**CMS Cost Reporting Policies for Islets Undermines Intent of Legislation Enacted to Support Islet Transplant Research**

In an effort to support islet transplant research, in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Congress included a provision mandating Medicare coverage of islet transplants performed for Medicare beneficiaries participating in certain NIH-funded clinical trials. However, current CMS policy mandates that Organ Procurement Organizations (OPOs) impose the same Standard Acquisition Charge (SAC) for pancreata procured for islet transplant research and for whole organ (pancreas) transplants. This policy threatens the continued viability of islet transplant research and is inconsistent with Congressional intent to encourage such research.

The impact of CMS' policy is exacerbated by a number of unique features of islet transplants. Islets from several (3-5) pancreata are often necessary to achieve insulin independence in a single recipient and therefore the cost of a islet transplant reflects more than one organ's acquisition charge. In addition, over 50% of pancreas islet isolations do not yield the required threshold of islets, and therefore the islets are not transplanted, further aggravating the cost issue.

As the result of this combination of factors, a shrinking number of programs are participating in clinical research involving the performance of islet transplants. Currently, there are only eight programs performing islet transplants in the United States, about half the number of U.S. centers participating in such clinical trials five years ago. In 2010, only 18 islet transplants were performed in this country, as reported to the CITR (Clinical Islet Transplant Registry), down from over 60 islet transplants in 2002 and 41 islet transplants in 2005. The cost of obtaining pancreata for islet transplant research under CMS' current policy is a major factor contributing to the reduced research activity in this area.

This pressing problem can be alleviated in a manner that is consistent with the governing legislation by considering islets as tissue and not organs for OPO cost reporting purposes, so that the SAC assigned to pancreata destined for whole organ transplantation would no longer apply to pancreata destined for islet transplantation and related research. We urge CMS to consider the following:

i) In the past, CMS considered islets to be tissue and not organs, and there have been no compelling reasons to change this.

ii) Typically, organs are procured and transplanted (vascularized) within a few hours. In contrast, tissue is procured, then processed, then transplanted. In this respect, islets which are processed for several hours to days prior to implantation (non-vascularized) are similar to tissues (such as heart valves) and dissimilar to organs.[1]

iii) Islets are regulated by the FDA, as are tissues (e.g. heart valves). In contrast, vascularized organ allografts are not regulated by the FDA (hearts).

[1] In fact, we recently made the opposite argument for vascularized composite tissue grafts, making the case that because these are not processed and they are vascularized, they should be treated as organs and not tissue for regulatory purposes. Our arguments are internally consistent.

iv) The evaluation of a pancreas for a whole organ transplant versus islet transplant is completely different. Whereas the whole organ requires visual inspection intra-operatively to determine anatomical and other considerations by the procuring surgeon, this is not necessary for islets and the decision to use a pancreas for islets can be made without direct visualization, again reminiscent of the difference between hearts and heart valves.

v) Timely considerations of HLA typing and cross-match are necessary for whole organ transplantation, but not for islets. In contrast, islets must meet release criteria and this decision is made after processing, similar to other tissues.

vi) Pancreata are eligible for islet transplants only after they have been rejected for whole organ transplants; therefore the quality of the organs used for islet transplants is generally inferior to those used for whole organ transplants. Under these circumstances, it is inappropriate to require the OPO to charge the same amount for pancreata used for whole organ and islet transplants.

It is anticipated that subjecting pancreata procured for islet transplants to the same cost reporting principles applicable to tissue will reduce the amount of OPO overhead included in the SACs for islets sufficiently to assure the continued viability of islet transplant research.

Regarding concerns about the impact of such a change on the cost of other organs (lack of overhead contribution from islets), it should be noted that the number of islet cell transplants performed in the U.S. is minimal in relation to the total number of transplants performed . For this reason, reducing the SACs for islets would produce a negligible impact on other organs. Only 50-60 pancreas are being utilized for islet transplants out of nearly 28,000 transplanted organs; simple math dictates the impact of treating these as tissue rather than whole organs for cost reporting purposes will have a minimal impact on the SACs for other organs.

In fact, it is possible that reducing the cost of islets may reinvigorate the field, and that increased demand for pancreata for islet research may generate revenue from pancreata that otherwise would be wasted. We would anticipate that such increased revenue would offset any marginal increase in SACs for other organs.

In summary, current CMS policy regarding cost allocation for pancreata used for islet transplant clinical trials and related research has brought the field to near standstill and is a threat to developing the field further. This is inconsistent with Congressional intent to encourage islet cell transplants and make these transplants available to Medicare patients. Changing this policy is absolutely essential to revive the field.

We thank you for your consideration and would be happy to provide more details upon request.