determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act [1] sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.[2]

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the Commissioner of Food and Drugs may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

The ASPR requested that the Secretary issue the declaration to allow the Department to take measures based on information currently available about monkeypox virus. The determination of a public health emergency or a significant potential for a public health emergency, and the declaration that circumstances exist justifying emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus* by the Secretary of HHS, as described below, enable the Commissioner of Food and Drugs to issue EUAs for in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus* for emergency use under section 564 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On August 9, 2022, pursuant to section 564 of the FD&C Act, I determined that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad that involves monkeypox virus.

III. Declaration of the Secretary of Health and Human Services

On September 7, 2022, on the basis of my August 9, 2022 determination that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad and that involves monkeypox virus, I declared that circumstances exist justifying authorizations of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUAs issued by the Commissioner of Food and Drugs pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Xavier Becerra,

Secretary, U.S. Department of Health and Human Services.

Footnotes

1. 42 U.S.C. 247d–6b.
2. As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Public Law 113–5, the Secretary may make a determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary is no longer required to make a determination of a public health emergency in accordance with section 319 of the PHS Act, 42 U.S.C. 247d to support a determination or declaration made under section 564 of the FD&C Act.

[FR Doc. 2022–19752 Filed 9–12–22; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before October 13, 2022.

ADDRESSES: Written 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.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Evaluation of the Extension of the Certified Community Behavioral Health Clinic (CCBHC) Demonstration Program.

Type of Collection: New.

OMB No.: 0990–NEW—Office of the Assistant Secretary for Planning and Evaluation.

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the U.S. Department of Health and Human Services (HHS) is requesting Office of Management and Budget (OMB) approval for new data collection activities to support its

evaluation of the extension of the Certified Community Behavioral Health Clinic (CCBHC) demonstration program.

Section 223 of the Protecting Access to Medicare Act (Pub. L. 113–93; PAMA) authorized the CCBHC demonstration to allow states to test a new strategy for delivering and reimbursing a comprehensive array of services provided in community behavioral health clinics. The demonstration aims to improve the availability, quality, and outcomes of outpatient services provided in these clinics by establishing a standard definition for CCBHCs and develops a new Medicaid prospective payment system (PPS) in each state that accounts for the total cost of providing nine types of services to all people who seek care. The PPS in each state is designed to provide CCBHCs with the financial support and stability necessary to deliver these required services. The demonstration also aims to incentivize quality through quality bonus payments to clinics and requires CCBHCs to report quality measures and costs.

Need and Proposed Use of the Information: PAMA mandates that HHS submit reports to Congress about the Section 223 demonstration that assess (1) access to community-based mental health services under Medicaid in the area or areas of a state targeted by a demonstration program as compared to other areas of the state, (2) the quality and scope of services provided by certified community behavioral health clinics as compared to community-based mental health services provided in states not participating in a demonstration program and in areas of a demonstration state that are not participating in the demonstration, and (3) the impact of the demonstration on the federal and state costs of a full range of mental health services (including inpatient, emergency, and ambulatory services). The ability of ASPE to provide this information to Congress requires a rigorously designed and independent evaluation of the CCBHC demonstration. The information collected under this submission will help ASPE address research questions for the evaluation and inform required reports to Congress. ASPE is requesting approval of this information collection for a three-year period. Information will be collected from individuals (CCBHC clients), businesses (CCBHC staff) and from state governments.

The total annual burden hours estimated for this information collection request are summarized in the table below.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
State official interviews	27	1	1	27
CCBHC leadership interviews	10	1	1	10
CCBHC client focus groups	14	1	1	14
CCBHC survey	50	1	3	150
Total	101	.....	.....	201

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2022–19757 Filed 9–12–22; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; DSR Member Conflict.

Date: October 14, 2022.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aiwu Cheng, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892, *Aiwu.cheng@nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; Clinical Studies.

Date: October 27, 2022.

Time: 9 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yun Mei, MD, Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite #670, Bethesda, MD 20892, (301) 827–4639, *yun.mei@nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; In Utero Treatments of Congenital Dental and Craniofacial Disorders Using Precision Medicine Approaches.

Date: October 28, 2022.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aiwu Cheng, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892, *Aiwu.cheng@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS.)