of chronic rhinosinusitis without nasal polyps or allergic fungal rhinosinusitis.

This guidance finalizes the draft guidance of the same title issued on December 10, 2021 (86 FR 70505). FDA considered comments received on the draft guidance in this finalized guidance. Chronic rhinosinusitis is characterized by inflammation of the nasal mucosa and paranasal sinuses and can be further divided into chronic rhinosinusitis with and without nasal polyps. Nasal polyps are inflammatory hyperplastic growths that protrude into the nasal passages. Symptoms of CRSwNP include nasal congestion, nasal discharge, facial pain or pressure, and loss of smell. Nasal polyps have associated morbidity that can have substantial impact on day-to-day functioning. Because of differences in natural history and treatment between chronic rhinosinusitis with and without nasal polyps, this guidance specifically addresses aspects of trial design, safety and efficacy assessment for CRSwNP. Changes from the draft to the final guidance include considerations for efficacy assessments for CRSwNP.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Chronic Rhinosinusitis With Nasal Polyps: Developing Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information contained in 21 CFR part 312 relating to investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to new drug applications have been approved under OMB control number 0910–0001. The collections of information contained in 21 CFR part 601 relating to biologics license applications have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13884 Filed 6–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0438]

Agency Information Collection Request; 60-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 August 29, 2023.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

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: FY2020 Teen Pregnancy Prevention (TPP) Program Performance Measures.

Type of Collection: Extension.

OMB No.: 0990–0438.

Abstract: The Office of Population Affairs (OPA), in the Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), requests a renewal clearance for the collection of performance measures specifically for FY2020 Teen Pregnancy Prevention (TPP) Program grantees. Collection of performance measures is a requirement of all TPP awards and is included in the NOFOs. The data collection will allow OPA to comply with federal accountability and performance requirements, inform stakeholders of grantee progress in meeting TPP program goals, provide OPA with metrics for monitoring TPP grantees, and facilitate individual grantees' continuous quality improvement efforts within their projects. OPA requests clearance for one year to cover reporting during the no-cost extension period of the awards.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Grantees (partners and sustainability)	All TPP grantees	90	2	15/60	45
Grantees (training)	All TPP Grantees	90	2	15/60	45
Grantees (dissemination)	All TPP Grantees	90	2	30/60	90
Grantees (Stakeholder Engagement)	All TPP Grantees	90	2	15/60	45
Grantees (Reach and Demographics)	Tier 1 and Tier 2 Phase II Grantees	64	2	3	384
Grantees (Dosage)	Tier 1 and Tier 2 Phase II Grantees	64	2	2	256
Grantees (Fidelity and Quality)	Tier 1 and Tier 2 Phase II Grantees	64	2	2	256

ANNUALIZED BURDEN HOUR TABLE—Continued

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Total			2		1,155

Sherrette A. Funn,

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

[FR Doc. 2023–13909 Filed 6–29–23; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information: Draft HHS 2023 Framework To Support and Accelerate Smoking Cessation

AGENCY: Office of the Assistant Secretary for Health (OASH), Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice of request for information.

SUMMARY: The Department of Health and Human Services (HHS or Department) is issuing this request for information (RFI) to receive input from the public on the Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation to guide the Department's efforts to sustain and strengthen existing programs and drive further progress toward smoking cessation, with an emphasis on serving populations and communities disproportionately impacted by smoking-related morbidity and mortality.

DATES: To be assured consideration, comments must be received at the email address provided below, no later than midnight Eastern Time (ET) on July 30, 2023. HHS will not reply individually to responders but will consider all comments submitted by the deadline. Please do not provide confidential information as comments may be published or otherwise used for agency purposes.

ADDRESSES: Please submit all comments via email to *HHSSmokingCessation Framework2023@hhs.gov* as a Word document, Portable Document Format (PDF), or in the body of an email. Please include ''Request for Information: Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation'' in the subject line of the email message.

FOR FURTHER INFORMATION CONTACT: Please submit questions for further information to Sarah Boateng, Principal Deputy Assistant Secretary for Health. Email: *sarah.boateng@hhs.gov* at (202) 205–0725.

SUPPLEMENTARY INFORMATION: The mission of HHS is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

On February 22, 2022, President Joe Biden and First Lady Jill Biden reignited the Cancer Moonshot, setting an ambitious, achievable goal: to reduce the death rate from cancer by at least 50 percent over the next 25 years and improve the experience of people and families living with and surviving cancer, ultimately ending cancer as we know it. Additionally, on January 20, 2021, President Biden signed Executive Order 13985, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,* which directed the Department to make achieving health equity part of its mission by developing programs, policies, and activities to address the disproportionately high and adverse health disparities in underserved communities. Then on February 16, 2023, President Biden signed Executive Order 14091, *Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.* This second Executive Order reaffirmed the Administration's commitment to health equity by extending and strengthening equity-advancing requirements for agencies.

To support the executive order initiatives, and to pursue the Administration's priorities for advancing health equity and driving down cancer deaths, the Office of the Assistant Secretary for Health (OASH) is leading the development of a framework to support and accelerate smoking cessation. The Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation (the Framework) will provide direction to enhance collaboration and coordination across HHS, and with Federal and non-Federal stakeholders, drive further progress toward smoking cessation and delivering equitable outcomes for all persons in America. The draft Framework was developed with valued input from subject matter experts across HHS Operating Divisions. The Framework aims to accelerate smoking cessation and reduce smoking-related health disparities by building on current activities and collaborations across the Department, including work guided by the HHS Tobacco Control Strategic Action Plan developed in 2010.

The scope is focused on cessation of the use of commercial cigarettes, cigars, and cigarillos, for people of all ages across the lifespan. The Department also recognizes the importance of tobacco use prevention and cessation of other tobacco products. These issues as well as those related to e-cigarettes are topics that are out of scope for this phase but will be addressed in a later phase of this effort.

The purpose of this request for information (RFI) is to seek public comment on the Draft 2023 Framework to Support and Accelerate Smoking Cessation. Please see the Draft Framework below, followed by an RFI in the form of questions to the public.

Draft U.S. Department of Health and Human Services 2023 Framework To Support and Accelerate Smoking Cessation

Background

Cigarette smoking is the leading cause of preventable disease, disability, and death in the United States, including about 30% of all cancer deaths. Enormous progress has been made over the last 60 years in driving down rates of cigarette smoking. In 2021, 11.5% of U.S. adults smoked cigarettes, down from an all-time high of 42%, and two-thirds (66.5%) of all adults who ever smoked cigarettes have quit. Despite this progress, cigarette smoking still claims approximately 480,000 American lives every year.

Furthermore, the gains that have been made over the past several decades have not occurred equally across the population, leaving behind many of those who have the least resources and who face the greatest barriers to quitting. Encouraging and assisting every person in America to quit smoking is critical to ensuring a healthier future for all people in America and to helping achieve the Cancer Moonshot goal of reducing cancer death rates by at least half over