

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

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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

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