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president



Of Missions and Mission Statements

I used to be skeptical of mission statements. Too often, it seemed, they were nostrums that were full of glittering generalities that looked good in publications and on wall plaques, but had little relevance to the daily actions of whoever promulgated them. Many organizations are still like that. The ASTS has a mission statement that serves to direct the actions of the Society. If what we are doing does not serve to fulfill our mission, then we need to give serious consideration to continuing along that path. Among other items, the mission statement provides that the ASTS should "guide those who make policy decisions that influence the practice and science of transplantation: and "advance the professional development and careers of transplant surgeons, scientists and physicians".

In recent months the ASTS has been particularly active along these lines. We have been increasingly active in pursuing legislative and regulatory changes favorable for our patients and for transplant professionals. In the last Chimera (Vol XV, no. 4, summer 2004) covered the Congressional fly-in detailing the attempts of the ASTS to get the funding for the Organ Donation and Recovery Improvement Act (promoting organ donation is also part of our mission). Although it was late in the appropriations process, the Senate did pass favorable report language suggesting to the Agency of Healthcare Research and Quality (AHRQ) that it strongly favored the bill. This may enable the AHRQ to fund part of the bill (having to do with organ preservation research) out of uncommitted funds. On November 30 we held a

meeting with the AHRQ, the Health Resources and Services Administration (HRSA), and the Division of Transplantation under Jim Burdick (who also is a member of the ASTS) to further our activities to obtain funding for the Organ Donor Bill. The meeting with the AHRQ was to discuss how the ASTS could assist the agency with fulfilling its new authorizations and implementation of the ASTS-initiated "report language" (language of the bill stating the intent of Congress). We will continue to try to get the bill funded next year. Several other regulatory issues were also discussed in that issue of the Chimera (page 15).

These issues continue to be at the forefront of the ASTS Council, Legislative Committee and other committees. The ASTS has been particularly active in trying to obtain reimbursement for procedures previously included in organ recovery but not separately covered. Mike Abecassis has been particularly diligent in helping the ASTS achieve CPT codes for "backbench procedures". He has worked closely with Dr. John Gage, chairman of the General Surgery Coding and Reimbursement Committee of the American College of Surgeons (ACS) and the ACS representative on the Resource Utilization Committee (RUC) to shepherd these codes through the CPT Editorial Committee and the RUC. Through this process, the AMA and CMS have published the codes in the 2005 Medicare Fee Schedule that went into effect January 1, 2005. There are still some issues outstanding regarding valuations of some of these codes which the ASTS is in the process of resolving. The ASTS is grateful to Dr. Abecassis for his efforts on behalf of the society.

The ASTS is also taking an active role in evaluating the potential transplant codes that would be proposed for review at the third 5-year review process by the RUC this upcoming year. With the help of the ACS we are in the process of making determinations about which transplant codes, if any, will be recommended for review as we look for rank order anomalies within the families of codes being evaluated.

CMS recently provided for funding of islet transplantation that will make it extremely difficult for transplant centers to perform islet transplantation and not lose money. We have established a task force to address this issue and to persuade CMS to enable islet transplantation to at least be budget neutral. Other issues the ASTS is preparing to address are CMS regulations for transplant centers which were released February 4, 2005, and the federal mandate requiring transplant centers provide post-transplant data with no provision for funding for it.

Dealing with legislative and regulatory issues may not be as important as other components of the ASTS mission, such as educating new transplant surgeons and the promotion and dissemination of research and new information to its members. Nevertheless, we will continue to speak out for our patients' and members' rights by addressing legislative and regulatory issues where and when appropriate. The ASTS is grateful to the many members who tirelessly devote time pursuing these efforts.

Best Regards,

Richard J. Howard, MD, PhD

President

Call-For-Nominations

Call For Nominations Deadline is April 15, 2005

The American Society of Transplant Surgeons' Nominating Committee requests nominations from the Membership for the 2005/2006 offices of President-elect, Secretary, and two Councilors-at-Large. Candidates must be Regular Members in good standing and be willing to serve, if nominated.

To nominate an ASTS Member for a position on the 2005-2006 Council, please send a letter of nomination by April 15, 2005 to:

Richard J. Howard, MD, PhD President & Nominating Committee Chairman American Society of Transplant Surgeons 1020 North Fairfax St., Suite 200 Alexandria, VA 22314

Fax: 703-684-6303



CHIMERA – GOVERNMENT RELATIONS REPORT

The 108th Congress was historic in terms of legislation impacting the health care system and transplantation—the Medicare Modernization Act of 2003 and the Organ Donation and Recovery Improvement Act of 2004 among them.

ASTS has been engaged on multiple fronts to impact the implementation of these new laws. Following the ASTS "Legislative Day" in June, ASTS continued to press for funding of the new law in FY 2005, which began on October 1, 2004, and has begun to work directly with agencies such as the Agency for Healthcare Research and Quality ("AHRQ") and the Health Resources and Services Administration's Division of Transplantation ("DoT") to implement the new law in coordination with ASTS-initiated projects. With regard to the implementation of the Medicare Modernization Act ("MMA"), ASTS reviewed and submitted formal comments on proposed guidelines issued by the United States Pharmacopeia on formulary design in new Medicare drug plans and proposed regulations issued by the Centers for Medicare and Medicaid Services (CMS) that implement the new drug benefit and managed care plans (see the regulatory report on page 8).

The 109th Congress, which began its work on January 3, 2005, is likely to continue a health care agenda. Legislation impacting the implementation of the MMA, the Medicaid pro-

gram, medical malpractice reform, medical savings accounts, and Association Health Plans are likely to feature prominently. Additionally, ASTS will engage Congressional appropriators on the importance of providing new funding for the organ donation law.

Organ Donation and Recovery Improvement Act— ASTS Report Language Included, but No New Funding

The Organ Donation and Recovery Improvement Act of 2004 was signed into law on April 5, 2004. This legislation will assist current efforts by the federal government, states, and other entities to promote organ donation, reduce the waiting list, provide for travel and subsistence reimbursement for living donors, fund hospital-based organ coordinators, and improve the practice of organ recovery, preservation, and transportation. The law was developed in close consultation with ASTS and marks the culmination of three years of efforts to secure enactment of this new legislation.

However, despite the best efforts of ASTS members to engage Congressional appropriators as well as other transplant-related interest groups, it appears that for FY 2005, no new funding will be available to fund these programs. This is largely due to the timing of the bill's passage, in that it occurred too late in the year to secure FY 2005 funds. The Health Resources and Services Administration's Division of Transplantation was levelfunded at \$24.6 million. Because of

ongoing funding for the war in Iraq and pressure to reduce the deficit, very few programs received increases. Additionally, all federal programs outside of defense and homeland security were subject to a .83 percent across-the-board cut in spending.

Although no new funding was included in the omnibus spending bill, ASTScrafted "report language" was included in the Senate appropriations bill that encourages the creation of a scientific network to improve the recovery, preservation and transportation of organs. Report language is nonstatutory language often included in appropriations bills that expresses the desire of Congress to direct federal agencies toward certain programmatic priorities. It was included in the Senate-approved Labor, HHS, and Education Appropriations bill. The language is restated below and is virtually identical to the language originally submitted by ASTS.

> Organ Donation.—The Committee recognizes that there is presently no formal mechanism to scientifically evaluate the efficacy of many new medications, devices, surgical techniques, and technical innovations that are being developed to improve organ preservation and maximize organ usage. The Committee encourages AHRQ to study and develop scientific evidence in support of efforts to increase organ donation and improve the recovery, preservation, and transportation of organs.

As a result of the report language, ASTS leaders met with the Director of the Agency for Healthcare Research and Quality Director, Carolyn Clancy, M.D., and Director of the HRSA Division of Transplantation, Jim Burdick, M.D., on November 30, 2004, about the report language and other programs authorized under the organ donation law.

ASTS plans to make a significant effort to engage Congress in 2005 to include funding for the organ donation law in FY 2006. Because the bill did not pass until April, 2004, there was a compressed timetable to seek funding in FY 2005. With a full year and Congressional staff aware of the need to fund these programs, the chances are better than this past year, but securing funding for new programs in this fiscal year's environment will continue to be a challenge.

Election Results Impact on Congress and Committees

Amidst President Bush's reelection on Tuesday, November 2, the Senate and House of Representatives saw Republican gains that will impact health policy in the 109th Congress. The gains will likely reinforce in Congress the potential of the president to succeed in his second-term health policy goals that could impact health insurance coverage and rising malpractice premiums—medical liability reform, health savings accounts, and Association Health Plans.

Senate Elections—Republicans increased their control of the Senate by netting an additional four seats, giving the party a 55-seat majority. There were several closely watched races, most of which resulted in GOP victories.

In South Dakota, Senate Minority Leader Tom Daschle lost his seat to Republican Congressman John Thune,

marking the first time a Senate leader has lost his bid for reelection in over 50 years. Minority Whip, Harry Reid (D-NV) has accepted the position of Senate Minority Leader following Daschle's defeat and will continue into the 109th Congress as the highest ranking Democrat in Congress. Congressman Johnny Isakson (R-GA) will take the seat of Senator Zell Miller (D-GA) who is retiring. GOP candidate Mel Martinez narrowly beat out Betty Castor in Florida for a Senate seat vacated by retiring Democrat Bob Graham. Republican Congressman David Vitter took 51% of the vote in Louisiana, replacing retiring Democratic Senator John Breaux. In North Carolina, Republican Congressman Richard Burr will take the seat of Senator and former Vice Presidential candidate John Edwards. Congressman Jim DeMint (R-SC) will take the seat of retiring Democratic Senator Ernest F. Hollings (D-SC). Former Congressman and practicing OB-GYN Tom Coburn (R-OK) defeated Congressman Brad Carson (D-OK) to succeed retiring Budget Committee Chairman Don Nickles. Overall, these newly elected Republican Senators, particularly Coburn, are considered very conservative and replace Democrats who were considered moderate or liberal.

Illinois Democratic State Senator Barack Obama easily took the Senate seat left vacant by retiring GOP Senator Peter Fitzgerald. Obama delivered the keynote speech at the Democratic National Convention and has been viewed as a rising star in the party. Colorado elected Democratic candidate Ken Salazar to take the Senate seat of retiring GOP Senator Ben Nighthorse Campbell.

House Elections—The Republicans gained five seats in the House of Representatives bringing the GOP majority to 233 seats with Democrats holding 199 seats, and one

Independent who generally votes with Democrats. (One race in Louisiana to succeed Congressman Chris John (D) is subject to a run-off election in December.) Despite the gains, Republicans did suffer several losses, most notably Congressman Phillip Crane (R-IL)—the longest-serving Republican in the House and the second highest ranking Republican on the House Ways and Means Committee.

Committee Changes—With the GOP gains in the House and Senate and the retirement of several Democratic and Republican legislators, some significant changes are likely in committee leadership and composition, especially with regard to the committees with jurisdiction over transplant issues.

There will likely be one less Democrat on the Senate Finance Committee, the Senate Committee with jurisdiction over both Medicare and Medicaid. Chairman Charles E. Grassley (R-IA) will remain Chair of the Finance Committee, which has jurisdiction over Medicare and Medicaid. Senator Don Nickles (R-OK) will be retiring this year and Senators Michael Crapo (R-ID) and Norm Coleman (R-MN) are both said to be interested in taking his place on the Finance Committee. With the retirement of Senators Bob Graham (D-FL) and John Breaux (D-LA) and the loss of Minority Leader Tom Daschle (D-SD), Democrats will likely look to Senators Evan Bayh (D-IN) and Hillary Clinton (D-NY) to join the Finance Committee.

The leadership of the House Energy and Commerce Committee, which has jurisdiction over most transplant issues and Medicaid (it shares jurisdiction over Medicare with the House Ways and Means Committee), will likely remain intact. The Republicans will lose retiring Congressmen and former Chairman Billy Tauzin (R-LA) and James Greenwood (R-PA), as well as newly elected Senator Richard Burr (R-

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NC). Greenwood was a very active member on transplant issues in the past. The Democrats will lose Peter Deutsch (D-FL), Karen McCarthy (D-MO), and Chris John (D-LA). Changes in this committee's membership will not be announced until December. The Health Subcommittee lost two Republicans (Congressmen Greenwood and Burr) and one Democrat (Congressman John).

The House Ways and Means Committee lost several Republicans and two Democrats. In addition to Congressman Phillip Crane (R-IL), the Committee will also lose Amo Houghton (R-NY), Jennifer Dunn (R-WA), Max Collins (R-GA), Scott McInnis (R-CO), Gerald Kleczka (D-WI), and Max Sandlin (D-TX). Nancy Johnson, Chair of the Health Subcommittee, has stated that she wishes to remain in her position despite Jim McCrery (R-LA) and Clay Shaw's (R-FL) apparent interest in her leadership position. The Ways and Means Health Subcommittee lost two Republicans (Crane and Dunn) and one Democrat (Kleczka).

Secretary of HHS-Several months ago, Secretary Tommy Thompson publicly indicated that he would not be returning to head the Department of Health and Human Services in January 2005 regardless of a second term for the Bush Administration. Immediately all eyes turned to the apparent replacement, Administrator of the Centers for Medicare and Medicaid Services, Dr. Mark McClellan.

However, despite a round of cabinet resignations, Thompson's name was not among them. At the time of this writing, it remains unclear whether or not he will serve during President's Bush's second term.

Preview of Upcoming Issues in the 109th Congress

Health Savings Accounts-President Bush is proposing an expansion of previous efforts to promote "Health Savings Accounts." (HSAs) HSAs are tax-free savings accounts that promote the use of high-deductible catastrophic health plans and allow people to spend the account's funds on routine medical care, prescription drugs, and medically-related items and services. In addition to promoting their use, the president is also proposing to give low-income families a \$1,000 contribution to their HSAs and a \$2,000 refundable tax credit to buy a policy for major medical expenses. The president would also give tax credits to small firms for contributions to employees' HSAs.

Democrats largely oppose HSAs on the grounds that the plans would favor the wealthiest and healthiest individuals, thereby taking the "good risks" out of the overall insurance pool. Lowincome individuals, they argue, would not be able to afford even the premiums to high-deductible plans, the contributions to such accounts, and that health insurance companies could "cherry pick" the healthiest beneficia-

ries, thus leaving the sickest to receive insurance from government plans. This may, in turn, significantly increase costs for these populations.

Association Health Plans-President Bush will be advocating for Association Health Plans (AHPs) in the 109th Congress in an effort to allow small business to cover more employees. The concept of AHPs has been around for the past 8 years in Congress, passed the House of Representatives several times, but never enacted into law due to the opposition of Congressional Democrats. AHPs would essentially allow un-affiliated small businesses to form risk sharing arrangements across state lines, thus, presumably, lowering the cost of health insurance premiums to those businesses and allowing more diverse and affordable coverage. Supported by many independent business groups, the President is touting AHPs strongly to small businesses as a means to lower their health care costs. Democrats charge, however, that AHPs would be a bad idea for consumers, low income persons, and the sickest. Because AHPs would not be subject to state insurance regulations, the existing web of consumer protections in the individual insurance market (mostly state-based) would be superseded by a looser set of federal rules that would permit risk selection and denials of coverage. AHPs, Democrats further argue, would allow insurance companies to offer products with no standards, potentially harming consumers.

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Medical Malpractice Reform-One of the most contentious and often talked about issues this election year among health care providers is the issue of medical liability reform. President Bush, as well as Republicans in Congress, has hammered Democrats relentlessly on the issue of rising costs and reduced access to health care because of rising malpractice insurance premiums. Blaming over-zealous trial lawyers, they have put forward numerous proposals that passed in the House, but failed in the Senate, which would cap non-economic damages at \$250,000. In addition to the caps on damages, Bush also states that his proposal would reserve punitive damages for cases of "egregious conduct," ensure that old cases cannot be brought years after an event, and provide that defendants should pay judgments in proportion to their degree of fault.

Given the larger and more conservative majorities in the Senate and House of Representative, the chances of enactment of some sort of medical liability reform appear stronger than in previous Congresses, but this is an issue that remains very controversial.

Pancreatic Islet Cell Transplantation Act of 2004

In one of the few bills to move through Congress prior to the November elections, the "Pancreatic Islet Cell Transplantation Act of 2004" was signed into law by President Bush on October 25, 2004. During late September and early October, Congressional committees drafted the legislation, largely under the radar screen, that would allow Organ Procurement Organizations (OPOs) to count pancreata used for islet cell transplantation for certification purposes and provide additional government study on issues relating to islet transplantation. It is assumed that the bill will become law; it would accomplish the following:

- OPO Certification—The bill would allow pancreata procured by an OPO and subsequently used for islet isolation or research to be counted for purposes of certification or recertification.
- Annual Assessment on Pancreatic Islet Cell Transplantation—In conjunction with the annual report of the Diabetes Mellitus Interagency Coordinating Committee, the Committee shall include an assessment of the following issues:
 - The adequacy of Federal funding for taking advantage of scientific opportunities relating to pancreatic islet cell transplantation.
 - Current policies and regulations affecting the supply of pancreata for islet cell transplantation.
 - The effect of xenotransplantation on advancing pancreatic islet cell transplantation.
 - The effect of United Network for Organ Sharing policies regarding pancreas retrieval and islet cell transplantation.
 - The existing mechanisms to collect and coordinate outcomes data from existing islet cell transplantation trials.
 - Implementation of multiagency clinical investigations of pancreatic islet cell transplantation.
 - Recommendations for such legislation and administrative actions as the Committee considers appropriate to increase the supply of pancreata available for islet cell transplantation.

The Diabetes Mellitus Interagency Coordinating Committee facilitates collaboration among agencies that conduct diabetes-related activities. Specifically, DMICC is charged with coordinating the research activities of the National Institutes of Health relating to diabetes mellitus and its complications, managing the related activities of all Federal programs, and contributing to the adequacy and technical soundness of these activities by providing a forum for exchange of information.

The new law will likely afford the opportunity for ASTS to share its views on islet cell transplantation, including issues relating to the reimbursement of pancreata.

Conclusion

ASTS will continue into the 109th Congress to raise the importance of funding the Organ Donation and Recovery Improvement Act. Funding for FY 2006 will be crucial to getting the new authorizations funded for the long term. ASTS will continue to work directly with the AHRQ and HRSA to develop ASTS-led projects endeavors that enhance the science of transplantation and maximize organ recovery. In addition to organ donation law funding, ASTS will also continue to monitor and respond as necessary to emerging health care reform efforts and a possible Medicare Modernization Act reform bill and/or Medicaid restructuring bill.

Regulatory and Reimbursement Update

Over the past several months, ASTS has been involved in several efforts to improve coverage and payment for transplant-related services. These efforts relate to reimbursement for immunosuppressive drugs, dispensing fees for pharmacies that supply immunosuppressive drugs, the new Medicare Part D prescription drug benefit, development of new backbench codes, and hospital reimbursement for pancreatic islet cell transplants.

Medicare Payment for Pancreatic Islet Cell Transplants

The Medicare Prescription Drug, Modernization and Improvement Act of 2003 (MMA) requires the Medicare to cover islet cell transplants for Medicare beneficiaries who participate in certain NIH-sponsored clinical trials

In May 2004, CMS proposed a reimbursement methodology for pancreatic islet cell transplantation that deviated substantially from longstanding Medicare payment policy for transplants and that would have resulted in payment that was significantly below transplant center costs of performing the procedure. Specifically, CMS proposed to establish an "add on" payment for pre-transplant services, islet acquisition, and islet isolation, rather than reimbursing for these services on the basis of the standard cost pass-through methodology generally applicable to solid organ transplants. If adopted, this approach would have established a dangerous precedent that could have threatened the current organ acquisition cost pass-through system over the long term. In addition, CMS proposed DRG assignments for the inpatient costs involved that were inappropriate and that failed to recognize the actual costs involved in islet transplants.

ASTS was successful in preventing CMS from adopting this inappropriate methodology for reimbursing for pancreatic islet cell transplantation. ASTS spearheaded the formation of a coalition of several other stakeholders including AST, AOPO, JDRF, UNOS, Cell Transplant Society, IPITA, The Transplantation Society, NATCO, and ASMHTP. These groups submitted a joint statement to CMS strenuously objecting to the departure from cost pass-through treatment for islet acquisition costs, and requesting CMS to reconsider the proposed DRG assignments for islet transplants.

On August 3, 2004, CMS published the Final Rule, which modified its proposal substantially in response to the views expressed by ASTS and the rest of the transplant community. Specifically, CMS agreed to continue to pay for islet acquisition and pre-transplant services on a cost pass-through basis; under the final rule, the "add-on" payment methodology will be used only for the islet isolation costs.

ASTS remains concerned that the final rule does not appear to allow an add-on payment for islet isolation costs when islets do not meet release criteria. ASTS is also concerned about the final DRG assignments for islet transplants and about CMS circumvention of the established AMA valuation process in determining the level of payment for the physician's services involved in islet transplants, and is continuing to pursue these issues with CMS.

New Backbench Codes

In the fall of 2003, ASTS submitted to the CPT Editorial Panel a request for several new codes to describe backbench procedures performed on donor organs. The new codes, which describe both "standard" back bench work and backbench reconstruction work, were approved by the CPT Panel last February and appear in the 2005 CPT Book. They include new codes to describe backbench services associated with lung, heart/lung, liver, pancreas and kidney transplants. In addition, existing transplant code descriptors have been modified to substitute the language "including cold preservation" for "including preparation and maintenance of allograft," to clarify that these codes do not include backbench work. The new codes will become effective January 1, 2005.

Medicare policy requires that the AMA's Relative Value Update Committee (RUC) develop work and practice expense inputs for all new codes and submit its recommendations to CMS. The RUC, in turn, seeks recommendations from the affected specialty – in this case transplant surgeons. ASTS conducted surveys of the physician work involved for the backbench reconstruction codes and submitted its recommendations to the AMA's Relative Value Update Committee. ASTS did not conduct surveys for the new "standard" backbench codes because it is ASTS' view that those services are reimburseable to the hospital as organ acquisition costs. The RUC approved the ASTS recommendations and forwarded them to CMS.

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CMS adopted the ASTS/AMA recommendations for work values for the new backbench reconstruction codes in the final 2005 Medicare physician fee schedule. With respect to the "standard" backbench codes, CMS has determined that, at least for the time being, these codes should be "carrier-priced"-- each individual Medicare carrier will be responsible for setting its own price for these services. ASTS believes standard backbench should be considered an extension of the organ excision procedure and therefore, that CMS' position is inconsistent with existing government policy which treats organ excision as an organ acquisition cost. ASTS will be communicating with CMS on this issue in an effort to change the current CMS policy.

Payment for Immunosuppressive Drugs

CMS has proposed to bundle payment for OKT3 provided in the hospital outpatient department into payment for other services starting in 2005. Currently, OKT3 is reimbursed separately at a rate of \$792.33. ASTS was successful in convincing CMS to drop its proposal to "bundle" payment for OKT3. Instead, CMS will continue to pay for OKT3 separately. The 2005 payment amount is \$747.31. If CMS had proceeded with its proposed policy, hospitals would have been grossly underpaid for this expensive drug.

Pharmacy Dispensing Fee

The MMA requires that pharmacies that dispense immunosuppressive and certain other drugs be paid a dispensing fee. CMS initially proposed to implement this provision with a dispensing fee of only \$10, which was considerably less than the amount requested by the specialty pharmacy organization in order to cover its costs. ASTS submitted comments to CMS urging it to increase the dispensing fee and expressing concern that if the fee is not adequate, pharmacies may decide not to carry immunosuppressive drugs. CMS has agreed with the position of ASTS and the specialty pharmacies and has increased the pharmacy dispensing fee from \$10 to \$24. In addition, Medicare will pay pharmacies a \$50 dispensing fee for immunosuppressive drugs dispensed during the first month post-transplant.

Implementation of Medicare Prescription Drug Benefit

Model Formulary Guidelines

Under the MMA, the United States Pharmacopeia (USP) is required to develop model formulary guidelines (Model Guidelines) for use by Prescription Drug Plans (PDPs) offering the new Part D prescription drug benefit. In August of this year, the USP issued draft guidelines for public comment. The guidelines consisted of a list of therapeutic categories of drugs and pharmacologic "classes" within those categories. A prescription drug plan (PDP) formulary that includes at least two drugs in each pharmacologic class is deemed to meet the MMA's formulary requirements with respect to non-discrimination.

Significantly, however, the draft Model Guidelines do not require PDPs to provide coverage for *any* transplant-related immunosuppressive medications. As a result, the immunosuppressive drugs needed by transplant recipients enrolled in Medicare Part D (who are ineligible for Part B immunosuppressive coverage) may not be covered under Medicare Part D. ASTS submitted written comments to USP expressing this concern and providing specific recommendations for modifications of the Model Guidelines to address the needs of transplant patients.

It is anticipated that the Model Guidelines will be finalized by the end of the year. However, the USP Guidelines are only recommendations to CMS and can be modified by the agency.

Part D Prescription Drug Benefit

The ASTS is also addressing the availability of immunosuppressive drugs under Medicare Part D through another avenue as well. Also in August of this year, CMS published a proposed rule implementing the new Part D prescription drug benefit. The proposed regulations contain no requirement that PDPs include immunosuppressive drugs on their formularies.

In its comments, ASTS brought this problem to CMS's attention, and set forth a number of recommendations to fill gaps in immunosuppressive coverage and to ensure compliance with immunosuppressive drug coverage requirements by PDPs. ASTS emphasized the need to provide such coverage in order to prevent the costly and medically unnecessary medical care that results from organ rejection, and expressed the view that Part D coverage requirements should mirror the coverage requirements applicable under Medicare Part B. We expect that final rules will be issued sometime next spring.

New DRG Assignment for VAD Procedures

As part of its hospital inpatient prospective payment rule issued in the spring, CMS proposed to move ventricular assist device (VAD) implantations to the DRG for heart transplants (DRG 103). ASTS supported this change because it believed it would result in more equitable reimbursement to hospitals for these costly procedures. However, in its comments to CMS, ASTS cautioned that the DRG reassignment is only appropriate if the VAD procedure takes place in a Medicare-certified heart transplant center and only if it involves a VAD that is approved for use outside the hospital. ASTS expressed concern that the inclusion of VAD procedures performed in hospitals that are not certified transplant centers in the same DRG as heart transplants may result in a gradual decrease in payment for the heart transplant DRG, since hospitals that are not certified transplant centers typically have lower costs and shorter lengths of stay.

In the final rule, CMS reclassified VAD procedures as it had proposed, but did not adopt the limits proposed by ASTS. Although it noted ASTS' concerns, the agency stated that it was unable to restrict use of DRG 103 to procedures performed in Medicare-certified heart transplant centers, since Medicare conditions of coverage do not impose such a limit with respect to the implantation of a VAD as a bridge to transplant.

Transplant Center Regulations

As reported in the last issue of Chimera, Medicare is in the process of developing new conditions of participation for Medicare-certified transplant centers and organ procurement organizations. The CMS proposed regulations were published February 4, 2005. There is a 60-day comment period and ASTS has established a Joint Task Force with the AST to respond and plans to meet with CMS staff to discuss ASTS' position. You can review the proposed regulations at http://www.cms.hhs.gov/cop/.

CMS-3835-P, Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants

CMS-3064-P, Conditions for Coverage for Organ Procurement Organizations

AMERICAN SOCIETY OF TRANSPLANT SURGEONS

STATEMENT ON SOLICITATION OF DONOR ORGANS

JANUARY 20, 2005

Because of recent events surrounding the solicitation of deceased and living donor organs the American Society of Transplant Surgeons (ASTS) stated our position on these and several related issues on November 11, 2004. There has been some misinterpretation of our statement that we wish to clarify. It should be emphasized that our positions on these issues remain the same, but this revised Statement hopefully provides explanations of our meaning and intent.

- 1. The ASTS believes that living and deceased organ donation represent altruistic acts. The ASTS has consistently been strongly opposed to the buying, selling, or brokering of organs for transplantation in agreement with the National Organ Transplant Act (NOTA) which makes it illegal to exchange organs for "valuable consideration".
 - a. The ASTS reaffirms this position.
- 2. The ASTS supports directed donation (living and deceased donor) to family members, friends, and individuals in which there is a relationship through a community such as school, place of worship, other organization or place of employment, or friendships developed through the internet except when solicitation is involved. In the absence of a wait-listed family member or friend, organ donation should proceed according to the standard policies and procedures of the organ procurement organization (OPO) and the allocation policies of the United Network for Organ Sharing (UNOS).
 - a. There has been confusion regarding the use of the terminology "pre-existing emotional relationship". It was never intended to preclude directed donation (living and deceased donor) to friends or individuals sharing a "relationship" through a community such as school, place of worship, other organization or place of employment, except when solicitation or discrimination is involved. We also recognize that legitimate friendships may develop through internet chat rooms and other non-commercial websites. Many transplant centers have transplanted recipients using organs from living unrelated and deceased organ donors under these circumstances in the past and will continue to do so. We believe this is ethically acceptable.
 - b. Although we understand there are issues of donor and donor family autonomy to be considered, we believe that the fairest system for all recipients on the waiting list is for deceased organs to be allocated according to established UNOS policies, and not according to public knowledge of a potential recipient because of newspaper, TV, internet, or radio stories. Ultimately decisions regarding "directed donation" in these situations will need to be made by OPOs and transplant centers. The transplant community should continue to discourage such "directed donation" and educate the public regarding the current allocation policies and their benefits.
- 3. The ASTS supports "Live Donor Paired Exchange" programs where two donor-recipient pairs exchange donors when the donors are related to or have a pre-existing emotional relationship with the intended, but incompatible recipient.
 - a. The discussion in 2a applies here as well.
- 4. The ASTS supports "List Paired Exchange" programs where an ABO-incompatible live donor donates to the waiting list, in accordance with the local OPO and/or institutional guidelines for allocation, and the potential recipient is elevated on the UNOS deceased donor waiting list.
 - a. There are legitimate concerns regarding the impact on O recipients on the list that must be considered.

- 5. The ASTS supports "Good Samaritan" live organ donation when the donation is in accordance with publicly disclosed institutional, regional, and/or OPO standards which preserve equity and justice in allocation to a patient on the waiting list i.e. nondirected donation.
 - a. The ASTS recognizes, however, there are situations where a Good Samaritan donor presents to a transplant center, undergoes evaluation, and when a match run is performed a patient at another center is at the top of the match run. We believe that the center doing the evaluation should be able to select a patient at their center from the match run for transplantation.
- 6. The ASTS is strongly opposed to the solicitation of organs (deceased) or organ donors (live) by recipients or their agents, whether this is through personal or commercial websites, billboards, media outlets or other forms of advertising when the intent of such solicitation is to redirect the donation to a specific individual rather than according to the fair policies of allocation (UNOS policy on organ allocation) which all members on the waiting list abide by. We believe that such solicitation and directed donation will undermine the trust and fairness on which the system of organ transplantation depends. Society, in particular potential recipients and their families, must believe that the current organ allocation system is protected from discriminatory practices that will disadvantage certain classes of individuals.

The ASTS recommends that its membership not participate in transplants in which solicitation has occurred. Participation in directed donation may take place when there is a relationship between the donor and recipient through a community such as school, place of worship, other organization or place of employment, or the donation is offered to the next person on the appropriate waiting list. Furthermore, the ASTS believes that a transplant surgeon should not be compelled to participate in a transplant that he or she believes is ethically improper.

New Backbench Codes - Effective Jan. 1, 2005

The ASTS, under the direction of Dr. Mike Abecassis, was successful in obtaining new backbench codes for transplant surgery. These codes were issued by CMS and are published in the 2005 Medicare Fee Schedule. Please consult the ASTS Website at www.asts.org for information on how to effectively utilize these new transplant billing codes.

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American Society of Transplant Surgeons

Position Paper on Live Vascular Grafts

Richard B. Freeman, M.D., John Roberts, M.D. January 2005

ive vascular grafts procured from deceased donors have been an integral part of human transplantation^{1,2,3} for more than 25 years. In addition, live vascular allografts have been used often for recipients of liver^{4,5}, pancreas⁶ and kidney⁷ transplants to reconstruct damaged, diseased or surgically unsuitable donor or recipient vessels. Both fresh and preserved vessels from 3rd party donors have been used in the cited cases. Because many lives and organs have been saved in cases where no other suitable vascular reconstruction would have been possible, this routine practice should be considered potentially life saving for the transplant recipient. For many years it has been standard practice to procure vessels at the time of organ retrieval for use in reconstructing vascular inflow and outflow for solid organ transplant grafts. These live vessels are used in the original recipient or subsequently in combination of another donor's organs in another recipient.

Recently, the first case of Rabies transmission from donor to recipient was reported to have occurred via a vascular graft procured from a donor infected with rabies . This incident has focused attention on the practice and storage of these vascular grafts and how this practice should be monitored and overseen. All recipients of organs and grafts from this particular donor contracted rabies. We wish to point out that the failure to identify the infection in the donor of these grafts was the root cause for the transmission of this disease to the recipients, *not* a failure of the vascular allograft storage or handling procedures at the transplant center. The ASTS is firmly committed to working to prevent inadvertent transmission of any infection from donor to recipient. However, increased regulation of vascular allograft storage and use conditions will not prevent this type of system failure. In the absence of solid data indicating that storage of these allografts per se poses increased risks for recipients, we urge caution in proposing new regulations of this well-established and highly successful practice.

The ASTS strongly supports improved tracking of these important vascular grafts so that donor conditions can be effectively communicated when new clinical data becomes available after the time of donor procurement procedure. This heretofore unreported event (transmission of rabies) that has driven the recent examination of these policies could potentially have been managed differently if such tracking mechanisms had been in place. However, the ASTS also wishes to emphasize that restricting the current practice of routine preservation, storage, and use of these life-saving vessels will potentially jeopardize the lives of many recipients, negatively affect utilization rates of donor organs, and adversely impact transplantation results.

The Organ Procurement and Transplantation Network (OPTN), which has responsibility for developing policies for organ donation and transplantation in the US, recently addressed this issue. At the November, 2004 OPTN Board Meeting, the following policy proposal resolution was approved:

- ** RESOLVED, that Policy 5.8 "Vessel Recovery, Storage, and Transplant" as set forth below is hereby approved for public comment.
- 5.0 Standardized Packaging and Transporting of Organs, Vessels, and Tissue Typing Materials No changes to Policies 5.1-5.7.3
- 5.8 Vessel Recovery, Storage, and Transplant

- 5.8.1 The practice of vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant) should not be disrupted.
- 5.8.2 The sanction for vessel recovery and storage for use in a subsequent solid organ transplant from a different donor must be sustained: (for example when the vessels and the liver pancreas allograft are being transplanted from different donors with different UNOS ID numbers). The vessels cannot be used in non-transplant recipients.
- 5.8.3 If the vessels are stored and subsequently used for the intended recipient or another transplant recipient, the Organ Procurement Organization and the Organ Procurement Transplant Network must be notified.
- 5.8.4 The consent forms used by the recovering Organ Procurement Organization must include language that indicates that vessels will be used for transplant.
- 5.8.5 If the vessels are being stored, the procedure of packaging, labeling, storage, the medium and temperature, the location, and the duration of storage must be addressed by the organ transplant community using the following standards.
- 5.8.5.1 The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial, HTK, or others).
- 5.8.5.2. The vessels must be stored in a sealed container labeled with the UNOS Donor ID Number for tracking.
- 5.8.5.3 The vessels must be stored in a secured refrigerator at 4 degrees.
- 5.8.5.4 The vessels can be stored up to a maximum of 7 days.
- 5.8.5.5 The vessels do not have to be cultured.
- 5.8.5.6 There must be daily monitoring of the vessels with documented security and temperature checks
- 5.8.5.7 A log of stored vessels must be maintained by the transplant center at the point of storage.

The American Society of Transplant Surgeons fully supports the intent of this policy, but would like to make the following comments:

Many ASTS members indicate that they routinely store these vascular grafts for longer than seven days and have used them successfully. As indicated above, there is a paucity of data in the literature on this subject. In one published report, live vascular allografts were used for reconstruction of failing kidney allografts after being stored for as long as 10 days with good graft results and without significant infectious risk⁷. In another recent, unpublished study, to be presented at the upcoming American Transplant Congress meeting, 59 live vascular allografts were placed in recipients within 7 days of procurement and 27 placed more than 14 days after the initial transplant. There was no difference in liver allograft survival and no evidence of increased infectious transmission . The ASTS feels that current practice and the available evidence suggests that there is no data documenting what limits are reasonable for storage time for these live vascular grafts. We feel the 7-day limit proposed in this policy is too short and that item 5.8.5.4 should be modified to read:

5.8.5.4 The vessels should be stored up to a maximum of 7-14 days, but clinical judgment is required, as there is no data defining the safe limits of live vascular graft storage.

The policy language is somewhat confusing. The ASTS would also suggest the following changes to make it more clearly understood:

5.8.2 The vessels may be transplanted with an organ from another donor (for example, when the vessels and the liver pancreas allograft are being transplanted from different donors with different UNOS ID numbers). The vessels cannot be used in non-transplant recipients.

5.8.5 The procedure of packaging, labeling, storage, the medium and temperature, the location, and the duration of storage must be addressed by the organ transplant community using the following standards.

5.8.5.2. The vessels must be stored in a sealed sterile container labeled with the UNOS Donor ID Number for tracking.

In relationship to 5.8.3, the ASTS suggest that the notification and tracking process be managed via UNET as an extension of the current processes to track the organs.

5.8.3 If the vessels are stored and subsequently used for the intended recipient or another transplant recipient, the Organ Procurement Organization and the Organ Procurement Transplant Network must be notified.

The ASTS welcomes the opportunity to provide comment on this issue. Our Society represents that vast majority of transplant surgeons performing transplant procedures in the US. Our membership has the most direct experience and knowledge about the use of these vascular grafts and we are grateful to be able to supply the community with our input. (See paper online at www.asts.org for list of citations.)

ASTS Resources Are Always Available on the WEBSITE

Check out the ASTS Website at

www.asts.org

for updated information on ASTS activities and position statements.



FELLOWSHIP MATCH

The inaugural Abdominal Transplant Surgery Fellowship Match is taking place this summer for positions matriculating in 2006. ASTS accredited abdominal transplant fellowship programs must participate in the Match as a condition of accreditation.

The American Society of Transplant Surgeons (ASTS) is the sponsoring organization for the Abdominal Transplant Surgery Fellowships and has requested that the National Resident Matching Program (NRMP) conduct a Match for this subspecialty. The NRMP site has detailed information at *www.nrmp.org*, click on Fellowship Matches at the top, click on Participating Fellowships on the left, and finally click on Abdominal Transplant Surgery Fellowship.

Abdominal Transplant Surgery Fellowship Schedule for Match Conducted in 2005 Appointment Year 2006

April 27, 2005 - Registration Opens at 12:00 p.m. EST June 29, 2005 - Rank Order List Opens at 12:00 p.m. EST August 3, 2005 - Rank Order List Closes at 9:00 p.m. EST August 17, 2005 - Match Day

The application process is independent from the Match and unique to individual institutions. Transplant Fellowship Programs should continue using their individual application and interview process to evaluate potential transplant fellowship candidates for their program. However, applicants should be informed about the Match and advised that they need to register for the Match on the NRMP site at www.nrmp.org and submit a rank order list to be matched with a transplant fellowship program.

Please consult the ASTS website at *www.asts.org* or contact the ASTS office at 703-684-5990 if you have any questions or would like additional information.

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Expert Witness Policy

The ASTS supports the American College of Surgeons Expert Witness Policy (see accompanying letter on next page) and encourages all ASTS members to sign the ACS Expert Witness Affirmation when testifying and give it to the attorney representing that party on whose behalf you are testifying. The form can be downloaded from the ASTS website at www.asts.org as well as the ACS website.

American College of Surgeons

Expert Witness Affirmation

As a member of the medical profession and the American College of Surgeons, I affirm my duty, when giving evidence or testifying as an expert witness, to do so solely in accordance with the merits of the case. Furthermore, I declare that I will uphold the following professional principles in providing expert evidence or expert witness testimony.

- 1. I will always be truthful.
- I will conduct a thorough, fair, and impartial review of the facts and medical care provided, not excluding any relevant information.
- I will provide evidence or testify only in matters in which I have relevant clinical experience and knowledge in the areas of medicine that are the subject of the proceeding.
- I will evaluate the medical care provided in light of generally accepted standards, neither condemning performance that falls within generally accepted practice standards nor endorsing or condoning performance that falls below these standards.
- I will evaluate the medical care provided in light of the generally accepted standards that prevailed at the time of the occurrence.
- I will provide evidence or testimony that is complete, objective, scientifically based, and helpful to a just resolution of the proceeding.
- I will make a clear distinction between a departure from accepted practice standards and an untoward outcome.
- I will make every effort to determine whether there is a causal relationship between the alleged substandard practice and the medical outcome.
- I will submit my testimony to peer review, if requested by a professional organization to which I belong.
- I will not accept compensation that is contingent upon the outcome of the litigation.

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Date Certified	Date Recertified



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April 2004

Dear Colleague,

Fellows of the American College of Surgeons serve as expert witnesses on behalf of both plaintiffs and defendants in medical liability cases, By providing testimony that is fair and accurate, the expert witness can contribute to a just outcome and improve the quality of surgical care.

The College has developed the enclosed Expert Witness Affirmation, a document that declares the witness will uphold certain professional principles in providing expert evidence or expert witness testimony. The affirmation is consistent with the College's "Statement on the Physician Acting as an Expert Witness" and is intended for voluntary use by Fellows who wish to make explicit their commitment to knowledgeable and ethical expert witness testimony.

Those Fellows who testify may sign the affirmation and give it to the attorney representing the party on whose behalf they intend to testify. During litigation, the document can be used to examine the witness and enhance the qualifications of those who have signed it. Conversely, witnesses who chose not to sign the affirmation can be cross-examined about their failure to do so. Such affirmations have proven useful to members of other organizations that have similar statements and may assist in the promulgation of credible and appropriate expert testimony.

Sincerely,

Thomas R. Russell, MD, FACS

Executive Director

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ASTS 2005 Winter Symposium

"The Science and Art of Immunosuppression"

STS held its 5th Annual State of the Art Winter Symposium on January 21-23, 2005 at the Eden Roc Resort & Spa in Miami Beach, Florida. Over 270 registrants participated in the symposium in addition to over 180 registrants from NATCO who held its 2005 Transplant Institute in conjunction with the ASTS Winter Symposium.

The symposium on "The Science and Art of Immunosuppression" was arranged by the ASTS planning committee: Elizabeth Pomfret (Chair), Sandy Feng, Douglas Hale, Stuart Knechtle, John Magee, and Michael Mulligan. Abstracts were reviewed by Niraj Desai, Seth Karp, Paul Morrissey, Jim Pomposelli, Andrew Posselt, and Mary Ann Simpson.

The Eden Roc Resort & Spa is one of America's top 15 hotel spas. The hotel has two outdoor pools and is located on the beach. Meeting participants enjoyed dinners outside and walks along the boardwalk.

A webcast with CME credits is available on the ASTS website at www.asts.org. A summary report of the meeting is being submitted to the American Journal of Transplantation for publication.

ASTS

would like to THANK the following sponsors of the 2005 Winter Symposium:

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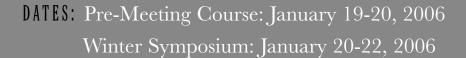




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INFORMATION & REGISTRATION: www.asts.org

Abstracts will be accepted.



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5116

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The United Network for Organ Sharing (UNOS) seeks a DIRECTOR OF MEDICAL AFFAIRS/RESEARCH to join the staff at the UNOS headquarters offices in Richmond, VA. Candidates must have an M.D. degree and clinical expertise in transplantation. Responsibilities include provision of clinical perspectives to the staff in the planning and conduct of Organ Procurement and Transplantation Network (OPTN) contract-related operations, including participation in OPTN policy development, policy compliance, professional and lay education, and analytical activities. The Director will also assist UNOS staff and their collaborators with the development of research projects, grant proposals, and peer-reviewed publications as part of UNOS corporate activities. The person in this position will directly oversee a department of 20 biostatisticians and SAS analysts and will work with other senior staff throughout the organization. The successful candidate will have demonstrated leadership abilities and an interest in team work. A full position description is available at www.unos.org. UNOS is located in the Virginia Research Biotechnology Park in Richmond, VA, located 90 miles south of Washington, D.C. The Richmond area is economically strong, with safe neighborhoods, good public schools, 2 major universities, 3 transplant centers, plus many recreational and cultural activities. Salary will be commensurate with experience. The starting date is negotiable, however, UNOS would like to fill the position by fall 2005. Applications should include curriculum vitae, bibliography, and the names of at least 4 individuals from whom letters of reference may be solicited. Please submit applications to: employment@unos.org or Human Resources, UNOS, P. O. Box 2484, Richmond, VA 23218. Minorities encouraged to apply. EOE

CLINICAL INSTRUCTOR ABDOMINAL TRANSPLANTATION The Dept of Surgery of UNC-CH is seeking a fultime faculty member in the Division of Abdominal Transplantation. Fixed-term appointment will be at the rank of Clinical Instructor. The applicant must have a minimum of an RN/BSN, preferably MSN or MPH. This position requires extensive training and experience in clinical research trials. A minimum of 5 years experience in human subjects' research and clinical trials and/or epidemiology in an academic research environment is preferred; emphasis will be given to those individuals with prior solid organ transplantation research experience and demonstrated knowledge of federal regulations and local policies that provide research oversight, including Federal Code of Regulations and UNC-Chapel Hill's standard operating procedures. The position requires a strong commitment to clinical research. Interested applicants should forward curriculum vitae to: Dr. Kenneth Andreoni, Division of Abdominal Transplantation, Dept. of Surgery, UNC-CH, CB# 7211, Chapel Hill, NC 27599. Email to: krao@med.unc.edu.

OCHSNER CLINIC FOUNDATION SECTION OF ABDOMINAL TRANSPLANTATION is seeking a BC/BE Abdominal Transplant Surgeon who has completed an ASTS-approved transplant fellowship. The candidate will be joining a busy group of 3 surgeons performing 100 liver transplants and 70 kidney transplants along with laporoscopic donor nephrectomies, living-related liver transplants and pancreas transplants. Ochsner Clinic Foundation is a fully integrated health care delivery system with a 78bed acute care hospital, employing over 600 physicians in over 80 specialties and sub-specialties. A competitive salary and benefits package will be offered to selected applicant. We enjoy the advantage of practicing in a favorable malpractice environment in Louisiana. Interested physicians should send curriculum vitae to address below. CVs will be reviewed by Dr. James D. Eason, Section Head of Abdominal Transplantation. Please send CV to: Ochsner Clinic Foundation, Ref. #AABT4,Professional Recruiting Department, 1514 Jefferson Highway, New Orleans, LA 70121, Information (800) 488-2240, Fax (225) 761-5441, E-mail: profrecruiting@ochsner.org

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INCOMPATIBLE KIDNEY TRANSPLANT (CLINICAL) FELLOW The Johns Hopkins University, School of Medicine is seeking a board eligible general surgeon or urologist to join the Division of Transplantation for one year of dedicated fellowship training in incompatible kidney transplantation. This is an extremely active and innovative renal transplant program, with protocol driven-care of a large population of highly-sensitized, crossmatch positive, and ABO incompatible recipients and live donor pairs. Focus will be given to desensitization paradigms including experience with plasmapheresis, IVIg, anti-CD20 treatment, splenectomy, paired kidney exchange protocols, advanced histocompatibility and pathology techniques, and novel experimental regimens. High volume surgical experience will be provided in renal transplantation including complex redo live donor kidney transplants, laparoscopic donor nephrectomy and splenectomy, and cadaveric renal transplantation. It is expected that at the completion of this fellowship the surgeon will be able to organize and run an incompatible kidney transplant program. Significant research opportunities are also obtainable through extensive databases maintained by the Johns Hopkins Incompatible Kidney Transplant Program and basic science research in B-cell tolerance and accommodation. Applicants must be committed to providing transplant patient care as a member of a cohesive, multi-disciplinary team of nephrologists, coordinators, nurse practitioners, administration, and support staff. Prior training in solid organ transplantation is optional. Interested applicants may obtain more information by submitting a letter of interest and curriculum vitae to: Robert A. Montgomery, MD, PhD, Chief, Division of Transplantation, Director, The Johns Hopkins, Comprehensive Transplant Center, The Johns Hopkins University School of Medicine , 720 Rutland Ave., Ross 765, Baltimore, MD 21205, breeb@jhmi.edu.

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