

section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20764 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10786]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; ZANVASTRO (zilganersen)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that ZANVASTRO (zilganersen), approved September 3, 2026, manufactured by Ionis Pharmaceuticals, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2771.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will

award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined ZANVASTRO (zilganersen), manufactured by Ionis Pharmaceuticals, Inc., meets the criteria for a priority review voucher. ZANVASTRO (zilganersen) injection is indicated for the treatment of Alexander disease in pediatric and adult patients.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about ZANVASTRO (zilganersen), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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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; Applicant Organizational National Provider Identifiers and Centers for Medicare & Medicaid Services Certification Numbers Form

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 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 November 9, 2026.

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 Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title:

Applicant Organizational National Provider Identifiers and Centers for Medicare & Medicaid Services Certification Numbers Form, OMB No. 0906–XXXX—New.

Abstract: HRSA is proposing a new form to collect organizational National Provider Identifiers (Type 2 NPIs) and Centers for Medicare & Medicaid Services (CMS) Certification Numbers (CCNs) from organizations that apply for HRSA award funding through Grants.gov. The form will be completed as part of the Grants.gov funding application. This collection is limited to organizational identifiers and will only collect an NPI and/or CCN only from organizations that already have one. An organization is not required to have, or to obtain, an NPI or CCN in order to apply for or receive HRSA funding, and individual applicants (persons) are not asked to provide an individual (Type 1) NPI. Organizational NPIs are issued by the CMS through the National Plan and Provider Enumeration System. CCNs are issued by CMS to providers and suppliers that obtain Medicare or Medicaid certification.

The purpose of this proposed collection is to strengthen the evidence HRSA uses to understand how it meets its mission of improving health outcomes through access to quality services, a skilled health workforce, and innovative, high-value programs. This collection is authorized under section 301 of the Public Health Service Act (42 U.S.C. 241), which authorizes the Secretary of HHS to conduct and support research, investigations, experiments, demonstrations, and studies relating to the causes; diagnosis; treatment; control; and prevention of disease, and to collect and make available information on those activities, including the provision of technical assistance on statistical methods.

HRSA collects this information to support research, program evaluation, and evidence-building consistent with its broader obligations to measure whether award recipients meet program objectives (e.g., 2 CFR 200.301(a)) and to ensure the data underlying HRSA's performance reporting are reliable and accurate (e.g., 31 U.S.C. 1115(b)(7)–(8)), and consistent with the agency evidence-building plan obligations of the Foundations for Evidence-Based Policymaking Act of 2018 (see 5 U.S.C. 312). These provisions inform why reliable provider identity data are useful to HRSA; the authority for this collection is 42 U.S.C. 241. Further, collecting information will enhance accountability in HRSA funding and enable the agency to minimize fraud, waste, and abuse by ensuring that its funding of entities is non-duplicative with funding provided by CMS.

Linking HRSA program data to other datasets, and particularly to datasets at CMS, is currently difficult because HRSA lacks an identifier that reliably and consistently identifies funded organizations across its many programs and across externally available health-care delivery-system data. The Unique Entity Identifier (UEI) obtained from *SAM.gov* identifies the legal entity that receives an award, but it is not used in health-care transactions and does not appear in CMS claims, encounter, certification, or quality datasets.

Organizational NPIs and CCNs address this gap because they are already embedded as standard provider-identity keys in widely used, publicly available CMS datasets. The organizational NPI is the standard unique identifier for organization health care providers used in HIPAA-standard transactions and is therefore a stable, externally recognized organizational key; this descriptive fact about how NPIs are used is the reason HRSA considers the NPI a reliable identifier, and is not the legal authority for this collection. CCNs identify Medicare- and Medicaid-certified institutional providers and are the standard key for linking certified facilities to CMS institutional claims, certification files, cost reports, and facility-level quality data.

A 60-day notice was published in the **Federal Register** on July 28, 2026, vol. 91, No. 143; pp. 47253–47255. There were no public comments.

Need and Proposed Use of the Information: All applicants for HRSA funding through *Grants.gov* must obtain a UEI from *SAM.gov* before beginning a funding application. Because UEI does not appear in CMS provider and claims data, collecting organizational NPIs and CCNs from organizations that already

have them allows HRSA to link its program and award data to publicly available external datasets that use those identifiers. Such linkage supports more accurate, efficient, and credible agency analyses of program reach, utilization, cost, quality, and outcomes.

For organizational applicants, the organizational NPI and CCN function as enterprise-level provider-identity keys that connect HRSA's internal funding, program, and service-site data to the external health-care delivery system. The organizational NPI connects funded organizations—including non-institutional providers such as health center organizations, clinics, group practices, laboratories, pharmacies, behavioral health organizations, and telehealth providers—to Medicare professional and supplier claims, Medicare Advantage encounter data, Transformed Medicaid Statistical Information System data, and National Plan and Provider Enumeration System organizational reference files. The CCN connects funded or supported certified facilities—such as hospitals, Critical Access Hospitals, Rural Health Clinics, Federally Qualified Health Centers, hospices, home health agencies, and end-stage renal disease facilities—to CMS institutional claims, the Provider of Services files, Healthcare Cost Report Information System cost reports, and CMS facility-level quality and outcomes data.

Using these identifiers, HRSA can, for example: identify the full set of HRSA programs that support the same provider organization or facility, in order to understand portfolio-level funding concentration, overlap, and potential duplication; distinguish among the legal awardee, the service delivery site, the billing organization, and the certified facility, which are frequently different entities; validate that an organization or facility is represented in CMS certification and enumeration data; detect duplicate or fragmented records across programs using durable, externally verifiable anchors rather than name-and-address matching alone; and build more credible evaluation datasets that compare funded organizations to appropriate comparison groups over time.

This proposed collection differs from HRSA's current practice of collecting these data in two ways. First, it standardizes the collection of organizational (Type 2) NPIs and CCNs across HRSA-supported programs rather than collecting them inconsistently program by program. Second, it does not collect individual (Type 1) NPIs. The collection is limited to organizations that already hold these identifiers;

organizations without an NPI or CCN are not required to obtain one, and their eligibility for HRSA funding is unaffected by whether they provide an identifier.

Data collected through this information collection will be used solely for research, evaluation, and analysis of program reach and effectiveness and for purposes of accountability and oversight—for example, identifying entities funded across HRSA and HHS, assessing program performance through internal and external data linkage, and supporting de-duplication, aggregation, and disaggregation of program data. Because this collection is limited to organizational identifiers, it does not collect individual NPIs or other personally identifiable information, and it is not designed to retrieve records about individuals. Data from this ICR will not be used to verify eligibility or compliance for cash or in-kind assistance under HRSA programs.

HRSA recognizes that these identifiers have inherent limitations and intends to account for them analytically: an organizational NPI may represent a parent organization, subpart, or billing unit rather than a specific site; a CCN identifies a certified facility rather than its corporate owner or the HRSA awardee; NPI issuance does not validate licensure or credentialing; and claims and certification data do not capture all HRSA-funded activity (for example, enabling services, outreach, case management, workforce training, technical assistance, uninsured care, and public-health infrastructure). Accordingly, HRSA will treat external claims and certification data as complementary evidence and will maintain time-aware linkages that account for changes in NPI status, CCN status, ownership, and organizational structure.

Likely Respondents: Organizations applying for HRSA funding through *Grants.gov* that already have an organizational NPI and/or a CCN.

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	Applicant type	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Applicant NPIs and CCNs Form ..	No NPI or CCN	3,400	1	3,400	0.02	68.00
	One NPI and/or CCN	1,700	1	1,700	0.05	85.00
	Two or more NPIs and/or two or more CCNs.	1,275	1	1,275	0.10	127.50
Total		6,375		6,375		280.50

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026-20731 Filed 10-8-26; 8:45 am]

BILLING CODE 4165-15-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; Data System for Organ Procurement and Transplantation Network, OMB No. 0906-0110—Revision

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA 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 November 9, 2026.

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 30-day 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 Samantha Miller, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0906-0110—Revision.

Abstract: Section 372(a) of the Public Health Service Act requires the Secretary of HHS to provide for the continued operation of the Organ Procurement and Transplantation Network (OPTN). Section 372(b)(1)(A) provides that the OPTN shall be operated through awards to public or private entities made by the Secretary. The OPTN is a unique public-private partnership that links professionals involved in the U.S. donation and transplantation system. HRSA, in alignment with the Paperwork Reduction Act of 1995, submits OPTN Board of Directors (BOD)-approved data elements for collection to OMB for official federal approval.

A 60-day Notice was published in the **Federal Register**, Vol. 91, No. 94, FR pp. 27964 (May 15, 2026). There was one comment from a Transplant Center. The commenter requested that HRSA identify the Board-approved revisions and the specific data collection forms affected. The commenter also requested clarification regarding whether the Patient Safety Contact Management and Patient Transfer forms are revisions to existing forms or new data collection requirements, the rationale for the new forms, and how duplicative data collection and additional administrative burden would be avoided. HRSA responded that draft data collection instruments may be requested at any time during the public comment period and will be made available in both clean and redline formats during the 30-day **Federal Register** Notice public comment

period. HRSA clarified that the Patient Safety Contact Management and Patient Transfer forms are new data collection forms and that their inclusion is described in the notice and reflected in the Estimated Annualized Burden Hours table. HRSA also identified where stakeholders can find the rationale for the proposed revisions to existing forms and the addition of new forms. HRSA encourages interested stakeholders to review these materials for additional background on the OPTN policy development process (<https://www.hrsa.gov/optn/policies-bylaws/public-comment>).

Need and Proposed Use of the Information: HRSA and the OPTN BOD use data to develop organ procurement, allocation, and transplantation policies; evaluate member compliance with OPTN policies and HHS regulations; assess member performance; promote patient safety; and fulfill the requirements of the OPTN regulations at 42 CFR part 121. In particular, the regulatory authority in 42 CFR 121.11 (<https://www.ecfr.gov/current/title-42/section-121.11>) requires the OPTN to maintain specified records and make OPTN data available, consistent with applicable laws, to OPTN members, the Scientific Registry of Transplant Recipients, HHS, and the public for evaluation, research, and other purposes.

This is a request to revise the currently approved OPTN information collection, which includes time-sensitive, life-critical information related to transplant candidates; potential organ donors, organ matching and allocation; histocompatibility testing; organ labeling and packaging; and pre- and post-transplant clinical information for transplant recipients and donors. These data are collected from transplant hospitals, organ procurement organizations, and histocompatibility laboratories.

HRSA and the OPTN use these data to (1) facilitate matching and placement