as well as new recommendations.

Much of CDC's health communication takes place within campaigns that have fairly lengthy planning periods and/or timeframes that accommodate the standard federal process for approving data collections. Short-term qualitative interviewing and cognitive research techniques have previously proven invaluable in the development of scientifically valid and population-appropriate methods, interventions, and instruments.

This request includes studies investigating the utility and acceptability of proposed sampling and recruitment methods, intervention contents and delivery, questionnaire domains, individual questions, and

interactions with project staff or electronic data collection equipment. These activities will also provide information about how respondents answer questions and ways in which question response bias and error can be reduced.

This request also includes collection of information from public health programs to assess needs related to initiation of a new program activity or expansion or changes in scope or implementation of existing program activities to adapt them to current needs. The information collected will be used to advise programs and provide capacity-building assistance tailored to identify needs.

Overall, these development activities are intended to provide information that will increase the success of the surveillance or research projects through increasing response rates and decreasing response error, thereby decreasing future data collection burden to the public. The studies that will be covered under this request will include one or more of the following investigational modalities: (1) structured and qualitative interviewing for surveillance, research, interventions and

material development; (2) cognitive interviewing for development of specific data collection instruments; (3) methodological research; (4) usability testing of technology-based instruments and materials; (5) field testing of new methodologies and materials; (6) investigation of mental models for health decision-making to inform health communication messages; and (7) organizational needs assessments to support development of capacity. Respondents who will participate in individual and group interviews (qualitative, cognitive, and computer assisted development activities) are selected purposively from those who respond to recruitment advertisements.

In addition to utilizing advertisements for recruitment, respondents who will participate in research on survey methods may be selected purposively or systematically from within an ongoing surveillance or research project. Participation of respondents is voluntary. CDC requests OMB approval for an estimated 20,000 annual burden hours. There is no cost to participants other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response (in hours)	Total burden hours
General public and health care providers	Screener	10,000	1	15/60	2,500
	Interview	5,000	1	1	5,000
	Focus Group Interview	5,000	1	2	10,000
	Survey	5,000	1	30/60	2,500
Total	20,000

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics (NCHS), ICD-10 Coordination and Maintenance (C&M) Committee Meeting.

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

ACTION: Notice of meeting.

SUMMARY: The CDC, National Center for Health Statistics (NCHS), Classifications and Public Health Data Standards Staff, announces the following meeting of the ICD-10 Coordination and Maintenance (C&M) Committee. This meeting is open to the public, limited only by the number of audio lines available. Online registration is not required.

DATES: The meeting will be held on September 13, 2022, from 9 a.m. to 5 p.m., EDT, and September 14, 2022, from 9 a.m. to 5 p.m., EDT.

ADDRESSES: This is a virtual meeting. Information will be provided on each of the respective web pages when it becomes available. For CDC, NCHS: https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm. For the Centers for Medicare & Medicaid Services (CMS), HHS: <https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials>.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Purpose: The ICD-10 Coordination and Maintenance Committee is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Tenth Revision, Clinical Modification (CM) and ICD-10 Procedure Coding System (PCS).

Matters To Be Considered: The tentative agenda will include discussions on the ICD-10-CM and ICD-10-PCS topics listed below. Agenda items are subject to change as priorities dictate. Please refer to the posted agenda for updates one month prior to the meeting.

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 Bivalve 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 NTAP-related 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)(iii) 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 are:

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-and-answer 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-NTAP-related 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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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 that:

(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.