

Background and Brief Description

Section 2(a) of Public Law 102–493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), 42 U.S.C. 263a–1(a)) requires that each assisted reproductive technology (ART) program shall annually report to the Secretary through the Centers for Disease Control and Prevention: (1) Pregnancy success rates achieved by such ART program, and (2) the identity of each embryo laboratory used by such ART program, and whether the laboratory is certified or has applied for such certification under the Act. The required information is currently reported by ART programs to CDC as specified in the Assisted Reproductive Technology (ART)

Program Reporting System (OMB Control No. 0920–0556, Exp. 8/31/2021). CDC seeks to continue OMB approval for a period of three years. The revised total burden estimate is higher than the previous approval, due to an increase in the utilization of ART in the United States.

The estimated number of respondents (ART programs or clinics) is 456, based on the number of clinics that provided information in 2018; the estimated average number of responses (ART cycles) per respondent is 670. Additionally, approximately 5–10% of responding clinics will be randomly selected each year to participate in data validation and quality control activities; an estimated 35 clinics will be selected to report validation data on 70 cycles

each on average. Finally, respondents may provide feedback to CDC about the usability and utility of the reporting system. The option to participate in the feedback survey is presented to respondents when they complete their required data submission. Participation in the feedback survey is voluntary and is not required by the FCSRCA. CDC estimates that 50% of ART programs will participate in the feedback survey.

The collection of ART cycle information allows CDC to publish an annual report to Congress as specified by the FCSRCA and to provide information needed by consumers. OMB approval is requested for three years and there are no costs to respondents other than their time. The total estimated annualized burden is 219,904 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---------------------|---------------------------|-----------------------|------------------------------------|--|
| ART Clinics | NASS Reporting Form | 456 | 670 | 43/60 |
| | Data Validation | 35 | 70 | 23/60 |
| | Feedback Survey | 255 | 1 | 2/60 |

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention
[30Day–21–1238]
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 “US Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications,” also commonly known as a “TB Follow-Up Worksheet” 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 03/09/2021 to obtain comments from the public and affected agencies. CDC received one comment 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.

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

The US Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications (OMB Control No. 0920–1238, Exp. 06/30/2021)—Reinstatement with Change—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Global Migration and Quarantine (DGMQ) collaborated with the Division of TB Elimination (DTBE) to revise the proposed worksheet to capture follow-up medical examination information after a person with tuberculosis classification has arrived in

the US. The overseas medical examination determines whether the applicant has an inadmissible condition of public health significance (a Class A condition) or has a health-related condition that is admissible, but might require extensive medical treatment or follow-up (a Class B condition), such as treated tuberculosis. Applicants with Class A (inadmissible) conditions can only enter the United States if they are granted a waiver. Applicants who have Class A conditions include those who; (1) Have a communicable disease of public health significance, (2) do not have documentation of having received vaccinations against vaccine-preventable diseases, (3) have a physical or mental disorder with associated harmful behavior, or (4) abuse, or are addicted to drugs (42 U.S.C. 252, 8 U.S.C. 1182, and 8 U.S.C. 1222 provide for the physical and mental examination of applicants in accordance with regulations prescribed by the HHS Secretary). CDC highly recommends that persons with overseas class A or B tuberculosis receive domestic follow-up medical examination information to prevent new transmission of tuberculosis. This is the primary rationale for collecting domestic tuberculosis follow-up information.

The US foreign-born population continuously had the highest incidence of tuberculosis compared to the US non-foreign-born population. According to CDC, the 2019 TB case rate was 14.2 per 100,000 for foreign-born persons compared to 0.9 per 100,000 for US-born persons. The proportion of TB cases occurring in the foreign-born population was found to be approximately 70.9% of the national case total. CDC strongly recommends US-bound immigrants and refugees with class A or B tuberculosis to receive follow-up examinations for tuberculosis in the US.

The purpose of this data collection is to methodically gather tuberculosis follow-up outcome data to monitor and track US-bound persons with overseas class A and B tuberculosis to assist in the national effort to prevent new transmission of tuberculosis. To accurately determine recent US arrivals receiving domestic follow-up medical examinations, US health departments

will provide domestic follow-up outcome information to CDC by completing The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications, also commonly known as the TB Follow-Up Worksheet. Without this data, DGMQ will not have a method of tracking and monitoring newly-arrived persons with overseas class A or B tuberculosis. DGMQ will use information reported on the TB Follow-Up Worksheet to ensure that tuberculosis programs are effectively tracking newly-arrived persons and coordinating follow-up medical examinations with state and local clinicians in the US.

Since the previous approval of the "US Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications" data collection instrument in 2018, there have been changes made in the data collection instrument to clarify wording, add additional options for respondents to select, and enhance data collection quality. There are also clarifications made in the "Purpose and Use of Information Collection" in Supporting Statement A to further clarify information what the data collection instrument collects. In the "Respondent Universe and Sampling Methods" section of Supporting Statement B, there are clarifications made to explain how respondents gain access to and use the Electronic Disease Notification (EDN) system and the data collection instrument. There is an increase from 550 respondents to 1548 respondents due to the increase in the number of individuals throughout the United States requesting access to the EDN system to access medical records for U.S. arrivals, and complete the EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications for U.S. arrivals with TB classifications. There is no change to the burden per respondent to complete a follow-up form.

Several indicators will be calculated to measure domestic tuberculosis program performance, including the percentage of aliens with class B tuberculosis with complete US medical examinations. This program performance monitoring activity will be

ongoing throughout the year. State and local health departments will voluntarily report evaluation outcome findings on a continuous basis once evaluation results for an individual becomes available.

Data collected by DGMQ will be used to help evaluate the efficacy and efficiency of overseas tuberculosis diagnoses, treatments, and prevention activities along with panel physician performance. Currently, DGMQ does not have an effective method of determining the accuracy of chest x-rays read overseas and the aptness of overseas treatment for tuberculosis. This data will provide DGMQ with a method of evaluating panel physician performance and overseas treatment and prevention activities. The proposed TB Follow-Up Worksheet contains sections that allow US physicians to review overseas chest x-rays and treatment and indicate any concerns or errors. A negative consequence of not collecting this information is that DGMQ will not be able to efficiently analyze data to determine which panel physicians have the most inaccuracies. Plans for formal evaluations of US panel physicians are contingent upon the approval of the TB Follow-Up Worksheet.

If technical instructions for tuberculosis diagnosis and treatment are followed properly overseas, persons with overseas classification B tuberculosis should not have tuberculosis disease during their US follow-up examinations. The form will help DGMQ understand what factors may contribute to a domestic diagnosis of tuberculosis. The TB Follow-up Worksheet contains a section that collects patient diagnoses and treatment recommendations. Without this information, DGMQ staff will not be able to accurately identify and resolve factors that contribute to tuberculosis disease. This form of monitoring is ongoing and will occur with every instance an alien is diagnosed with tuberculosis disease during follow-up examinations.

There are no costs to the respondents other than their time. The total estimated annual burden are 2,322 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---|---|-----------------------|------------------------------------|--|
| EDN data entry staff at state and local health departments. | US Tuberculosis Follow-up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications. | 1,548 | 3 | 30/60 |

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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 meeting. This meeting is open to the public, limited only by audio. Online Registration is not required.

DATES: The meeting will be held on September 14, 2021, from 9:00 a.m. to 5:00 p.m., EDT, and September 15, 2021, from 9:00 a.m. to 5:00 p.m., EDT.

ADDRESSES: This is a virtual meeting. Information will be provided on each of our respective web pages when it becomes available. For CDC/NCHS https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm. For CMS <https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings>.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Purpose: The ICD-10 Coordination and Maintenance (C&M) Committee is a public forum for the presentation of proposed modifications to the International Classification of Diseases,

Tenth Revision, Clinical Modification and ICD-10 Procedure Coding System.

Matters To Be Considered: The tentative agenda will include discussions on 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 fostamatinib(1), (2)
2. Administration of betibeglogene autotemcel (beti-cel)(1)
3. Administration of RBX2660(1)
4. Pressure-controlled Intermittent Coronary Sinus Occlusion
5. Measurement of Exhaled Nitric Oxide (FeNo)
6. Histotripsy of Liver
7. Replacement of Meniscus with Synthetic Substitute (1)
8. Section X Updates
9. Addenda and Key Updates

(1) Applicant intends to submit a New Technology Add-on Payment (NTAP) application for FY 2023.

(2) Request is for an April 1, 2022 implementation date.

Presentations for procedure code requests are conducted by both the requestor and CMS during the Coordination & Maintenance 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 technology add-on payment (NTAP) related ICD-10-PCS procedure code requests that involve the administration of a therapeutic agent. 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 only display 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 2021 at: <https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials>.

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

1. Administration of fostamatinib
2. Administration of betibeglogene autotemcel (beti-cel)
3. Administration of RBX2660

These topics will not be presented during the September 14-15, 2021 meeting. CMS will solicit public comments regarding any clinical questions or coding options included for these three procedure code topics in advance of the meeting continuing through the end of the public comment period. The deadline to submit comments for topics being considered for April 1, 2022 implementation is October 15, 2021 and the deadline to submit comments for topics being considered for an October 1, 2022 implementation is November 15, 2021. Members of the public should send any questions or comments to the CMS mailbox at: ICDProcedureCodeRequest@cms.hhs.gov by the designated deadline dates mentioned above.

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 14, 2021