

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This guidance finalizes the draft guidance of the same title issued on December 10, 2021 (86 FR 70505). FDA considered comments received on the draft guidance in this finalized guidance.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](mailto:Sherrette.Funn@hhs.gov) or by calling (202) 264–0041 and [PRA@HHS.GOV](mailto: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](mailto:Sherrette.Funn@hhs.gov), [PRA@HHS.GOV](mailto: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](mailto:HHSSmokingCessationFramework2023@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](mailto: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