meet the requirements of the country to which the product is to be exported. The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or offered for sale in domestic commerce in the United States as allowed under section 801(e) of the FD&C Act. In general, the notification identifies the product being exported (*e.g.,* name, description, and in some cases, country of destination) and specifies where the notifications were sent. These notifications are sent only for an initial export. Subsequent exports of the same product to the same destination or to certain countries identified in section 802(b) of the FD&C Act (21 U.S.C. 382(b)) would not result in a notification to FDA.

The recordkeepers for this information collection are exporters of products that may not be sold in the United States who are regulated by the following FDA Centers: Center for Drug Evaluation and Research (CDER); Center for Biologics Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Veterinary Medicine (CVM); Center for Food Safety and Applied Nutrition (CFSAN); and Center for Tobacco Products (CTP). Respondents to this collection of information maintain records demonstrating their compliance with the requirements in 21 CFR 1.101.

In the **Federal Register** of February 15, 2019 (84 FR 4473), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.101(d) (CBER)	5	92	460	15	6,900
1.101(d) (CDER)	5	180	900	15	13,500
1.101(d) (CDRH)	160	1	160	15	2,400
Total					22,800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1.101 (b), (c), (e) (CBER, CDER, CDRH, CFSAN, and CVM)	320	3	960	22	21,120
1.101(b) Office of International Programs only	1	189	189	22	4,158
1.101(b) (currently regulated Tobacco Products)	322	3	966	22	21,252
Total					46,530

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have adjusted our burden estimate, which has resulted in an overall decrease of 129,543 hours to the currently approved burden. The reporting burden estimate for CDRH has been adjusted to correct an error and corresponding miscalculation in the previous burden estimate and has been updated based on recent internal data. This adjustment contributed to the overall burden estimate reduction by eliminating 8,030 responses and 120,450 hours from the reporting burden estimate. CBER's estimated reporting burden for the information collection in table 1 reflects a decrease of 7,575 hours and a corresponding decrease of total annual responses (193 to 92). We attribute this adjustment to a normal variation in the number of submissions we received over the last few years. CTP's current number of respondents and recordkeeping burden hours in table 2 are expected to decrease by 23 respondents and 1,518 hours. This is based on summary derived from the monthly operational reports that manufacturers and importers of tobacco products are required to file with the Alcohol and Tobacco Tax and Trade Bureau.

Dated: May 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10537 Filed 5–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, 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 a meeting is scheduled to be held of the National Vaccine Advisory Committee (NVAC). The meeting will be open to the public via teleconference; a public comment session will be held during the meeting.

DATES: The meeting will be held on Tuesday and Wednesday, June 4–5, 2019. 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 one week prior to the meeting at: *http://www.hhs.gov/nvpo/nvac/meetings/index.html.* Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend

the meeting and/or participate in the public comment session should register at *http://www.hhs.gov/nvpo/nvac/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, at the National Vaccine Program Office, U.S. Department of Health and Human Services, Room L129, Mary E. Switzer Building, 330 C. Street SW, Washington, DC 20024. Phone: (202) 690–5566; email: *nvac@hhs.gov.*

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 the June 2019 NVAC meeting, sessions will consist of presentations vaccine communications, adult immunization, and updates from two newly formed working groups. 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 comments at the NVAC meeting during the public comment periods designated on the agenda. Public comments made during the meeting will be limited to two minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit written comments. Written comments should not exceed two pages in length. Individuals submitting written comments should email their comments to the National Vaccine Program Office (*nvac@hhs.gov*) at least five business days prior to the meeting.

Dated: May 10, 2019.

Ann Aikin,

Acting Designated Federal Official.

[FR Doc. 2019–10574 Filed 5–20–19; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Modified Systems of Records Notice for State-Provided Physician Records (Renamed Health Professional Service Delivery Data), 09–15–0066; Privacy Act of 1974; System of Records

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

ACTION: Notice of a Modified System of Records.

SUMMARY: In accordance with requirements of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS) is updating an existing system of records maintained by the Health Resources and Services Administration (HRSA), System No. 09–15–0066 ''State-Provided Physician Records for the Application Submission & Processing System.'' The system of records covers service delivery data pertaining to individual health care providers practicing in eligible primary care, mental health, and dental disciplines, which is used by state partners to apply for, and by HRSA to designate, health professional shortage areas and medically underserved areas and populations. The modifications include adding a unique identifier for providers, known as the National Provider Identifier; and changing the system name to ''Health Professional Service Delivery Data Used to Designate Health Professional Shortage Areas (HPSAs) and Medically Underserved Areas and Populations (MUA/Ps).''

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is applicable May 21, 2019, subject to a 30-day period in which to comment on the new and revised routine uses, described below. Please submit any comments by June 20, 2019.

ADDRESSES: Written comments may be submitted by email to *sdb@hrsa.gov* or by mail, addressed to: ATTN: HRSA/BHW/DPSD, 5600 Fishers Ln., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: General questions about the revised system of records may be submitted by email to *sdb@hrsa.gov,* or telephone to 301–594–5968, or by mail addressed to Dr. Janelle McCutchen, Division of Policy and Shortage Designation, Bureau of Health Workforce (BHW), Health Resources and Services Administration (HRSA), 5600 Fishers Ln., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: This system of records was established in 2005 (see 70 FR 1724) and was last comprehensively updated in 2010 (see 75 FR 19652). The primary reason for updating the system of records again is to add a unique identifier for providers, known as the National Provider Identifier, which HRSA will obtain from CMS' National Plan and Provider Enumeration System (NPPES), System No. 09–70–0555 (formerly 09–70–0008; the number was changed to 09–70–0555 in 2010). On behalf of the Secretary of HHS, NPPES collects and maintains information needed to uniquely identify an individual physician or non-physician practitioner, assign a National Provider Identifier (NPI) to that physician or non-physician practitioner, and maintain and update the information in that health care provider's record in NPPES.

In addition to reformatting the System of Records Notice to comply with OMB Circular A–108 and updating office names in the System Location and System Manager sections, modifications made to the system of records include the following substantive changes:

1. The system name has been changed to ''Health Professional Service Delivery Data Used to Designate Health Professional Shortage Areas (HPSAs) and Medically Underserved Areas and Populations (MUA/Ps)'' to more clearly indicate the nature of the records.

2. Section 330 of the Public Health Service Act (PHSA) (42 U.S.C. 254b) and the U.S. Code citation for Section 332 of the PHSA (42 U.S.C. 254e) have been added to the Authorities section.

3. The Purposes section has been expanded to include additional purposes for which records may be used, such as: (1) Creation of aggregate datasets to use in conducting workforce analyses; and (2) granting Organizational Points of Contact access to the system to validate provider data.

4. The Categories of Individuals section has been updated to specify that the collection of health professional service delivery data is limited to providers who are assigned a National Provider Identifier by the NPPES.

5. The Categories of Records section now states a record category and includes an updated list of data elements.

6. The Record Source Categories section now includes the new data source, NPPES.

7. The Routine Uses section, which formerly contained four routine uses, now contains 11 routine uses, of which two are revised and seven are new. Specifically:

- Routine use 1 (authorizing disclosures to HRSA's state partners) was revised to be consistent with each