Matters considered at the meeting will include current strategies to reduce the risk of Zika virus (ZIKV) transmission by blood and blood components, an update on the Transfusion Transmissible Infections Monitoring System (TTIMS), and testing blood donations for hepatitis B surface antigen. The meeting will be open to the public.

DATES: The meeting will be held on April 2, 2020, from 8:30 a.m. to 3:45 p.m. and April 3, 2020, from 8:30 a.m. to 12:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For security information, please refer to *https://www.fda.gov/about-fda/white-oak-campus-information/public-meetings-fda-white-oak-campus.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

For those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://collaboration.fda.gov/bpacapril20/.*

FOR FURTHER INFORMATION CONTACT: Christina Vert or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993–0002, 240–402–8054, *christina.vert@fda.hhs.gov,* or 240–402–8106, *joanne.lipkind@fda.hhs.gov,* respectively, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For those unable to attend in person, the meeting will also be available via webcast. The webcast will be available at the following link for both days: *https://collaboration.fda.gov/bpacapril20/.*

SUPPLEMENTARY INFORMATION:

Agenda: On April 2, 2020, in the morning, the BPAC will meet in open session to discuss and make recommendations on strategies to reduce the risk of ZIKV transmission by blood and blood components. The committee will discuss whether universal testing of blood donations for ZIKV is an appropriate strategy considering the decline of ZIKV cases in the United States and worldwide. In the afternoon, the committee will meet in open session to hear an update on the TTIMS. Sponsored by the FDA, the National Institutes of Health National Heart, Lung and Blood Institute, and the Department of Health and Human Services Office of the Assistant Secretary for Health, TTIMS collects incidence, prevalence and risk factor data for certain transfusion-transmitted infections, including human immunodeficiency virus, in U.S. blood donations. On April 3, 2020, the committee will meet in open session to discuss and make recommendations on testing for hepatitis B surface antigen (HBsAg) in blood donations. The committee will discuss whether testing for HBsAg can be discontinued considering the sensitivity of hepatitis B virus nucleic acid testing and hepatitis B anti-core testing of blood donations in the United States.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 25, 2020. On April 2, 2020, oral presentations from the public will be scheduled between approximately 10:50 a.m. to 11:20 a.m. and 3:15 p.m. to 3:45 p.m. On April 3, 2020, oral presentations from the public will be scheduled between approximately 11 a.m. to 11:30 a.m. Those individuals interested in making oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 16, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 17, 2020.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Christina Vert (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02873 Filed 2–12–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network OMB No. 0915–0184–Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 13, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network OMB No. 0915–0184–Revision

Abstract: This is a request for OMB approval for revisions of the application documents used to collect information for determining if the interested party is compliant with membership requirements contained in the final rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN), (42 CFR part 121) ''the OPTN final rule.''

Need and Proposed Use of the Information: Membership in the OPTN is determined by submission of application materials to the OPTN (not to HRSA) demonstrating that the applicant meets all required criteria for membership and will agree to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273, *et seq.*, the OPTN final rule, OPTN Policies, and OPTN Bylaws. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b–8 (section 1138) requires that hospitals in which transplants are performed be members of, and abide by, the rules and requirements of the OPTN (that have been approved by the Secretary of HHS) as a condition of participation in Medicare and Medicaid. Section 1138 contains a similar provision for the organ procurement organizations (OPOs) and makes membership in the OPTN and compliance with its rules and requirements (that have been approved by the HHS Secretary), including those relating to data collection, mandatory for all transplant programs and OPOs.

Proposed Revisions to OPTN Membership Applications: Changes to the forms are proposed to make application requirements more clear and organized, and thus less cumbersome for applicants to complete. Proposed revisions include changes to wording to make questions more consistent with the language of the OPTN Bylaws (Bylaws). In addition, the applications have been revised so that the sequence of questions is parallel to that of the Bylaws. Using the Bylaws as a baseline, the revamped applications have been constructed in parallel order of the Bylaws so that an applicant can have the application and Bylaws side-by-side for easy reference. Additional proposed changes to the application include:

- A few major changes were made to the application order of documentation and attachments. The embedded transplant logs were revised in the form of a 'universal' surgeon and physician log that will be provided as a separate attachment to the application. This new log will provide applicants with all OPTN Bylaws requirements. We hope the added technology utilized in the log will help applicants complete the log with limited errors.
- Also within the applications, ''checkboxes''—fillable tables that were not checkboxes at all—were removed and working checkboxes were inserted. The ''narrative'' section was replaced by checkbox attestations, which will serve the same purpose—understanding relevant and recent surgeon and physician applicant experience.
- The previous membership applications had several places for the applicants to sign. The new application requests only one signature from each individual member applicant involved.
- Additional changes to the application process include streamlining previous application attachments for key personnel and living donor components into one form for the respective organ application.
- Pediatric Bylaw Requirements, where applicable, were also given their own sections within the organ applications. Conversely, the Certificate of Assessment (formerly known as Certificate of Investigation) and the Primary Coverage Plan Checklist were pulled out of the previous organ specific applications and given their own, separate attachment. These changes will allow OPTN application reviewers to give these application components to applicants in as few attachments as possible. These changes will also allow the United Network for Organ Sharing Membership Team to give these important application components to applicants in as few attachments as possible, but are inclusive of all possible changes within a program.
- Further changes have been made to the Vascularized Composite Allograft (VCA) Transplant program applications, which were previously submitted as separate applications for OMB approval based on body part transplanted. These forms have been revised into one single application with sections for each VCA organ type.
- Personnel changes for Organ Procurement Organizations (OPOs) and Histocompatibility Laboratories have also been consolidated into organization applications. OPO and Lab applicants will be able to use one respective application for new and/or personnel changes.
- Given these changes, the overall burden has decreased significantly from an estimated 7,016 total burden hours to 4,755 hours in this current proposed revision package, although some forms have been combined into one more comprehensive form resulting in increased burden hours for a particular form.

Likely Respondents: Parties seeking initial OPTN membership approval and then maintenance of existing OPTN approval. Applicants include the following: hospitals seeking to perform organ transplants, non-profit organizations seeking to become an organ procurement organization, and medical laboratories seeking to become an OPTN-approved histocompatibility laboratory. In addition, there are other OPTN membership categories for organizations and individuals who want to participate in the organ transplant system, and they are also required to fill out an appropriate application.

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
OPTN Membership Application for Transplant Hospitals	2	1	2	3	6
OPTN Certificate of Assessment and Program Coverage Plan Membership Application	2	1	2	3	6
OPTN Membership Application for Kidney Transplant Programs	189	2	378	3	1,134
OPTN Membership Application for Liver Transplant Programs	110	2	220	3	660
OPTN Membership Application for Pancreas Transplant Programs	120	2	240	3	720
OPTN Membership Application for Heart Transplant Programs	142	2	284	3	852
OPTN Membership Application for Lung Transplant Programs	60	2	120	3	360
OPTN Membership Application for Islet Transplant Programs	4	2	8	2	16
OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	53	2	106	2	212
OPTN Membership Application for Intestine Transplant Programs	90	2	180	3	540
OPTN Membership Application for Organ Procurement Organizations (OPOs)	10	1	10	3	30
OPTN Membership Application for Histocompatibility Laboratories	27	2	54	3	162
OPTN Representative Form	20	2	40	1	40
OPTN Medical/Scientific Membership Application	7	1	7	1	7
OPTN Public Organization Membership Application	4	1	4	1	4
OPTN Business Membership Application	2	1	2	1	2
OPTN Individual Membership Application	4	1	4	1	4
OPTN Membership Application Surgeon or Physician Log*	.....	.....	.....	.....	.....
Total = 18 forms	846	.....	1,661	.....	4,755

*The OPTN Membership Application Surgeon or Physician Log accompanies every individual organ application. The burden to complete is built into the organ application data.

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. 2020–02870 Filed 2–12–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Preparedness and Response; Statement of Organization, Functions and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AN, Office of the Assistant Secretary for Preparedness and Response (ASPR), as last amended at 83 FR 33941 (July 2018), 79 FR 70.535 (Nov. 26, 2014), 78 FR 25277 (April 30, 2013), 78 FR 7784 (Feb. 4, 2013), 75 FR 35.035 (June 21, 2010) to add the Strategic National Stockpile (SNS). This notice transfers the Office of the Director, Strategic National Stockpile, to the Office of the Principal Deputy Assistant Secretary (ANC), Division of Resource Management (ANC3) pursuant to 5 U.S.C. Appendix (the Reorganization Plan No. 1 of 1953 and the Reorganization Plan No. 3 of 1966) and 31 U.S.C. 1531, and effective October 1, 2018 the functions, personnel, assets, and liabilities of the SNS to the Office of the Secretary, Office of the Assistant Secretary for Preparedness and Response (ASPR).

The changes are as follows.

I. Delete AR.20 Functions in its entirety and replace with the following:

Section AN.20 Functions.

A. Immediate Office of the Assistant Secretary for Preparedness and Response: The Immediate Office of the Assistant Secretary for Preparedness and Response (IO/ASPR) is headed by