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The Honorable Kathleen Sebelius
Secretary of the Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Madam Secretary:

On behalf of the American Society of Transplant Surgeons ("ASTS"), I am writing to you regarding Medicare payment policies that have inadvertently contributed to substantial reductions in islet cell transplant research throughout the country. ASTS is an organization comprised of over 1500 transplant surgeons, physicians and scientists dedicated to excellence in transplantation surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

Islet cell transplantation has the potential to revolutionize treatment for Type I diabetes; however, this procedure is currently considered investigational and would be ineligible for Medicare coverage under generally applicable Medicare coverage rules. Congress – intending to support research in this area – authorized and appropriated funds for a clinical trial to be conducted by NIH and specifically required that the clinical trial include Medicare beneficiaries. In a highly unusual provision, Congress required that Medicare cover not only the "routine costs" of Medicare beneficiaries participating in the study but also transplantation-related investigational items and services (including islet cells). See Section 733 of Pub. L. 108-173 (Section 7339b) (the "Medicare Modernization Act" or "the MMA").

Clinical trials authorized by the MMA have not yet begun to enroll patients and a major NIH sponsored multi-center registration trial in Medicare beneficiaries has had to scale back planned enrollment from 130 patients (half randomized to islet transplantation) to a pilot study of 24 islet transplant recipients.

Ironically, rather that furthering islet transplantation research, as Congress intended, CMS policy with respect to islet cell transplantation has substantially increased the cost of conducting research in this area, by triggering significant increases in the cost that all islet cell research institutions – not only those planning to participate in the MMA-authorized trial – must pay for the pancreas tissue necessary to obtain the islet cells for transplantation ("pancreas islet tissue").

The CMS policies at issue and their impact on islet transplant programs throughout the United States are addressed at length in the attached "White Paper," which has also been accepted for publication in the leading North American journal, the *American Journal of Transplantation*, and endorsed by the following societies and foundations:

American Society of Multicultural Health and Transplant Professionals
American Society of Transplantation (AST)
American Society of Transplant Surgeons (ASTS)
Association of Organ Procurement Organizations
Cell Transplant Society
International Pancreas and Islet Transplant Association
Juvenile Diabetes Research Foundation
Organ Procurement and Transplant Network/United Network for Organ Sharing
Principal Investigators of the NIH-sponsored Clinical Islet Transplant Consortium
Principal Investigators of the NIH-sponsored Islet Cell Resource Centers
The Organization for Transplant Professionals (NATCO)
The Transplantation Society

I. The Problem

The basic problem is that Medicare payment policies require Organ Procurement Organizations (OPOs) to charge research institutions the same amount (the Standard Acquisition Charge (SAC)) for pancreas islet tissue as for pancreata procured for whole organ (pancreas) transplants. Section 2773.2 of the Provider Reimbursement Manual Part I ("PRM-I") states:

> 2773.2. Pancreata Used for Pancreas Islet Cell Transplants – The Medicare Modernization Act of 2003 requires Medicare to pay for islet cell transplants for Medicare patients included in the National Institutes of Health study on islet cell transplants. The pancreata procured for islet cell transplants require the same quality and care as pancreata procured for solid organ transplants. Accordingly, pancreata procured for islet cell transplants must be assigned a full charge and treated as solid organs for procurement purposes.

As the result of this policy, the cost of pancreas islet tissue used in conjunction with islet cell research has increased to approximately $24,000/pancreas, and in some areas, even more.

It appears that Section 2773.2 reflects a change from prior policy, which evidently directed OPOs to utilize the same pricing policies for pancreas tissue as for other tissues. In fact, the Instructions for Form CMS-216-94, Provider Reimbursement Manual, Part II (PRM-II"), § 3300, which is used by OPOs to report their costs, still reflects the prior policy:

> When the OPO has acquired organs other than kidneys, complete a separate Worksheet A-2 for each type of organ. The OPO must also go through cost finding when other internal organs are acquired to ensure that overhead is allocated to all types of acquisitions. However, tissues, such as skin, cornea, bone, heart valves, and **pancreas islet** absent adequate cost finding methodology need not go through cost finding. Rather, income received is offset against cost associated with transplant coordinator costs on Worksheet A.

(Emphasis added). It is our understanding that this policy is not currently in effect, although it remains in the OPO Instructions for Form CMS-216-94.

Section 2773.2, requiring equal SACs for pancreata used for whole organ and for islet cell transplants, became effective in January, 2005. Since that time, the number of islet cell transplants has declined sharply:

2005 - 41 new islet allograft recipients
2006 - 21 new islet allograft recipients
2007 - 15 new islet allograft recipients

As explained below, for an islet transplant recipient to become insulin independent, on average two infusions of islets are required, and, in order to obtain an islet product suitable for each infusion, two or three pancreata may be necessary, since some pancreata will yield islets that do not meet release criteria. Therefore, it may require four to six pancreata to achieve insulin independence through islet transplantation, in light of wastage and considering the quality of the pancreata available for islet cell transplantation. Accordingly, institutions participating in islet cell transplantation clinical trials now may need to budget from $96,000 to $144,000 solely to cover the cost of the pancreata necessary to perform a single islet cell transplant – and this estimate may be conservative in some areas of the country where the SAC for pancreata are higher. This financial burden has made the continued pursuit of islet cell research financially unsustainable for many institutions. And all of this has transpired before a single Medicare beneficiary has become eligible for a Medicare covered islet cell transplant.

Nor does this policy result in a significant financial benefit for the Medicare program. It may be argued that, if the SAC for pancreas islet tissue does not reflect the true cost of procuring it (which CMS erroneously assumes to be equal to the cost of procuring pancreata for whole organ transplantation), the costs attributable to procuring pancreas islet tissue will be inappropriately apportioned to the kidney cost center (which is reimbursed primarily by the Medicare program) and to cost centers for other solid organs that are reimbursed by Medicare and other third party payers. However, in light of the relatively few pancreata procured for islet cell transplantation research, we do not believe that this cost is substantial.

Moreover, the administrative and overhead costs associated with the SAC for pancreas islet tissue likely otherwise would be allocable to the pancreas cost center, under the "Intent to Transplant" Ruling discussed below. Therefore, reversing the current policy, which has significantly increased the cost of islet cell research, likely would not have a significant negative impact on the Medicare Program.

II. Analysis

Current CMS policy fails to recognize that islet cell research – although covered by Medicare – has not lost its basic character as a research activity. It is not clinically established, and should not be subject to the same cost finding and allocation rules applicable to clinically established procedures. In choosing to mandate Medicare coverage for islet cell research, Congress fundamentally determined that, in light of the extraordinary promise of this research, it should be subsidized by the Medicare program. The MMA subsidy is generous: The Act requires CMS to pay not only for the "routine costs" of the islet cell transplants provided to Medicare-eligible study participants, but also for investigational items and services, such as the islet cells themselves, which would not be eligible for payment even under CMS's established "clinical trial policy," which covers only "routine" clinical costs of study participants. So far as we are aware, there is no precedent for this type of Medicare support for an NIH clinical trial. It is indeed ironic, then, that the MMA has hurt, rather than helped, islet cell research.

No provision of the Medicare statute or applicable regulations mandates this result. Rather, the extraordinary and unintended increase in the cost of pancreas tissue used for islet cell research is a function of CMS's decision to apply to this pancreas islet tissue the same cost reporting rules initially formulated for the transplantation of pancreata as solid organs. By applying the same rules to pancreas tissue used as a source of islet cells and pancreata intended for whole organ transplantation, CMS fails to recognize clear and crucial distinctions between these two categories of pancreata.

First, Medicare cost reporting principles generally, and the concept of a "standard acquisition charge" specifically, were formulated to identify and allocate costs among a relatively large number of reimbursable events, using the statistical power of averages. Conceptually, Medicare cost finding and allocation rules are not equally applicable to items and services that are relatively uncommon and isolated. It is not even clear that the concept of a "standard" charge has an appropriate place in the establishment of Medicare policies for pancreas islet tissue utilized for islet transplantation. The PRM-I, § 2771.A, states:

> The standard charge does not represent the acquisition cost of a specific organ. It is a charge which reflects the average cost associated with each particular type of organ acquisition, i.e., the actual cost of procuring all organs of each specific type (cadaveric or live donor) averaged over billable organs by type.

It is clear from this definition that the concept of a "standard charge" was intended for use in pricing where there are numerous organs of the same type. By contrast, what is at issue here is pancreas tissue to be used in limited clinical trials involving a relatively small number of Medicare beneficiaries and conducted in 7-8 participating research institutions located throughout the country.

For example, it may be anticipated that each institution participating in the scaled-back NIH multi-center study may enroll 3-4 Medicare study participants over the next two years, and most of these research institutions use different OPOs. Under these circumstances, it does not appear that a sufficient number of procurements will be effectuated by any single OPO for it to be appropriate to apply Medicare cost reporting and allocation rules developed for whole organ transplantation.

Second, the application of standard Medicare cost reporting and allocation principles is not necessary to ensure appropriate allocation of costs between Medicare and non-Medicare payers. Medicare is the only third party payer that has indicated that it will cover islet cell transplant research at all, and coverage is mandated only for transplants that are performed in the context of a limited pilot clinical trial. All other payers consider these transplants to be investigational and do not provide any coverage, so the establishment of a SAC based on general accepted Medicare cost principles is not necessary for the purpose of ensuring that each payer bears its fair share of these costs.

Third, the quality of the pancreata utilized for islet cell research is fundamentally different from the quality of the pancreata used for whole organ transplantation. A pancreas is eligible for consideration for islet cell research purposes only after it has been rejected for solid organ transplantation. Pancreata procured for islet cell research often otherwise would be discarded. In light of the differences in the quality of the pancreata used for islet cell research and that used for whole organ transplantation, it is entirely inappropriate for CMS to require that the same SAC be imposed for both.

Fourth, CMS assumes that the cost of retrieving a pancreas is the same, regardless of whether the pancreas is used for whole organ transplantation or for islet cell research purposes. This ignores the fact that a decision to retrieve a pancreas for islet cell research purposes cannot be made until the pancreas is clearly and unequivocally rejected for whole organ (pancreas) transplantation. This decision generally cannot be made until the recovery team is in the operating room, where they can visualize the pancreas and determine its anatomic and physiological suitability for transplantation. Once the pancreas is rejected for whole organ transplantation and the decision is made to procure the donor's pancreas for islet cell research purposes, the procurement costs are relatively minimal – fundamentally consisting of the operating room time necessary to excise the organ and the related surgeons' fees; perfusion costs; and transportation costs.

Thus, a number of the services performed by OPOs in conjunction with their procurement of whole organs are not relevant to the procurement of pancreata for islet cell transplantation research. For example, the type of histocompatibility matching and other matching that is generally performed in advance of organ procurement in the case of whole organs generally is not performed in advance when a pancreas is procured for islet cell isolation. Rather, matching (other than blood type matching) is generally performed after the isolation of the islets, by the islet isolation facility or transplant center involved. Likewise, the OPO services necessary for coordinating the laboratory, imaging, and other tests that may be necessary to determine the suitability of an organ for solid organ transplantation are not necessary to determine the suitability of a pancreas for islet cell isolation.

In general, anatomic features of an organ that may make it unsuitable for whole organ transplantation are irrelevant to determine whether or not a pancreas is acceptable as a potential source of islets, and so OPO assistance is not needed to coordinate or disseminate information regarding the anatomy of the organ that is subject to recovery. Nor does the clinical care of the donor depend in whole or in part on whether or not a pancreas is recovered for research purposes – fundamentally as salvage – at the conclusion of the process. Thus, in fact, the costs of coordinating procurement of a pancreas are not identical for whole organ transplantation and for islet research purposes.

Fifth, while the field is evolving and researchers are learning more about which pancreata are likely to yield islets that meet release criteria, at this stage only approximately 50% the pancreas islet tissue intended for use in islet cell transplants yields islets that meet the standards necessary for implantation (the "release criteria"). By contrast, approximately 20% of pancreata procured for whole organ transplantation are wasted, and the percentages are even lower for kidney (3-4%) and liver (approximately 5%). CMS has established payment mechanisms for ensuring that the costs of wastage are not borne disproportionately by the OPO or by the transplant center involved. Under OPO cost reporting principles, the costs of wastage that are incurred by the OPO are spread and absorbed by increases in the SAC of usable organs, and a transplant center that accepts an organ that ultimately proves unsuitable for transplant may be reimbursed for at least part of the cost incurred through the organ acquisition cost center (in the case of Medicare patients) and by negotiated rates (in the case of non-Medicare patients).

By contrast, while some OPOs agree to charge transplant centers a "research" rate for pancreata that yield islet cells that do not meet release criteria, a number of OPOs insist upon charging the same rate for pancreas islet tissue intended for islet cell research as for pancreata intended for whole organ transplantation – regardless of whether the islet cells meet release criteria. These OPOs are apparently relying on the language of PRM-I §2733.2, which does not distinguish between pancreas islet tissue whose islets meet release criteria and those whose islet cells do not. At this stage, it is unclear whether or not CMS will allow transplant centers participating in the NIH study authorized by the MMA to report as "organ acquisition costs" the cost of pancreata whose islets do not meet release criteria, since doing would substantially increase the costs of each covered islet cell transplant covered by Medicare under the MMA.[1] And research institutions have no payment mechanism for retrieving the costs of pancreata that yield unusable islets for non-Medicare patients.

Sixth, because insulin independence generally requires two islet infusions and because not all pancreata yield islets that meet release criteria, islets obtained from four to six pancreata may be necessary in order for a single patient to achieve insulin independence through islet transplantation. By contrast, a whole organ (pancreas) transplant obviously requires just one transplantable organ.

[1] Since these transplants are not currently reimbursed by any third party payer, it is our understanding that transplant centers that intend to participate in the NIH study generally have not established islet cell transplantation cost centers to capture the non-research costs associated with islet cell transplants.

Therefore, by requiring OPOs to charge the same amount for a pancreas used for a solid organ transplant as for pancreas islet tissue used for islet cell research, CMS is making the continued provision of islet cell transplantation financially prohibitive for transplant centers, which are solely dependent on research funding to cover the costs of their islet cell transplant programs.

Seventh, under a CMS Ruling specifically applicable to solid organs, (CMS 1541-R) (December 21, 2006) (the "Intent to Transplant Ruling"), OPOs are required to allocate substantial organ procurement costs if an organ procurement team "intends" to procure an organ for transplantation—regardless of whether the organ is actually surgically procured from the deceased donor and ultimately transplanted. The SACs charged for pancreata intended for whole organ transplantation are subject to this ruling and, accordingly, reflect substantial OPO overhead. Since PRM-I, § 2773.2 requires OPOs to charge the same amount for pancreata procured for whole organ transplantation and for islet cell research purposes, this overhead is likewise reflected in the SACs paid by research institutions for the pancreas tissue needed for the research.

However, the Intent to Transplant Ruling does not by its own terms apply to retrieval of pancreas tissue for islet cell research purposes. And while it may be reasonable to find an "intent to transplant" before the retrieval team reaches the operating room in the case of a solid organ (pancreas) transplants, there can be no "intent to transplant" islets until after the transplant team visually inspects and rejects a pancreas for whole organ transplantation. It is not until that time that procurement of the pancreas for islet cell research purposes even can be considered. Thus, allocation of OPO administrative and overhead costs to pancreas islet tissue procured for research purposes on the basis of the "Intent to Transplant Ruling" would be entirely inappropriate.

In short, while it is clearly inappropriate to treat "like" items and services differently, it is equally inappropriate to treat different items and services as if they were alike. By treating pancreas islet tissue intended for islet cell research in the same way as pancreata intended for whole organ transplantation, CMS payment policies are contributing to the potential demise of critical diabetes research that Congress sought to advance.

III. Options

Our concerns regarding the impact of CMS policies on islet cell research can be addressed through the establishment of Medicare payment policies that recognize the unique status of pancreas islet tissue procured for islet cell research, as distinguished from pancreata procured for whole organ transplantation. We would recommend that CMS consider the following options:

- Reinstate cost reporting policies that treat pancreas islet tissue procured for islet cell research in the same manner as other tissue procurement. As indicated above, it appears that, prior to the adoption of PRM Section 2773.2, the Medicare Program directed OPOs to apply the same policies to "pancreas islet tissue" as it applies to other types of tissue procurement. See PRM-II, § 3300. PRM-I, § 2773.1 sets forth the cost reporting policies applicable to other forms of tissue procurement, requiring the establishment of a schedule of charges for eye and other tissue services.

These charges are offset against the cost of all procurement services. Charges are established in a manner that approximates the cost of the service. In the case of pancreas tissue procurement, we recommend that OPOs be directed to include only direct costs (Operating Room time attributable to excision of the pancreas, applicable surgical fees, and perfusion and transportation of the pancreas tissue) in establishing the charge. Thus, the simplest and most straightforward resolution of the concerns raised would be to revert to the Medicare policy that evidently was in effect prior to the adoption of PRM-I, § 2733.2.

- Treat pancreas islet tissue as "unusable" pancreata for cost reporting purposes, and offset the revenue obtained for this pancreas islet tissue as a revenue offset against pancreas cost center. This approach recognizes that pancreata are available for islet research only if they are found to be unusable for whole organ transplantation, and provides a mechanism to reduce the OPO's costs for otherwise unusable organs by using revenues obtained for pancreas islet tissue to offset otherwise allowable costs of the pancreas cost center.

- Establish a separate cost center subject to special cost allocation rules, for the procurement of pancreas islet tissue and other "metabolically active" tissue. For the reasons set forth above, we do not believe that it is appropriate to subject pancreas islet tissue to the same overhead allocation rules that are applicable to solid organs under the Intent to Transplant Ruling. The costs accumulated in any such new cost center should include only the costs directly attributable to the retrieval, perfusion, and transportation of the tissue involved.

- Treat costs of procuring pancreas islet tissue as research costs. At this stage, islet cell transplantation is clearly an investigational procedure – albeit an investigational procedure that Congress has decided to subsidize through the Medicare Program. The decision by Congress to provide Medicare coverage for these research activities does not change the essential character of the services as research – fundamentally, Medicare-subsidized research. For this reason, we believe that it would be appropriate for OPOs to be instructed to treat the costs associated pancreas islet tissue intended for islet cell isolation to a research cost center. OPOs could be directed to establish charges for this tissue, in a manner consistent with its charging practice for other research-related items and services.

- Establish a national payment formula for the establishment of charges for pancreas islet tissue. Finally, in light of the limited number of pancreata involved, it may be appropriate for CMS to establish a formula for OPOs to use in establishing its charges for pancreas tissue procured for islet cell research. For example, the available data suggests that (a) only approximately one half to one third of pancreata yield islets that meet release criteria; and (b) islets from at least two pancreata are necessary for each islet cell transplantation. Accordingly, it may be appropriate for CMS to direct OPOs to establish charges for such islet pancreas tissue that are approximately 25% of the charges for pancreata utilized in whole organ transplants.

We would be delighted to work with CMS to develop other options for addressing this problem. We would like to schedule a meeting with attendance by officials from CMS, NIH, and other relevant agencies to discuss this matter further, and would appreciate you contacting Katrina Crist, Executive Director, at 703.414.7870 or via e-mail at katrinacrist@earthlink.net to arrange a mutually convenient meeting date.

Sincerely yours,

John P. Roberts, MD
President

cc: Barry Straube, MD
Director, Clinical Standards, CMS