American Diabetes Association®

Official Statement

Contact: Virginia Cramer, (703) 253-4927
press@diabetes.org

The American Diabetes Association Statement on Improving Patient Access to Deceased Donor Islet Cells and Cell Products

ARLINGTON, Va. (Nov. 9, 2026) – The American Diabetes Association® (ADA) submitted organizational comments in response to the U.S. Department of Health and Human Services (HHS) Request for Information (RFI), *"Improving Patient Access to Deceased Donor Islet Cells and Cell Products."* The ADA appreciates HHS's action to explore a pathway to regulate deceased donor islet cells as organs for transplantation. Under the current regulatory framework, deceased donor islet cells are classified as biologic drugs, which creates barriers to patient access. This targeted policy change has the potential to expand access to a lifesaving treatment for a small, well-defined group of adults living with type 1 diabetes. These individuals often experience recurrent severe hypoglycemia, despite intensive diabetes management and education, and at times are unable to safely achieve glycemic targets.

In its comments, the ADA highlights key considerations related to federal oversight, implementation, and access to care, including:

- **Organ-based oversight for unmodified deceased donor islet cells:** The ADA supports classifying unmodified deceased donor islet cells as organs subject to oversight by the Health Resources and Services Administration (HRSA) through the Organ Procurement and Transplantation Network (OPTN). At the same time, the ADA emphasizes the importance of maintaining Food and Drug Administration oversight of islet products that undergo further manipulation, stem cell-derived islet products, and other manufactured cell therapies.
- **Limited and appropriate patient population for islet transplantation:** This change should be narrowly tailored to patients who meet eligibility criteria consistent with the patient population studied in the National Institutes of Health (NIH) Phase III clinical trial. For these individuals, islet transplantation represents an important treatment option that can reduce severe hypoglycemic events and improve quality of life.
- **International experience and real-world evidence:** The ADA points to Canada and the United Kingdom as the most relevant examples of successful organ-based oversight systems. Both countries regulate islets through organ and tissue transplantation frameworks, maintain

rigorous national quality standards for islet isolation, and have established clinical islet transplantation programs with documented patient outcomes.

- **Existing necessary infrastructure:** HRSA and the OPTN currently support aspects of islet transplantation through pancreas procurement and allocation systems, Organ Procurement Organization performance metrics, and the waitlisting of islet transplant candidates, providing a strong foundation for implementation.
- **Coverage and reimbursement challenges.** Expanding access will require not only an appropriate regulatory pathway but also adequate insurance coverage. The ADA encourages HHS to address coverage barriers, including the current limitation of Medicare coverage for islet transplantation to NIH-sponsored clinical trials.

The ADA appreciates and recognizes the contributions and partnership of clinicians, researchers, advocates, and people living with diabetes who have worked to advance patient access to islet transplantation. This RFI is an important next step following advocacy by ADA and the diabetes community to address this regulatory barrier. In a letter sent in June, ADA urged HHS to address this gap so innovative treatments can reach appropriate individuals living with type 1 diabetes. The ADA looks forward to continued collaboration with HHS and other stakeholders to ensure that eligible individuals with type 1 diabetes can benefit from safe, evidence-based, and potentially life-changing therapies.

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About the American Diabetes Association

The American Diabetes Association (ADA) is the nation's leading voluntary health organization fighting to end diabetes and helping people thrive. For 86 years, the ADA has driven discovery and research to treat, manage, and prevent diabetes while working relentlessly for a cure. Through advocacy, program development, and education we work to improve the quality of life for the over 155 million Americans living with diabetes or prediabetes. To learn more or to get involved, visit us at diabetes.org or call 1-800-DIABETES (800-342-2383). Join us in the fight on Facebook (American Diabetes Association), Spanish Facebook (Asociación Americana de la Diabetes), LinkedIn (American Diabetes Association), and Instagram (@AmDiabetesAssn). To learn more about how we are advocating for everyone affected by diabetes, visit us on X (@AmDiabetesAssn).