TABLE 1—RECIPIENTS AND AWARD AMOUNTS—Continued

Grant No.	Budget period start	Name	City	State	Estimated award amount
H80CS12886	MAR	LOWER LIGHTS CHRISTIAN HEALTH CENTER, INC.	COLUMBUS	OH	1,979,945
H80CS12877	MAR	CARING HANDS HEALTHCARE CENTERS, INC.	MCALESTER	OK	911,325
H80CS11462	MAR	LAPINE COMMUNITY HEALTH CENTER.	LA PINE	OR	637,178
H80CS00567	MAR	UMPQUA COMMUNITY HEALTH CENTER, INC.	ROSEBURG	OR	1,647,774
H80CS12880	MAR	COMMUNITY HEALTH CLINIC, INC	NEW KENSINGTON	PA	811,854
H80CS12881	MAR	NORTH SIDE CHRISTIAN HEALTH CENTER.	PITTSBURGH	PA	1,056,179
H80CS00008	MAR	MUNICIPIO DE SAN JUAN	SAN JUAN	PR	809,107
H80CS00298	MAR	REGENESIS HEALTH CARE, INC	SPARTANBURG	SC	1,817,294
H80CS00304	MAR	COMMUNITY HEALTH OF EAST TENNESSEE, INC.	LA FOLLETTE	TN	680,461
H80CS08767	MAR	UNIVERSITY COMMUNITY HEALTH SERVICES, INC.	NASHVILLE	TN	1,026,920
H80CS00299	MAR	BRAZOS VALLEY COMMUNITY ACTION AGENCY, INC.	COLLEGE STATION	TX	2,260,056
H80CS12850	MAR	HEALTH OPPORTUNITIES FOR THE PEOPLE OF EAST TEXAS, INC.	TENAHA	TX	559,561
H80CS07890	MAR	SOUTHWEST UTAH COMMUNITY HEALTH CENTER, INC.	ST GEORGE	UT	1,436,544
H80CS12871	MAR	GREATER PRINCE WILLIAM AREA COMMUNITY HEALTH CENTER, INC.	WOODBRIDGE	VA	1,396,823
H80CS00746	MAR	COMMUNITY HEALTH CENTER OF SNOHOMISH COUNTY.	EVERETT	WA	1,804,711
H80CS00280	MAR	ACCESS COMMUNITY HEALTH CENTERS, INC.	MADISON	WI	1,712,305
H80CS00662	MAR	KENOSHA COMMUNITY HEALTH CENTER, INC.	KENOSHA	WI	988,717
H80CS00294	MAR	CABIN CREEK HEALTH SYSTEMS, INC	DAWES	WV	1,248,529
H80CS00254	MAR	LINCOLN COUNTY PRIMARY CARE CENTER, INC.	HAMLIN	WV	1,002,444
H80CS00256	MAR	WIRT COUNTY HEALTH SERVICE ASSOCIATION, INC.	RAVENSWOOD	WV	1,263,923
H80CS00827	MAR	WOMENCARE, INC	SCOTT DEPOT	WV	1,707,595
H80CS00042	MAR	COMMUNITY ACTION OF LARAMIE COUNTY, INC.	CHEYENNE	WY	235,839

*This service area has a temporary 9-month budget period of April 1, 2026, through December 31, 2026. The scope of work from the predecessor health center was transferred to this health center to ensure continuity of services to the service area for this period. The period of performance for this service area will continue to use a January start date.

Purpose/Justification

HRSA will provide health centers with a current period of performance of January 1, 2023, through December 31, 2026, or February 1, 2023, through January 31, 2027, with a 6-month or 5-month extension with funds, respectively, through June 30, 2027. Health centers with a current period of performance of March 1, 2023, through February 28, 2027, will receive a 5-month extension through July 31, 2027. The extension will ensure continuity of services between their current period of performance end date and when a new award will be made for the service area.

Thomas J. Engels,

Administrator.

[FR Doc. 2026–19578 Filed 9–23–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Health Resources and Services Administration

[Docket No. FDA–2026–N–10738]

Improving Patient Access to Deceased Donor Islet Cells and Cell Products; Request for Information

AGENCY: Food and Drug Administration, Health Resources and Services Administration, Department of Health and Human Services.

ACTION: Notice; request for information.

SUMMARY: The Department of Health and Human Services (HHS) is opening a public docket to solicit input, supporting data, and comments to assist HHS as it considers how best to regulate deceased donor islet cells and/or deceased donor islet cell products for the treatment of Type 1 diabetes (T1D). The purpose of this information is to allow HHS agencies to better understand how best to regulate these therapies, including whether and how regulation could differ between isolated and otherwise unmodified deceased donor islet cells and deceased donor islet cell products. In this request for information, HHS will specify the type where appropriate or will refer to both types under the umbrella term of islet therapies. HHS seeks information on whether sufficient publicly available information exists to establish standards for how to transplant deceased donor islet cells and/or develop deceased donor islet cell products, as well as whether other publicly available data exist to support their safe and effective

use. Additionally, HHS seeks input on the possibility of defining unmodified deceased donor islet cells as organs, which would allow the procurement, allocation, and transplantation of these cells to be performed in accordance with applicable Organ Procurement and Transplantation Network (OPTN) policy and regulated by HRSA. Doing so would require OPTN establishing appropriate standards for safety, effectiveness, quality and consistency of islet cell processing and isolation, and surveillance and policies regarding the training and experience of transplant surgeons and transplant physicians in designated pancreatic islet cell transplant programs.

DATES: Either electronic or written comments on the notice must be submitted by November 9, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 9, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–10738 for ''Improving Patient Access to Deceased Donor Islet Cells and Cell Products; Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911; Fraser Byrne, Health Resources and Services Administration, 240–472–0297, or *HSBOAA@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

T1D, a chronic autoimmune disease where a patient's immune system destroys insulin-producing beta cells in the pancreas, remains a significant public health problem affecting millions of people globally with over 2 million individuals impacted in the United States. The Food and Drug Administration (FDA) has made significant progress in advancing treatments for T1D, moving beyond traditional insulin replacement. Islet therapies offer a viable option for eligible patients with T1D who meet strict criteria. To date, FDA has licensed one deceased donor islet cell product, Lantidra, which is an allogeneic pancreatic islet cellular therapy used in conjunction with concomitant immunosuppression, indicated for the treatment of adults with T1D who are unable to approach target hemoglobin A1c (HbA1c) because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education.

Islet cells and islet cell products, like Lantidra, may be developed from whole pancreata, procured from multiple deceased organ donors, and are not transplanted as whole pancreata. The National Organ Transplant Act, 42 U.S.C. 274 and its implementing regulations at 42 CFR 121 authorize the Health Resources and Services Administration (HRSA) and the OPTN to oversee organ donations, procurements, and transplants.

The OPTN is charged with developing organ allocation policies and managing the organ matching system and waiting list. Organs are a scarce national resource where demand far outpaces supply—there are currently over 100,000 people on the waiting list for an organ transplant. Patients needing a pancreas transplant are added to this national waitlist and charged a registration fee when added to the list. These patient registration fees support most of the annual costs of operating the OPTN. HRSA, as the federal agency overseeing the OPTN, also provides oversight of OPTN member

organizations (including transplant hospitals and organ procurement organizations) to ensure patient safety for donors and transplant recipients, equitable organ allocation, and compliance with OPTN policies.

Lantidra is licensed by FDA as a biological product under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). FDA's regulation of Lantidra includes ensuring the safety and effectiveness of Lantidra. FDA oversight covers the full manufacturing process for an islet cell product, including multiple critical steps that can affect product safety, purity, potency, viability, and sterility. This oversight extends to manufacturers, processing facilities, quality systems, product sponsors, and clinical administration of cellular therapies prior to marketing and continuing throughout the lifecycle of the product.

The Centers for Medicare & Medicaid Services (CMS) and the National Institutes of Health (NIH) also have a limited role regarding pancreatic islet cell transplantation. Section 733 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, 117 Stat. 2066, 2352) mandates that CMS cover the costs of the transplantation of pancreatic islet cells, but only in the context of an NIH-sponsored clinical trial. CMS also plays a role in its regulation of Organ Procurement Organizations (OPO). Specifically, the Pancreatic Islet Cell Transplantation Act of 2004 (Pub. L. 108–362, 118 Stat. 1703) requires that pancreata procured for use in islet cell transplantation or islet cell transplantation research be counted in performance metrics for OPO certification purposes.

II. Regulation of Deceased Donor Islet Cells and Cell Products

HHS is considering how to best regulate unmodified deceased donor islet cells and cell products to ensure patients' access while ensuring safety and effectiveness. To assist us in doing so, HHS seeks public input regarding how best to regulate these islet therapies. For example, we are seeking input to better understand whether sufficient publicly available information exists to establish standards for regulation of deceased donor islet cell products, which could streamline sponsor development and FDA evaluation of Biologics License Applications (BLAs) for such products, and specifically whether publicly available data exist to support their safe and effective use. Additionally, we are seeking input on the possibility of defining deceased donor islet cells as organs, which would allow the procurement, allocation, and transplantation of these cells to be regulated via HRSA's oversight of the OPTN rather than by the FDA pursuant to a BLA. Doing so would require OPTN establishing appropriate standards for safety, effectiveness, manufacturing quality and consistency, communicable disease control, and maintaining surveillance activities.

Currently, sponsors seeking to market an unmodified deceased donor islet cell product must submit a biologics license application under section 351 of the PHS Act. As noted above, we are seeking input to better understand whether sufficient publicly available information exists to establish standards for regulation of deceased donor islet cell products, which could streamline sponsor development and FDA evaluation of BLAs for such products and whether other publicly available data exist to support their safe and effective use. This is not the first time FDA has solicited input from interested parties to develop alternate approach to streamlining BLA development. For example, in 1998, FDA solicited clinical outcome data to develop proposed product standards and establishment and processing controls for unrelated allogeneic peripheral and placental/umbilical cord blood hematopoietic stem/progenitor cell products.[1]

FDA reviewed the aggregate body of the submitted data, along with the published literature, and determined collectively that the safety and effectiveness of certain cord blood products had been established. FDA subsequently issued a guidance [2] document articulating standards for those sponsors who wish to rely on the data submitted in the FDA docket.

III. Request for Public Comments

This request for information provides an opportunity for interested parties and the public—including sponsors, patients, transplant centers that may have participated in relevant studies, and other interested individuals and groups—to provide HHS with input, supporting data, and comments to assist HHS as it considers how best to regulate deceased donor islet cell products for the treatment of T1D. Specifically, HHS is interested in information that would help establish standards for how to develop and transplant deceased donor islet cell products and whether other publicly available data exist to support their safe and effective use, including data around how such cells and cell products are regulated and made available to patients outside the United States.

In evaluating potential regulatory approaches regarding the oversight of deceased donor islet cells and cell products, HHS is also considering the broader scientific, operational, and public health implications associated with the following proposed options. These include potential additional oversight of islet cells by the OPTN under HRSA's regulatory authority; whether reclassification of deceased donor islet cells as organs could establish precedent for other donor-derived cellular products; whether the OPTN framework, which was established to oversee allocation of vascularized organs, is appropriate for islet cellular therapies; and the potential effects of any regulatory change on treatment effectiveness, patient safety, product quality, provider participation, patient access, program costs, donor willingness, and Federal oversight responsibilities. HHS seeks information to better understand these considerations before determining whether any changes to the current oversight framework are warranted.

IV.A Questions for Consideration Regarding Food and Drug Administration Regulation

For deceased donor islet cell products that are intended to treat certain adult T1D patients, HHS is seeking the submission of information to determine if it would be possible to develop public standards based on publicly available data, including non-clinical and clinical data, and whether those data and the public standards would be sufficient to demonstrate the safety and efficacy of deceased donor islet cells product for certain subsets of patients with T1D. As part of this effort, FDA is seeking information to develop a set of standards to support licensure for deceased donor islet cell products for the treatment of adults with T1D who are unable to approach target HbA1c because of repeated episodes of severe hypoglycemia.

We seek input on the questions below. While the questions ask for information that would help establish standards for how to develop and

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[1] Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products; Request for Comments (63 FR 2985, January 20, 1998).

[2] See FDA's guidance ''BLA for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bla-minimally-manipulated-unrelated-allogeneic-placentalumbilical-cord-blood-intended-hematopoietic.*

manufacture deceased donor islet cell products and whether other publicly available data exists to support their safe and effective use, we welcome any additional comments related to standards for deceased donor islet cells that may improve our understanding and advance our public health mission. To help HHS review information efficiently, please identify the question to which you are responding by its associated category and number. If you are responding to more than one question, please identify each question to which you are responding, and categorize each response by question.

A. General

1. What publicly available data sources/information demonstrate quality source material for creation of deceased donor islet cellular products? Elements include, but are not limited to, donor eligibility, pancreas procurement parameters, organ quality acceptance criteria, and infectious disease testing. Information might include donor health status, donor age, donor body mass index for organ quality acceptance criteria, donor screening and testing records equivalent to the information required by 21 CFR part 1271, subpart C for donor eligibility; data on organ procurement procedures, ischemia time (warm/cold), preservation methods, shipping containers and conditions for organ procurement parameters; predefined acceptance criteria for organ or deceased donor islet cell quality: size, fibrosis extent, and results of all required communicable disease tests using FDA-licensed, -approved, or -cleared test kits; performed by Clinical Laboratory Improvement Amendments-certified laboratory for infectious disease testing.

2. What publicly available data sources/information demonstrate control of the manufacturing? Elements might include summary of control strategy, process validation data and facility and Current Good Manufacturing Practice (CGMP) compliance.

3. What publicly available data sources/information demonstrate product quality and potency? Elements include characterization, release tests, validated potency assays and lot-to-lot consistency data, and other quality parameters.

4. What publicly available nonclinical toxicology data supports use of existing immunosuppressive regimens?

a. Reproductive, developmental, and carcinogenic risk studies: Should these studies be waived for sponsors using conventional allogeneic islet products manufactured by methods frequently reported in the scientific literature for these endpoints, as considered by FDA.[3]

b. Novel route-of-administration safety data: Should animal model safety studies for the delivery route be waived where sponsors propose the standard percutaneous transhepatic portal vein delivery route?

5. What impact, if any, could reclassification of deceased donor islet cells as ''organs'' have on the existing regulatory framework for biological products regulated by FDA? What factors distinguish deceased donor islet cells from other biological products that justifies different regulatory treatment?

B. Data Sources

6. What types of information and data would be necessary to show that publicly available real-world evidence (RWE) is relevant to deceased donor allogeneic islet transplantation for the noted indication:

a. FDA welcomes data and information on the volume and duration of international clinical trial data.

b. Established and consistent clinical endpoints. Should FDA continue to apply the same primary endpoint in evaluating RWE that FDA considered in the 2009 Islet Guidance—composite HbA1c ≤6.5% and elimination of severe hypoglycemia to facilitate direct comparison with endpoint routinely applied in Collaborative Islet Transplant Registry (CITR) and international registries? [4]

c. Well-defined patient population with robust natural history as control: Should FDA apply criteria such as persistent, life-threatening hypoglycemia, poor glycemic control despite intensive insulin management and education, or hypoglycemia unawareness, as enrollment criteria?

d. Should FDA consider a robust external control, consistent with the 'historical control arm' design FDA's 2009 Islet Guidance referred to as sufficient for clinical trials? [5]

e. Are there additional reasons to support or limit RWE-supported deceased donor islet cell transplantation for the noted indication?

7. What real-world data (RWD) sources would be acceptable? Could available registries such as CITR, UK Transplant Registry/National Health Service Blood and Transplant (NHSBT), Edmonton Protocol cohort (University of Alberta), published peer-reviewed literature, or data generated from a sponsor-held U.S. investigational new drug (IND) be considered as data sources? What are the limitations and advantages of each category?

8. What are the criteria to determine the RWD fitness? Should criteria such as: data completeness, endpoint consistency, manufacturing comparability, confounding and bias, and generalizability to U.S. patients be included? What are their limitations and advantages?

C. Manufacturing Data

9. How should Product Standards Derivation be addressed? Should FDA, based on RWE review, establish product standards (potency specifications, viability thresholds, etc.),[6] that individual sponsors must demonstrate their product meets? [7]

D. Clinical Data

10. Should manufacturers or health care facilities be required to submit postmarketing data? Should the following be incorporated:

a. Clinical outcome data collection: Manufacturers required to collect and report product-related clinical outcomes from transplant centers (*e.g.,* graft failure, delayed engraftment, infusion reactions, infection transmission).[8]

b. Adverse experience reporting: Mandatory reporting of serious and unexpected adverse experiences of the type currently required by 21 CFR 600.80, including toxicity associated

[3] See FDA's guidance ''Considerations for Allogeneic Pancreatic Islet Cell Products,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-allogeneic-pancreatic-islet-cell-products,* Section III.F, p. 6.

[4] See FDA's guidance ''Considerations for Allogeneic Pancreatic Islet Cell Products,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-allogeneic-pancreatic-islet-cell-products,* Section IV.D.1, p. 9.

[5] See FDA's guidance ''Considerations for Allogeneic Pancreatic Islet Cell Products,'' Section IV.A, p. 6, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-allogeneic-pancreatic-islet-cell-products.*

[6] FDA has successfully applied this approach for cord blood products.

[7] See FDA's guidance ''BLA for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System,'' Section II.D, pp. 6–7, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bla-minimally-manipulated-unrelated-allogeneic-placentalumbilical-cord-blood-intended-hematopoietic.*

[8] See FDA's guidance ''BLA for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System,'' Section VIII.A, p. 45, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bla-minimally-manipulated-unrelated-allogeneic-placentalumbilical-cord-blood-intended-hematopoietic.*

with islet infusion and immunosuppressive regimens.[9]

c. Biological product deviation reporting: Required reporting of deviations from CGMP, applicable regulations, or established specifications that may affect safety, purity, or potency of a distributed product, within 45 calendar days of acquiring information reasonably suggesting that a reportable event has occurred, as is currently submitted on Form FDA 3486 as required by 21 CFR 600.14.[10]

d. Annual product quality review: Annual review of production and control records to evaluate product quality and determination of the need for changes in specifications or manufacturing controls.[11]

e. Postmarketing Registry contribution: Should manufacturers contribute standardized outcome data to CITR or a designated FDA registry supporting ongoing RWE generation for the U.S. patient population.

11. List additional data sources to address clinical risks associated with deceased donor islet cell transplantation. Risks include but are not limited to bleeding, blood clots, allograft rejection, immunosuppression related risks, graft function loss, and long-term burden of lifelong immunosuppression on patients who receive these transplants.

12. What information on product quality and manufacturing is needed to allow HHS to evaluate available effectiveness data regarding donor islet therapies? For example, some RWE is generated under international regulatory frameworks that treat unmodified deceased donor islets as tissue/organ products rather than biological products. Clinical outcomes data (efficacy and safety endpoints) from these international cohorts could be relevant and informative. However, manufacturing quality data from these cohorts may not be directly translatable to current standards for biological products because they were generated under tissue/organ frameworks rather than CGMP-equivalent manufacturing oversight. What standards and supporting data would explicitly distinguish between the use of international RWE for clinical outcomes support (high fitness) versus manufacturing quality support (limited fitness; must be supplemented by the sponsor's own CGMP data)?

13. What is the current data regarding long-term graft durability beyond 5 years, and how does it weigh against the risk of long-term immunosuppression use?

14. Please discuss the comparability of international RWE. How generalizable are the experiences of international cohorts to the U.S. T1D population? Are there differences in disease management practices, HbA1c targets, hypoglycemia thresholds and other factors that could significantly impact the interpretability and applicability of international RWE to the US T1D population?

IV.B Questions for Consideration Regarding HHS Oversight Framework

The OPTN framework, overseen by HRSA, is built on creating policy and equity for allocating scarce, life-saving resources to the many patients in dire medical need for a new organ. HRSA's existing authorizing statute [12] and regulations [13] define the organs that the OPTN is responsible for, including the pancreas. Reclassifying deceased donor islet cells as ''organs'' would be a departure for this established oversight framework.

1. *Existing shared oversight.* The current framework divides responsibilities between FDA oversight of manufacturing and biological product regulation and HRSA's oversight of the OPTN and its policies governing organ donation, procurement, and transplantation. Are there modifications to the existing shared oversight framework that could improve patient access to unmodified deceased donor islet cells and cell products without an alteration of FDA's and HRSA's current regulatory responsibilities? If so, please describe.

2. *Evidence of access barriers.* Stakeholders have expressed concern that the current regulatory structure, with most pancreatic islet cell transplants conducted under an IND, may have unintentionally limited the ability of providers to regularly or consistently perform islet cell therapies or infusions. Please provide RWD or documented delays in providing this care as clinically indicated for patients who would benefit from this therapy. Please provide quantitative data or documented evidence demonstrating that FDA regulatory requirements, rather than manufacturing capacity, reimbursement, clinical infrastructure, donor availability, or other factors, are the primary cause of limited patient access.

3. *Alternative approaches.* Please provide publicly available examples of alternative approaches to regulating deceased donor islet cells for transplant (*e.g.,* legal oversight frameworks implemented by other regulatory authorities).

4. *Implementation.* What operational changes may be necessary to implement reclassification of deceased donor islet cell products as organs under the OPTN framework? Please identify any policy changes that would be required and discuss any implementation challenges.

5. *Precedential effects.* If deceased donor islet cells were classified as organs for purposes of Federal oversight, what precedent could this establish for other donor-derived cellular products or future cell-based therapies? What factors should HHS consider in determining whether pancreatic islet cells are distinguishable from processed donor-derived cellular products?

6. *Suitability of the OPTN framework.* The OPTN framework was established primarily to oversee allocation of vascularized organs and transplant programs. What aspects of that framework are well suited—or not well suited—for oversight of processed cellular therapy products such as deceased donor islet cell products? Please identify any additional policies, expertise, or infrastructure that would be necessary.

7. *Manufacturing and product quality oversight.* FDA currently oversees manufacturing processes, quality systems, product release testing, potency, sterility, and other controls applicable to biological products. If regulatory oversight were transferred to HRSA, via its oversight of the OPTN, how should the full range of oversight functions across the products' life cycle be executed? Are there aspects of the current FDA framework that should continue at FDA, versus moving to HRSA via its oversight of the OPTN, regardless of the regulatory classification?

8. *Patient safety.* What patient safety risks should HHS consider when evaluating whether post-marketing oversight of deceased donor islet cell products should remain within the FDA biological product regulatory framework

[9] See FDA's guidance ''BLA for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System,'' Section VIII.C, p. 46, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bla-minimally-manipulated-unrelated-allogeneic-placentalumbilical-cord-blood-intended-hematopoietic.*

[10] See FDA's guidance ''BLA for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System,'' Section VIII.D, p. 46, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bla-minimally-manipulated-unrelated-allogeneic-placentalumbilical-cord-blood-intended-hematopoietic.*

[11] 21 CFR 211.180(e).

[12] 42 U.S.C. 274b(d)(2).

[13] 42 CFR 121.2.

or be wholly incorporated into the OPTN framework? Please address issues including communicable disease transmission, manufacturing variability, sterility, product potency, traceability, and post-market surveillance.

9. *Provider implications.* If deceased donor islet cell products were reclassified as ''organs'', would OPTN membership need to expand to include new types of providers (*e.g.,* endocrinologists) to perform these treatments? Or would the existing pool of providers at OPTN member institutions perform these treatments if islet cells are classified as ''organs''?

a. What are the potential provider implications?

b. What are the potential system costs and implications for each approach?

10. *Patient access.* If deceased donor islet cell products were reclassified as organs, what effect could that have on:

a. the number and geographic distribution of treatment centers;

b. patient travel requirements;

c. provider participation;

d. waiting times;

e. patient costs;

f. insurance coverage and

g. donor willingness to participate in organ donation?

11. *Operational and financial impact on OPTN.* The OPTN is funded primarily through organ transplant patient registration fees. What operational, administrative, or financial impacts would reclassification have on the OPTN, its member organizations, and patients waiting for an organ transplant? Please comment on potential effects on policy development, Board of Directors and committee workload, information technology systems, membership requirements, patient registration processes, and overall program costs.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–19563 Filed 9–23–26; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute on Deafness and Other Communication Disorders.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute On Deafness And Other Communication Disorders, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute on Deafness and Other Communication Disorders.

Date: October 28, 2026.

Time: 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Address: Porter Neuroscience Research Center, Building 35A, 35 Convent Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Lisa L Cunningham, Ph.D., Scientific Director, National Institute on Deafness, and Other Communication Disorders, National Institutes of Health, 35A Convent Drive, Rockville, MD 20850, (301) 443–2766 *lisa.cunningham@nih.gov.*

Information is also available on the Institute's/Center's home page: *https://www.nidcd.nih.gov/about/advisory-committees,* where an agenda and any additional information for the meeting will be posted when available.

Dated: September 21, 2026.

Rosalind M Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–19577 Filed 9–23–26; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6513–N–02]

Civil Monetary Penalty Amounts for 2026

AGENCY: Office of the General Counsel, HUD.

ACTION: Notice.

SUMMARY: This notice informs the public that inflation adjustments of civil monetary penalty amounts required by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) are not being made for 2026.

DATES: September 24, 2026.

FOR FURTHER INFORMATION CONTACT: Scott Knittle, Principal Deputy General Counsel, Office of the General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20024; telephone number 202–402–2244 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as from individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) (Pub. L. 114–74, Sec. 701), which further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410), requires agencies to make annual adjustments to civil monetary penalty (CMP) amounts for inflation. The annual adjustment is based on the percent change between the U.S. Department of Labor's Consumer Price Index for All Urban Consumers (''CPI–U'') for the month of October preceding the date of the adjustment, and the CPI–U for October of the prior year (28 U.S.C. 2461 note, section (5)(b)(1)). Pursuant to the 2015 Act, adjustments are rounded to the nearest dollar.[1]

II. This Notice

On April 17, 2026, the Office of Management and Budget informed the heads of executive departments and agencies that ''Due to the government shutdown, [the Bureau of Labor Statistics] was unable to produce the October 2025 data. Based on the lack of October 2025 CPI–U data, which is needed to make adjustments under the 2015 Act, there will be no updated cost-of-living adjustment multiplier for 2026 and agencies will continue using the 2025 civil monetary penalty levels as applicable.'' [2]

As such, this notice informs the public that the statutory annual inflation adjustments of civil monetary penalty amounts are not being made for 2026 and that all HUD civil money

[1] 28 U.S.C. 2461 note.

[2] OMB Memorandum M–26–11: *Cancellation of Penalty Inflation Adjustments for 2026, Regarding the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,* April 17, 2026, pp. 1–2.