eteplirsen injection for intravenous infusion, sponsored by Sarepta Therapeutics, Inc., for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.

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 Web site 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 Web site after the meeting. Background material is available at *http://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 April 11, 2016. Oral presentations from the public will be scheduled between approximately 12:40 p.m. and 2:40 p.m. Those individuals interested in making formal 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 April 1, 2016. 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 April 4, 2016.

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 Moon Hee V. Choi at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://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: March 9, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–05683 Filed 3–10–16; 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

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (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.

DATES: Comments on this ICR should be received no later than April 13, 2016.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

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

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Bureau of Health Workforce Performance Data Collection

OMB No. 0915–0061—Revision

Abstract: Over 40 Bureau of Health Workforce (BHW) programs award grants to health professions schools and training programs across the United States to develop, expand, and enhance training, and to strengthen the distribution of the health workforce. These programs are authorized by the Public Health Service Act (42 U.S.C. 201 *et seq.*), specifically Titles III, VII, and VIII. Performance information regarding these programs is collected in the HRSA Performance Report for Grants and Cooperative Agreements (PRGCA). Data collection activities consisting of an annual progress and annual performance report satisfy statutory and programmatic requirements for performance measurement and evaluation (including specific Title III, VII and VIII requirements), as well as Government Performance and Results Act (GPRA) requirements. The performance measures were last revised in 2013 to ensure they addressed programmatic changes, met evolving program management needs, and responded to emerging workforce concerns—especially as a result of the changes in the Affordable Care Act (Pub. L. 111–148). As these revisions were successful, BHW will continue to use the same progress and performance forms. BHW is reducing the reporting burden by eliminating the semi-annual performance report and moving to annual progress and performance reporting.

Need and Proposed Use of the Information: The purpose of the data collection is to analyze and report grantee training activities and education, identify intended practice locations, and report outcomes of funded initiatives. Data collected from these grant programs also provide a description of the program activities of approximately 1,700 reporting grantees to better inform policymakers on the barriers, opportunities, and outcomes involved in health care workforce development. The measures focus on five key outcomes: (1) Increasing the workforce supply of diverse well-educated practitioners, (2) increasing the number of practitioners that practice in underserved and rural areas, (3) enhancing the quality of education, (4) increasing the recruitment, training, and placement of under-represented groups in the health workforce, and (5) supporting educational infrastructure to increase the capacity to train more health professionals.

Likely Respondents: Respondents are awardees of BHW health professions grant programs.

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
Direct Financial Support Program	618	1	618	3.117	1,926
Infrastructure Program	149	1	149	4.57	681
Multipurpose or Hybrid Program	790	1	790	4.285	3,385
Total	1,557		1,557		5,992

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–05602 Filed 3–11–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (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, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, Parklawn Building, 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 the HRSA Information Collection Clearance Officer at (301) 443–1984.

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

Information Collection Request Title: Organ Procurement and Transplantation Network and Scientific Registry of Transplant Recipients Data System OMB No. 0915–0157—Revision.

Abstract: Section 372 of the Public Health Service (PHS) Act, as amended, requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). This is a request for revisions to current OPTN data collection forms associated with an individual's clinical characteristics at the time of registration, transplant, and follow-up after the transplant. These specific data elements of the OPTN data system are collected from transplant hospitals. The information is used to indicate the disease severity of transplant candidates, to monitor compliance of member organizations with OPTN rules and requirements, to report periodically on the clinical and scientific status of organ donation and transplantation and other purposes consistent with the law. Data are used 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 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 possible transmission of donor disease. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and members of the public for evaluation, research, patient information, and other important purposes.

Likely Respondents: Transplant programs, medical and scientific organizations, and public organizations.

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: (1) Review instructions; 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; (2) train personnel to respond to a request for collection of information; (3) search data sources; (4) complete and review the collection of information; and (5) to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.