available a draft guidance for FDA staff entitled ''Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine (CPG 7108.24)'' and gave interested parties an opportunity to submit comments by February 25, 2022, for us to consider before beginning work on the final version of the guidance. In the **Federal Register** of March 15, 2022 (87 FR 14538), in response to a request from stakeholders, we reopened the comment period until April 14, 2022.

We received comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include the addition of a detailed explanation for our revisions to the histamine levels set forth in the guidance. The guidance announced in this notice finalizes the draft guidance dated December 2021.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: October 22, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–25315 Filed 11–1–24; 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: Process Data for Organ Procurement and Transplantation Network

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of 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 and any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than January 3, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, MD 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 Joella Roland, the HRSA Information Collection Clearance Officer at (301) 443–3983.

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

Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network, OMB No. 0906–xxxx—New.

Abstract: Section 372 of the Public Health Service Act requires that the Secretary of HHS, by awards, provide for the establishment and operation of the Organ Procurement and Transplantation Network (OPTN), which, under oversight of the HRSA, operates the U.S. procurement and transplantation system. The Secretary and/or HRSA may direct the collection of data in accordance with the regulatory authority in 42 CFR 121.11 of the OPTN Final Rule. HRSA, in alignment with the Paperwork Reduction Act of 1995, submits data elements for collection to OMB for official federal approval.

Need and Proposed Use of the Information: HRSA and the OPTN Board of Directors use data to develop transplant, procurement, and allocation policies; to determine whether institutional members are complying with policy; to determine member-specific performance; to ensure patient safety, and to fulfill the requirements of the OPTN Final Rule. The regulatory authority in 42 CFR 121.11 of the OPTN Final Rule allows the Secretary of HHS to prescribe data collection. This regulatory authority requires OPTN data to be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, and members of the public for evaluation, research, patient information, and other purposes.

This is a request to expand the current OPTN data collection, approved under OMB No. 0915–0157. HRSA is submitting this new data collection, separate from OMB No. 0915–0157, since it includes new forms developed in response to an HHS Secretarial Data Directive that are not in use by OPTN. HRSA believes that separating these data collections will minimize confusion, increase clarity among OPTN members and stakeholders, and enable more direct feedback on the new forms. Both data collections include time-sensitive, life-critical data on transplant candidates and potential organ donor patients, the organ matching process, histocompatibility results, organ labeling and packaging, and pre-and post-transplantation data on recipients and donors. The OPTN collects these specific data elements from transplant centers.

HRSA and the OPTN use this information to: (1) facilitate organ placement and match donor organs with recipients; (2) monitor compliance of member organizations with federal laws and regulations and with OPTN requirements; (3) review and report periodically to the public on the status of organ donation, procurement, and transplantation in the United States; (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation; and (5) perform transplantation-related public health surveillance, including the possible transmission of donor disease.

This new collection consists of three new data forms as directed by the HHS Secretary, which were developed to improve the OPTN organ matching and allocation process and OPTN member compliance with OPTN requirements:

- One new form will collect data from the point of referral of a patient to an organ procurement organization (OPO) for potential deceased organ donation. These data will provide a more objective source of information on procurement practices, the management of donor patients, and how these practices inform the supply of deceased donor organs available for transplant. These data may also help to improve monitoring of OPO performance and would facilitate quality assurance and performance improvement efforts to reduce the variation in the quality-of-care OPOs provide to donors and donor families.
- Two new forms will expand data collection from the point of patient registration, referral, and evaluation at transplant centers. These data will enable collection of data from the point of referral. Pre-waitlisting data will provide insight into who gets referred

and by whom, who gets evaluated, and who gets placed on the organ transplantation waiting list. These data will also facilitate the OPTN's ability to address disparities in processes of care, improve access to organ transplantation, and assess overall system performance.

Once this collection is approved, HRSA will cease the use of the Death Notification Registration and the Deceased Donor Death Referral forms that are included within the existing OMB-approved Data System for Organ Procurement and Transplantation Network OMB No. 0915–0157. This decision was made to avoid unnecessary burden and redundancy in the data collected by this package and the existing OMB data collection instrument.

Likely Respondents: Transplant Centers, OPOs, and Histocompatibility Laboratories.

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 No.	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
1	Pre-Waitlist Transplant Referral Form	248	1,164.68	288,840.64	0.35	101,094.22
2	Pre-Waitlist Transplant Evaluation Form	248	594.22	147,366.56	0.40	58,946.62
3	Ventilated Patient Form	56	3,292.00	184,352.00	0.50	92,176.00
Total		552		620,559.20		252,216.84

The average burden estimates of both new pre-waitlist forms are based on the 2023 burden estimates of existing OMB-approved Transplant Candidate Registration forms, approved under 0915–0157. The average burden estimate of the Ventilated Patient Form is based on the average burden estimate of the 2024 burden estimates of existing OMB-approved Death Notification Registration form with an additional 0.08 hour per collected form burden to reflect an increase in total data fields.

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.

Amy P. McNulty,

Deputy Director, Executive Secretariat.

[FR Doc. 2024–25522 Filed 11–1–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Given the capacity constraints of the venue, the public is strongly encouraged to attend virtually via NIH videocast. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/*.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: December 12, 2024.

Time: 9:00 a.m. to 5:45 p.m.

Agenda: NIH Director's Report; Budget Update; Legislative Update; RECOVER 2.0 Early Career Intramural Investigator Highlight; ACD Working Group on Diversity Update; Accessibility, Disability Inclusion, and Disability Research at NIH; NExTRAC ENGAGE Update; Scientific Management Review Board. Other Business of the Committee.

Date: December 13, 2024.

Time: 9:00 a.m. to 12:15 p.m.

Agenda: Cancer Moonshot Update; ABCD Update; Alzheimer's Update; AMP Update Other Business of the Committee.

Place: National Institutes of Health, Building 1, Wilson Hall, One Center Drive, Bethesda, MD 20892.

Contact Person: Cyndi Burrus-Shaw, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–2433, email: *shawcy@od.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://acd.od.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.