TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
314.107(e)—notification of court actions or written consent to approval.	247	2	494	0.5 (30 minutes) ..	247
SUBPART G, H, I					
314.420—drug master files [FDA 3938]—original amendments.	36	27.2	981	61	59,841
DMFs—technical, administrative, REMS)	2,946	11.4	33,590	8	268,720
DMFs—annual reports	2,946	3.33	9,834	4	39,336
314.550—Promotional material and subpart H applications.	55	11.6	640	120	76,800
Total	.....	.....	.....	.....	4,118,933.5

Our estimated burden for the information collection reflects a decrease. We attribute this adjustment to improved operational efficiencies with regard to Agency data systems and digital submission processes.

Dated: November 10, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25239 Filed 11–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Coronavirus 2019 (COVID–19) Data Report OMB No. 0906–0053—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than December 16, 2020.

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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Coronavirus 2019 Data Report OMB No. 0906–0053—Extension.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low income people with HIV. Nearly two-thirds of clients (patients) live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of safety net providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States.

FY 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act

On March 27, 2020, the President signed into law the ''Coronavirus Aid, Relief, and Economic Security Act'' (CARES Act). The CARES Act appropriated $90 million to HRSA's RWHAP to prevent, prepare for, and respond to coronavirus disease 2019 (COVID–19). This funding supports 581 RWHAP Parts A, B, C, D and F recipients across the country, including city/county health departments, state health departments, health clinics, community-based organizations, and AIDS Education and Training Centers in their efforts to help prevent or minimize the impact of COVID–19 on RWHAP clients. The award provides RWHAP recipients the flexibility to meet evolving COVID–19 needs in their respective communities, including extending operational hours, increasing staffing hours, purchasing additional equipment, enhancing workforce training and capacity development, and providing critical services to people with HIV during this pandemic, such as home-delivered meals, emergency housing, and transportation.

HRSA's HIV/AIDS Bureau identified a new data collection need to support HRSA's requirement to monitor and report quarterly to the Secretary of HHS the COVID–19 activities conducted with the CARES Act funding. The COVID–19 Data Report (CDR) module will collect information on the types of services provided and number of people served for the treatment or prevention of COVID–19 among RWHAP clients (and immediate household members in limited circumstances). This module will be required for all providers (*e.g.,* recipients or subrecipients) who receive CARES Act RWHAP funding.

A 60-day notice published in the **Federal Register** on September 1, 2020, vol. 85, No. 170; pp. 54390–54391. There were no public comments.

Need and Proposed Use of the Information: HRSA proposes that service providers who receive CARES Act RWHAP funding report aggregate

information on the number of clients and immediate household members tested for COVID–19, the number of clients newly diagnosed (or presumed positive) with COVID–19, the cumulative number of clients with COVID–19, the number of clients who received services in each RWHAP service category (identified in Policy Clarification Notice 16–02 RWHAP Services: Eligible Individuals and Allowable Uses of Funds), and the types of services provided using telehealth technology in the CDR. The information obtained in this module will assist HRSA in understanding how CARES Act RWHAP funding is being used to support RWHAP clients and immediate household members and ensure that HRSA is compliant with federal reporting requirements.

Likely Respondents: All RWHAP providers (*e.g.,* recipients or subrecipients) who receive CARES Act RWHAP funding.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
CDR Module	2,045	12	24,540	3.2	78,528
Total	2,045		24,540		78,528

HRSA specifically requests comments on (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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–25219 Filed 11–13–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a virtual meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held December 4, 2020. The confirmed meeting times and agenda will be posted on the NVAC website at *http://www.hhs.gov/nvpo/nvac/meetings/index.html* as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at: *http://www.hhs.gov/nvpo/nvac/meetings/index.html* at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting or participate in public comment. Please register at *http://www.hhs.gov/nvpo/nvac/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, at the Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Mary E. Switzer Building, Room L618, 330 C Street SW, Washington, DC 20024. Email: *nvac@hhs.gov.* Phone: 202–695–9742.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During this NVAC meeting, NVAC will hear presentations to support the recent charge from Admiral Brett P. Giroir, MD, the Assistant Secretary for Health and Director of the National Vaccine Program, and respond to the following question: *The FDA standards for approval and licensure of vaccines for COVID–19 addresses safety and effectiveness and encourages inclusion of minorities, the elderly, pregnant women, and people with medical comorbidities in clinical trials. In particular, for COVID–19 vaccines, I am interested in the approach the nation should take in regard to vaccination of children, given that there will be relatively little data on children from some of the early clinical trials? As context, the case fatality rate for children under age 18 is .02%. What is the appropriate approach, and timing, of generating the needed data and proceeding to potential childhood vaccination as we move forward?* The NVAC will also review a draft report of the response to the full charge. Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: *http://www.hhs.gov/nvpo/nvac/index.html.*

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three