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Dear Friends,

I have recently been asked whether the ASTS is an exclusive society. Admittedly, living in a country in which freedom and equal opportunities are of highly valued, exclusiveness may be an anti-thesis to how we should present ourselves to the outside world. Yet, we do hold high (and maybe exclusive) standards for our members, which is a mere reflection of the efforts of the ASTS to provide the best possible care from professionals who know well the field of Transplantation Surgery.

Our society values high standards and wishes to advance an agenda that will lead to better transplant outcomes, provide outstanding opportunities for continuing surgical education, and participate in research endeavors that translate to better care of our patients. These issues were addressed in our yearly strategic meeting, in which we discussed the means by which the ASTS can work with various government agencies and UNOS in order to present an accurate assessment of what should be considered the standard criteria for accreditation of transplant programs and transplant surgeons. The ASTS Council believes that input from our membership is essential in order to avoid the implementation of unrealistic and inappropriate regulations, all of which may restrict our ability to provide the best care for our patients. Members of the Council and the Chair of the Standards for Organ Transplantation Committee will initiate a discussion with the membership, with the attempts to further define what is considered fair and acceptable standards for surgeons and transplant programs and yet maintain a high level of quality and safety for our patients. The recommendations from ASTS members will become available to any regulatory body which wishes to consult our Society and/or coordinate the implementation of such standards in the transplant community.

The potential for the ASTS to have an impact on these issues is clearly dependent on the ability to have access to members of Congress and other government departments, such as CMS, HRSA, and various House and Senate committees, all of which are involved in and responsible for implementation of these regulations. To approach these bodies, the ASTS has established efforts in Washington resulting in continuous transfer of necessary data and information to members of Congress, testifying in various committees, and submission of our opinions and recommendations. These are efforts that have been successful, work well for the transplant community, and have had a positive impact on our profession. Standards for programs and transplant surgeons is one of the more recent topics that is constantly under re-examination. Examples of other important issues are as diverse as Donor incentives, Medicare payment for immunosuppressive medications, and appropriate reimbursement for transplant procedures.

It is obvious that the ASTS must set up short and long term priorities for our political agenda, and we welcome your involvement and suggestions. Your concerns about these issues must be heard and I encourage you to keep an open and direct line of communication with me, or any other Council representative. Your input will be important, specifically in any future survey that you may receive regarding topics such as program requirements and surgical standards. It is our responsibility to clearly represent ALL our membership concerns, and we are committed to adhering to this important principle.

Just as reminder, please make all efforts to attend the upcoming 4th Annual ASTS Winter Symposium. This forum is becoming an important platform for presentations focusing on surgical topics, and is geared toward the need of the young and less established members of our Society, with expert input from the seasoned “elders”. The upcoming conference “Surgical Challenges in Transplantation” will be in Scottsdale, Arizona, on January 23-25, 2004.

Best Regards,

Abraham Shaked, MD, PhD
President
The ASTS Council met on September 23-24, 2003 in New York, New York. The following are committee reports presented at this meeting:

**Awards Committee Report:**

Thomas Peters reported that the short-term goals of the committee are looking at better communication with awardees and information about the career outcomes of the awardees. ASTS will post the list of past awardees on the website of the Society.

**Education Committee Report:**

Mitchell Henry requested and the Council approved the following recommendations of the Education Committee of the following accreditation applications: The University of Alberta at Edmonton for training of one fellow every two years in liver transplantation; Tufts New England Medical Center for training one fellow every two years in kidney and liver transplantation and for renewal application to approve Stanford University’s reaccreditation for kidney and liver programs.

**Membership Committee:**

David Mulligan reported that ASTS currently has 939 Members and eight pending applications.

**Scientific Studies Committee Report:**

Giacomo Basadona reported via written report that the committee has met several times on the phone during last year and in person during the most recent ATC meeting. One of its major initiatives is the research web page, a concept developed by some of the most junior members of the committee. Its goal is to foster collaborations among the Members of the Society in the field of clinical and basic research. Members are encouraged to post their research projects on the “research web page” when looking for possible collaborators and/or ideas on how to get the project started and eventually funded. To access the site go to www.asts.org and click into the Members Only section.

**Thoracic Organ Transplantation Committee Report:**

Mark Barr and Joren Madsen report that the Committee will be working with the STS once again this year on the 4th Annual joint ASTS/STS Symposium at the Society of Thoracic Surgeons meeting in San Antonio in January 2004. Topics and speakers will be: Current Strategies for the Optimal Utilization of Cardiac Assist Devices (Robert Kormos); Technical Considerations in Lung Transplantation (G. Alexander Patterson); and Immunosuppression in the 21st Century (James S. Allen). The session is anticipated to have 200 attendees, at least 50% of who should be surgical trainees. The Committee is also working to create a set of descriptions for “backbench” surgery in heart and lung transplantation, parallel to the efforts that have been made in abdominal transplantation by Mike Abecassis and the ASTS Reimbursement Ad Hoc Committee.
Vanguard Committee Report:

Sandy Feng reported about the 4th Annual ASTS State-of-the-Art Winter Symposium and the program prepared by the planning committee. She noted that there would be a two day pre-meeting course on fundamentals of clinical research transplantation. She next reported that the database project was moving along and that the first phase, which was designing and implementation of electronic membership application to enable easy transfer of demographic and research activities has been completed. They are currently working to create a mechanism to enable preexisting Members to update their profiles and the final phase will be an ASTS Pubmed search capability.

ASTS Foundation Report:

The Board of the ASTS Foundation met on September 24, 2003 in New York City. The Board voted upon and approved the mission statement of the Foundation which is: The American Society of Transplant Surgeons Foundation will advance the field of Transplantation by supporting the mission and activities of the American Society of Transplant Surgeons. The mission of the ASTS Foundation is to serve as the endowment vehicle of the ASTS. Funds generated will be used to provide support for ASTS sponsored initiatives such as education, fellowships and other training, and research.
Major legislation affecting transplantation continues to move forward as the first session of the 108th Congress approaches. Major structural reform of the Medicare program, including a new prescription drug benefit and a physician fee schedule update as well as organ donation legislation and appropriations for key federal transplant programs are all on the table this fall. Meanwhile, structural reform of the Medicaid program appears to be sidelined until next year along with medical malpractice reform legislation, which appeared to be dead in the water until President Bush renewed his call for a reform bill.

If Congress fails to act on Medicare reform this year—its current prospects being no more than 50/50—it is unlikely that the myriad reforms contained in the bill, including reform of the physician fee schedule, will be enacted into law. Furthermore, ASTS is actively involved with securing passage of organ donation legislation this year but time for passage of such a bill is getting short.

Medicare Reform and Prescription Drug Update

As reported in the summer issue of Chimera, Congress was swiftly moving toward passage of a comprehensive Medicare reform and prescription drug bill in June. In the last week of June, both the House and Senate passed competing Medicare bills that would reform Medicare in perhaps the most significant reform of the program since its inception in 1965. Both bills rely heavily upon private, managed care models for the provision of new Medicare plans and a prescription drug benefit. The House bill contains a controversial provision to begin Federal Employee Health Benefit Plan-style competition in 2010. Both bills would also reform many reimbursement formulas in traditional fee-for-service Medicare including reform of the physician fee schedule.

Following passage of the bills in June, both houses appointed Conference Committee members and set to work reconciling the vastly different approaches to Medicare reform and prescription drug coverage taken by the House and Senate. Despite the good intentions of conferees, little progress was made in late July or during the August Congressional recess with both parties posturing for advantage during the fall, when major action is expected. As of mid-September, the conferees have reached tentative agreements on several non-controversial elements of the Medicare bills: Medicare regulatory reform (which ASTS has long supported), a prescription drug discount card to provide some financial assistance until implementation of the drug benefit in 2006,
and a limited number of provider payment adjustments, including several provisions of interest to ASTS (see below).

Despite internal political difficulties among Republican conference leaders over how to resolve rural provider payment issues and the scope of managed care involvement in the Medicare program, President Bush and Senate Majority Leader Bill Frist (R-TN) have both expressed their confidence in Congress passing a Medicare bill before the end of the year. Frist stated that problems should be expected in the process to reach an agreement because of the complexity of the legislation. Optimism among House Republicans appears to be limited, though, as most House Republicans are insistent on strong private sector involvement in new Medicare plans.

GOP Medicare conferees have yet to decide whether negotiators or President Bush should set a firm deadline to finish work on a final Medicare bill but if one were selected, it would be no later than November 11, 2003. Finance Chairman Grassley has been encouraging conferees to adopt a deadline of Columbus Day, October 13. Frist stated that he “would like to see [a final bill] by the end of September.” However, many health care observers caution this deadline as highly unrealistic with actual negotiations likely extending late into the fall if a compromise appears possible.

Although the full conference committee has formally adopted staff-led compromises on the regulatory reform, drug discount card, and provider provisions, these provisions are what many describe as “low hanging fruit.” Among the issues still far from compromise are as follows:

**Prescription Drug Benefit**—Both the House and Senate bills call for drug benefits to be delivered either through private “drug-only” insurance plans, or as part of more comprehensive coverage by a “preferred provider organization,” HMO, or other private plan. The Senate bill calls for an annual deductible of $275, after which the plan would pay half (50 percent coinsurance) of the next $4,225 worth of drugs. After that, beneficiaries would have to pay all their own bills unless they reach $3,700 in out-of-pocket spending, after which the plan would pay 90 percent of remaining drug costs for the year.

The House bill calls for an annual deductible of $250, after which the plan would pay 80 percent of the next $1,750 worth of drugs. After beneficiaries spend $3,500 out-of-pocket, the plan would pick up 100 percent of drug costs for the rest of the year.

Both plans include special help for beneficiaries with low incomes and the out-of-pocket threshold for “catastrophic” coverage in the House bill varies for those with more than $60,000 in annual income.

**Premium Support**—The House bill, but not the Senate bill, calls for competition, beginning in the year 2010, between private health plans and Medicare’s traditional fee-for-service plan in areas where at least two private plans are offered.

This is perhaps the most significant difference between the bills that could slow the conference. Republicans maintain the provision will hold down Medicare costs, while Democrats believe it would effectively “privatize” the Medicare program and cause Part B premiums to be higher for beneficiaries who remain in traditional Medicare, who would more likely be those with complex, chronic, or expensive conditions. If conferees are able to reach a compromise on this issue early in the process, it would create a great deal of momentum to work out other controversial provisions.

**Federal Fallback**—The Senate bill, but not the House bill, calls for the federal government to provide a Medicare drug benefit in regions where fewer than two private “drug-only” plans are
ASTS will also continue to be engaged in the debate over organ donation legislation and will continue to work with key staff and Senators on passage of legislation this year.

offered. House Republicans are vehemently opposed to such a “fallback” because it would effectively create a federal drug plan that would have to set prices for covered pharmaceuticals. However, the lack of a fallback could prove to be a “poison pill” for Senate Democrats who supported the original bill.

Health Savings Accounts—The House bill incorporates the “Health Savings and Affordability Act,” which would authorize creation of two types of tax-preferred savings accounts. “Health Savings Accounts,” similar to Medical Savings Accounts, would be available to those covered by health plans with deductibles of at least $1,000 for individuals and $2,000 for families. “Health Savings Security Accounts” would be available to those with plans with lower deductibles; $500 for individuals and $1,000 for families. Money in both accounts would accrue tax free, and could be used for “qualified medical expenses” including medical treatment, prescription drugs, and long-term care services or insurance premiums. Democrats will oppose the inclusion of these non-Medicare provisions in the Medicare bill because these accounts, in their view, tend to appeal to healthier and younger people, thereby raising insurance costs on sicker and older populations. The biggest stumbling block for Republicans is the $174 billion price tag attached by the Congressional Budget Office.

Immunosuppressive Drug Coverage

Neither the Senate and House Medicare bills include a provision relating to coverage of immunosuppressive drugs in Part B of Medicare. Under both bills, immunosuppressive coverage would continue under Part B unchanged. Beneficiaries not qualifying for immunosuppressive coverage under Part B could receive coverage through the proposed privately-administered drug benefit, enhanced fee-for-service option, through a Medicare Advantage plan, or, beginning in 2010 under the House bill, a Medicare FEHBP-style plan. Under all of the proposed drug coverage options, issues relating to therapeutic classification, formularies, and tiered copayments could complicate the ability for patients seeking a specific immunosuppressive drug therapy to receive the appropriate course of treatment.

Although this initiative was spearheaded by the National Kidney Foundation, ASTS has been actively involved in speaking with members of the House and Senate regarding inclusion of this immunosuppressive drug provision in the Medicare bill. However, the chances for inclusion are very slim at this point. The general feeling among members of both committees is that coverage should be obtained under the proposed drug benefit, not by increasing coverage under Medicare Part B.

Payment Methodology

Demonstration for Surgical First Assisting Services of Certified Registered Nurse First Assistants Included in Medicare Bill

A demonstration project regarding the Medicare coverage of Surgical First Assisting Services of Certified Registered Nurse First Assistants (CRNFA) was included in the Senate-passed Medicare bill and was adopted officially by conferees on September 9. It should be noted, though, that this provision, along with the provision on pancreatic islet transplantation described below, is part of the larger Medicare bill and will not become law unless the full reform bill is enacted.

Under the demonstration, Health and Human Services (HHS) would establish a new payment methodology for surgical first assisting services furnished by a CRNFA to Medicare beneficiaries. Under the language, a CRNFA is defined as a registered nurse
who is 1) licensed to practice nursing in the State in which the surgical first
assisting services are performed; 2) has completed a minimum of 2,000
hours of first assisting a physician with surgery and related preoperative,
intra-operative, and postoperative care; and 3) is certified as a registered
nurse first assistant by an accreditation body recognized by the Secretary
of HHS. The demonstration would occur over a three-year period in five
states. The locations would be determined by the Secretary.

The new payment methodology under the demonstration project
would be the lesser of either 1) 80 percent of the lesser of the actual
charge for the services; or 2) 85 per-
cent of the amount determined under
the physician fee schedule as if fur-
nished by a physician.

Medicare Pancreatic Islet
Transplantation Demonstration
Included in Medicare Bill

Also adopted by the conferees on
September 9 was a provision establish-
ing a Medicare Pancreatic Islet Cell
Transplant Demonstration Project. The Secretary of HHS would establish
a demonstration project to test the appropriateness of pancreatic islet cell
transplantation in the case of Medicare beneficiaries with Type I diabetes and
end stage renal disease. The testing
would be conducted over five years.
Under the demonstration, the Secretary will submit a report including legisla-
tive and administrative recom-
mendations to Congress no later than
120 days after termination of the
project. The Secretary will also create a
payment methodology that, if possible,
bundles payments for all items and ser-
vice used throughout the project.

Physician Fee Schedule Update

The Centers for Medicare & Medicaid
Services (CMS) published a proposed
rule on August 15, 2003, that will
update payment rates under the
Medicare physician fee schedule for
2004, as well as revise a number of
other policies affecting Medicare Part
B payments under the fee schedule.
The rule proposes to cut physician
payments by 4.2 percent in 2004, but
that number could change as provi-
sions contained in the Medicare
reform legislation seek to reduce or
eliminate the cut.

The House bill would increase
Medicare provider payments at least
1.5 percent per year in 2004 and 2005
(over 2003 levels) and permanently
correct the sustainable growth rate
(SGR) formula, which is viewed by
many as a flawed method of updating
physician payments. The Senate bill,
despite expressing the “sense of the
Senate” that the payment formula is flawed and that physician payments
should be increased, does not change the current law directly. Rather, the
Senate contains “placeholder” lan-
guage to allow a conference on the
issue with House leaders.

The current physician fee schedule
is updated on an annual basis accord-
ing to the SGR formula specified by
statute, which is designed to rein-in
the growth in outlays for physician
services. The government lowers
Medicare payments when the amount
spent on provider services exceeds the
SGR. The SGR in turn is calculated
based on medical inflation, the pro-
jected growth in the domestic econo-
my, the projected growth in the num-
ber of beneficiaries in fee-for-service
Medicare, and changes in law or regu-
lation. Largely due to slow growth in
the economy and to a significant
growth in physician outlays in 2002,
CMS advised the Medicare Payment
Advisory Commission (MedPAC) in
March that the “update” for 2004
would be (-4.2) percent. If Congress
does not finish work on Medicare
reform before January 1, 2004, and
include provisions similar to the House
bill, the 4.2 percent cut will take effect
on the first day of the new year.

Action Expected this Year on Organ
Donation Legislation

Major organ donation legislation, for
which ASTS and other transplant
groups have been advocating, has
passed the House, been introduced in
the Senate, and is expected to see
action later this year. A version of the
legislation passed the House of
Representatives on March 12, 2003,
by a vote of 425-3. The Senate bill, S.
573, which was introduced by Senate
Majority Leader Bill Frist (R-TN) on
March 6, 2003, is beginning to gain
support in the Senate for action this
year. ASTS has sent letters of support
to both House and Senate sponsors
and has met with staff from Senator
Frist’s office and the Chairman of the
Health, Education, Labor, and
Pensions Committee, Judd Gregg (R-
NH), to share our support and con-
cerns on the pending legislation.

In discussions with key Senate
staff, ASTS has received a commit-
ment for consideration of major organ
donation legislation this year. Gener-
ally, the Frist bill, S. 573, repre-
sents the “consensus” of many mem-
ers with interests in organ donation.
ASTS is actively involved with staff
members from the House and Senate
on achieving a comprehensive organ
donation bill.

Medicaid “Dual Eligible” State Relief
in Medicare Bill; Structural Medicaid
Reform Debate Expected Next Year

In the 108th Congress, major efforts
to reform the Medicaid program are
underway. The inclusion of $20 billion
over two years in state fiscal relief in
the tax legislation enacted in early June
The National Governors Association has expressed bipartisan Medicaid reform plan earlier this year. The NGA has expressed interest in revisiting the issue next year. Both House and Senate Medicaid bills would reform the way the federal government reimburses states for costs associated with approximately 6.2 million “dually eligible” beneficiaries (enrolled in both Medicare and Medicaid). The NGA and other health care advocacy groups are supportive of the federal government assuming the high costs of these beneficiaries since under current law Medicaid pays for their prescription drug benefits.

The Senate Medicaid provision would provide approximately $17.5 billion over 10 years to states to help defray the costs associated with providing drug benefits to dual eligible beneficiaries. Under this provision, the federal government, not the states, would pay for Medicare Part B premiums for certain low-income seniors or persons with disabilities and would establish 100 percent matching for Medicare Part A deductibles and coinsurance for other certain low-income beneficiaries. However, because states often have differing eligibility levels for the categories covered in the legislation, the amount of fiscal assistance to each state is predicated on many state-specific details.

The House provision covers Medicaid costs that states pay for prescription drugs, but does not relieve states of non-drug Medicaid expenditures like the Senate bill. However, this approach is predicated on a steadily increasing federal match increasing up to 100% for all drug costs by 2020. The increasing match, which phases in slowly over 16 years, reduces the CBO score and immediate relief to states. The National Governors Association has endorsed the House provision as have many other major advocacy organizations. The Bush Administration has endorsed the Senate approach due to its lower cost.

**ASTS Submits Testimony to Appropriations Subcommittee on FY 2004 Priorities; House and Senate Move Forward with Appropriations Process**

ASTS submitted written testimony to the House and Senate Appropriations Subcommittees on Labor, HHS, and Education on fiscal year 2004 federal spending levels during the spring of 2003. ASTS focused on funding increases for the Division of Transplantation within the Health Resources and Services Administration and increased funding for NIH research, including research on transplant surgery. Final funding levels for the previous fiscal year, FY 2003, were in concert with ASTS’ FY 2003 recommendations, namely, $25 million (which, upon final passage was $24.8 due to an across-the-board spending cut of .66 percent) for the DOT and a 13% increase for NIH. ASTS’s recommendations for FY 2004 are $30 million for DOT and a 10% increase for NIH.

The House of Representatives passed the Labor, HHS, and Education spending bill in early July and the full Senate approved its bill in early September. Both bills have funded DOT at $24.8 million. This represents level funding from FY 2003, but still represents an overall non-cumulative increase of $10 million annually since FY 2001. A major amendment introduced by Senator Tom Harkin (D-IA) to increase appropriations for the NIH failed on procedural grounds. The amendment received 52 votes, but was forced to overcome rules that mandate a 60-vote majority for amendments that would exceed current budget authority. The amendment would have brought NIH funding closer to ASTS-recommended levels.

The bill now moves to what will likely be a contentious conference committee. None of the 13 appropriations bills have been resolved for FY 2004 even though the new fiscal year begins October 1, 2003. It is very doubtful that the Labor, HHS, Education bill will be completed before this deadline, but it is expected to be resolved later this year.

**Advisory Committee on Transplantation**

The HHS Advisory Committee on Transplantation (ACOT) is sched-
uled to meet in Washington on November 6-7, 2003.

In conjunction with the next ACOT meeting, members of the “Transplant Roundtable,” a Washington, DC, based coalition of transplant-related advocacy organizations of which ASTS is a member, plan to consider releasing individual statements reaffirming donor rights. The concept of this approach is to affirm that the wishes of the decedent donor may not be overruled by family members after death and, thereby, bring this donor rights approach to greater national attention. At its May 2003 meeting, the ASTS Council adopted and reaffirmed ASTS’s commitment to this policy. ASTS is actively involved with the Roundtable and will continue efforts to work with ACOT and HHS on donor rights and other organ donation policy.

Medical Malpractice Reform Legislation

On July 9, Senate Democrats blocked a Republican-backed medical malpractice bill, S.11, that would have capped noneconomic damages in malpractice lawsuits at $250,000. The 49-48 vote, largely along party lines, fell 11 votes short of the 60 required to break a Democratic filibuster and bring the measure up for a formal vote. All 49 votes for the measure were cast by Republicans, while two Republicans joined 45 Democrats and one independent in voting against the measure. The House earlier this year passed a bill, H.R. 5, similar to the Senate legislation. The House bill, sponsored by Congressman Jim Greenwood (R-PA), would cap noneconomic damages in malpractice lawsuits at $250,000 and would allow punitive damages of $250,000 or twice the amount of economic damages, whichever is higher. The legislation covers lawsuits filed against physicians, HMOs, pharmaceutical companies and medical device companies. The bill also would allow state governments to increase or decrease the cap; the legislation would not cap economic damages, which include medical costs and lost wages.

Given this defeat, it was unlikely that the Senate would return to this issue in the near future. But President Bush recently reaffirmed his interest in passing a bill, so the prospects for passage are at least marginally improved.

HRSA Division of Transplantation Awards Organ and Tissue Donation Grants

On August 20, HHS Secretary Tommy Thompson announced 13 grants worth $4.27 million to support social, behavioral and clinical intervention programs that lead to increased organ and tissue donation. Grants will be awarded from two HHS grant programs: Social and Behavioral Interventions to Increase Organ and Tissue Donation, and Clinical Interventions to Increase Organ Procurement.

The social and behavioral interventions program, established in 1999, emphasizes rigorous methodology and evaluation to test the efficacy of interventions meant to increase organ and tissue donation. Grants will be awarded from two HHS grant programs: Social and Behavioral Interventions to Increase Organ and Tissue Donation, and Clinical Interventions to Increase Organ Procurement.

The social and behavioral interventions program, established in 1999, emphasizes rigorous methodology and evaluation to test the efficacy of interventions meant to increase organ and tissue donation. Total funding for the eight awards is $2,776,690.

The clinical interventions program, funded for the first time in FY 2002 as part of Secretary Thompson’s “Gift of Life” Donation Initiative, evaluates clinical interventions to increase the number of organ donors and the number of organs recoverable from existing organ donors. It also promotes research to evaluate and disseminate model interventions with the greatest impact on donation. This year’s grants will support five projects, totaling $1,493,728.

Conclusion

It is likely that major action on Medicare will extend into the fall and possibly into the winter. If legislation passes, it will represent the most significant reform of the Medicare program since its inception in 1965 and will significantly shift Medicare toward private insurance as a model for the provision of Medicare-mandated benefits. ASTS will be actively involved in the Medicare debate and will continue to press for physician fee schedule reform and coverage of immunosuppressive drugs. ASTS will also continue to be engaged in the debate over organ donation legislation and will continue to work with key staff and Senators on passage of legislation this year.

Prepared by Peter W. Thomas, Esq., ASTS Legislative Counsel; and Dustin W.C. May, Legislative Director, Powers, Pyles, Sutter, and Verville, PC.
Over the past several months, ASTS has been involved in a number of initiatives related to Medicare coverage of and payment for transplant services. ASTS has been active with respect to Medicare payment both for transplant surgeons’ professional fees and hospital payment that may impact transplant patients’ access to medically necessary hospital services.

Medicare Coverage:

CMS is expected to issue a final coverage determination on ventricular assist devices very soon. In March of this year, ASTS, represented by Robert Kormos, MD, presented testimony before the CMS Medicare Coverage Advisory Committee supporting the extension of Medicare coverage for ventricular assist devices (VADs) as destination therapy for patients with end-stage heart failure who are not eligible for a transplant. The Advisory Committee voted in favor of extending coverage for VADs as destination therapy for patients who meet the criteria of the REMATCH study. The Committee also recommended that patients first be evaluated by a heart transplant center. The Committee was also in agreement that hospitals performing the procedure should meet certain facility requirements; however, the Committee did not make specific recommendations on what those requirements should be.

CMS was to have issued a national coverage decision by September 15 of this year. However, as of the time this issue went to press, no decision had yet been released.

Medicare Payment:

Physician Payment: Living Donor Liver Hepatectomy Codes

Expected to be Included in Medicare 2004 Fee Schedule

In the last issue of Chimera we reported that the AMA’s Relative Value Update Committee (RUC) had made recommendations to CMS regarding work relative value units for the new living donor liver hepatectomy codes. Relative value units are multiplied by the Medicare dollar conversion factor to determine the amount Medicare will pay for a service. The RUC accepted ASTS’ recommendations, and has recommended work relative value units (W-RVUs) for the living donor hepatectomy code that are significantly higher than the W-RVUs that are assigned to the single living donor hepatectomy code that is currently available.

The RUC did not finalize recommendations to CMS on certain aspects of the practice expense component of the service and indicated in its report that it would defer to ASTS and CMS on this issue. The practice expense relative value units are based primarily on office overhead and labor of the physician’s employees - both clinical and administrative. At issue was the amount of pre-service clinical staff time that is spent with the living donor. ASTS and CMS held a conference call in late July and reached a consensus on the appropriate amount of pre-service time for purposes of the practice expense inputs. We expect that the 2004 Medicare Fee schedule, to be published this fall, will include the new living donor hepatectomy codes and the RVUs will reflect the RUC and ASTS recommendations.

Physician Payment: ASTS Urges CMS to Restore Payment Reductions for Several Transplant Codes

ASTS will send a letter to CMS later this month urging that proposed payment reductions for transplant procedures in the 2004 Medicare physician fee schedule be restored. The reductions are believed to be due to standardization of certain practice expense inputs related to clinical staff time that were applied to all surgical procedures. However, the standardization appears to have had a disproportionately negative impact on transplant procedures.

Hospital Payment: ASTS to Seek Increases in Medicare Payment for Certain Immunosuppressive Drugs

ASTS will submit comments to CMS later this month on hospital outpatient reimbursement for certain immunosuppressive drugs. Last year ASTS was successful in restoring some of the proposed payment cuts for a number of anti-rejection drugs. This year, the proposed cuts are not as widespread - only two drugs are affected (OKT3 and Thymoglobulin) - but the proposed payment appears to be below hospital acquisition costs. ASTS will present CMS with data on hospital acquisition costs for these two drugs and urge that payment be increased to at least cover hospital costs.

ASTS is Seeking New CPT Codes to Describe Backbench Work on Donor Organs

ASTS is preparing applications for several new CPT Codes to describe backbench or back table dissection of donor organs prior to transplant. ASTS’ request to the AMA’s CPT Editorial Committee, to be submitted in October, will include new codes to describe standard backbench work and additional reconstruction work on donor organs. ASTS hopes to have the new codes approved in time for inclusion in the 2005 edition of the CPT.

Other Issues:

* Generic Substitution of Immunosuppressive Drugs

ASTS has prepared a letter to Secretary Thompson on the issue of inappropriate substitution of generic versions of immunosuppressive drugs without the physician’s knowledge and will urge the adoption of policies to prevent this practice.

* New Transplant Center Regulations to be Published this Winter

CMS is in the process of developing new regulations for transplant centers which will likely contain new volume standards for transplant procedures and new survival rates that Medicare certified transplant centers will be required to meet. ASTS has been in telephone con-
tact with CMS staff in charge of the regulations and we expect that ASTS representatives will meet with CMS staff once the proposed rule is published. CMS expects the publication date of the proposed rule to be sometime in January of 2004.


Compliance

Emerging Compliance Issues in Organ Transplant Reimbursement:
Seven Questions Every Transplant Center Should Ask
By Jeff Sinaiko, Veronica Jordan, and Emma Wollschlager

Sinaiko (jeff@sinaikohc.com) is senior vice president of Sinaiko Healthcare Consulting, a health care management consulting firm based in Los Angeles that specializes in billing, compliance, and operations improvement projects for hospitals, health systems, medical groups, and hospital-owned physician organizations nationwide. Wollschlager and Jordan are consultants specializing in these areas at the firm. For more information, call (310) 826-4935 or go to http://www.sinaikohc.com.

Organ transplants, one of the most extraordinary life-saving advancements in medical history, are also among the most expensive and complex services for hospitals to provide from operational, reimbursement and regulatory perspectives. Given the high cost of organ transplants, both the surgery itself as well as the pre- and post-transplant care necessary for successful outcomes, payors, including Medicare, pay special attention to payment and compliance issues surrounding organ transplants.

As a result of the complicated mechanics of transplant reimbursement, hospitals and health systems are at a significant risk for mistakes, false claims, and other compliance-related deficiencies. Indeed, BNA’s Health Care Fraud Report documented a case involving Sharp HealthCare in California that led to a $6.2 million settlement based on allegations of improper handling of various elements of transplant reimbursement (7 HFRA 387, 5/14/03). Another recent investigation of Tampa General Hospital in Florida turned up findings of cost report compliance issues that identified $1.4 million in overstated costs (7 HFRA 366, 5/14/03).

Moreover, it appears that the Office of Inspector General (IG) of the Department of Health and Human Services (HHS) is currently surveying transplant programs nationwide to gain more information on the subject and is expected to look carefully for possible reimbursement violations. In fact, the IG’s Work Plan for FY 2003 lists two areas of scrutiny related to transplant programs, whereas the FY 2002 Work Plan did not have any areas of focus devoted exclusively to Transplant Programs.

Complications in managing a transplant program are not due just to Medicare regulations, but issues arise because each organ (liver, kidney, heart, etc.) and each payor has their own separate set of complexities that must be managed. For example, payment for services provided to living organ donors is an issue in liver and kidney transplants, but not in heart transplants. Organ procurement reimbursement can be fairly straightforward until cadaveric organs are procured at one facility but used in several different facilities. Different payment mechanisms negotiated by a hospital’s contracting department cause complex coordination of care and financial arrangements based on payment mechanisms varying from case-rate to per-diem to fee-for-service to global or split billing.

As with much of billing in the industry today, compliance is dependent on day-to-day careful execution of complex and detailed accounting and careful monitoring. Regardless of how many payor contracts a program has, Medicare’s requirements and regulations tend to set the tone for how a program establishes its clinical operations and the resulting reimbursement and compliance efforts. For example, the technical component of pre-transplant services are reimbursed by Medicare on a cost-plus-margin basis through a hospital’s cost report, while the technical components of the surgery itself and the post-transplant services are reimbursed according to a fixed fee schedule. Of course, professional services are reimbursed separately by Medicare based on the physician fee schedule.

According to a recent report from BCS Research, tissue and organ transplantation in the United States cost $17.3 billion last year and is expected to grow at a 3.5 percent annual rate, which will amount to an estimated $20.5 billion by 2007.

More generally, the report documented that half of the health care expenditures in the United States each year are to treat the consequences of organ failure or tissue loss, an amount that exceeds $600 billion.

With this much money on the table, it is not surprising that transplant reimbursement is extremely complex. And with such scrutiny being placed on hospital reimbursement, now is a critical time to raise the issue of transplant cost reporting and operations to identify possible risk areas at your institution.

Key Components of Transplant Reimbursement Compliance

Regardless of the patient’s payor or the organ being transplanted, a key component to ensuring compliance is appropriately and meticulously accounting for expenses. One of the most significant nuances of organ transplant is the division of the care into phases: transplant evaluation, pre-transplant, transplant surgery and post-transplant. The common thread amongst most payors is that they have different payment mechanisms for each phase. Most commonly, however, the main division is between pre- and post-transplant.

Careful tracking mechanisms for distinguishing between the services provided for pre-transplant (“organ acquisition”) and post-transplant related care must be diligently maintained and all of the expenses and costs incurred for patient care must be tracked in this
time tracking is a time-consuming, tedious and generally manual task. The cleanest method of segregating a large portion of the time spent by the staff (collectively) on pre- and post-transplant patients is to designate pre-transplant clinic days and post-transplant clinic days (or mornings versus afternoons) and then allocating the total expenses for those clinics based on the relative number of clinic sessions. This split will help ease the administrative task of time tracking for the clinical employees, but to a lesser extent for the support staff as well. For functions that cannot be so clearly separated, worksheets, time studies, motion reports or other documentation methods (e.g. number of phone calls, number of registrations, etc.) should be used to track time spent on combined activities. Staff should track time ideally one week per month and time should be aggregated on a quarterly basis.

First, the tracking documents should be periodically monitored internally or externally audited to ensure that they reflect reality as much as possible and to correct problems identified before they appear on the cost report. Employee time sheets should be reflective of the actual hours worked. For example, while this seems obvious, experience indicates that unless monitored an employee who worked a 45-hour week can have the sum of her time allocated to the different transplant functions add up to 55 hours for that week.

Secondly, a logical look at the global numbers should be taken. For instance, if about one-third of clinic time is spent on post-transplant patients, then the sum of the hours allocated to post-transplant services, as documented on all employee’s time sheets, should be equivalent to one-third of the total time reported. Any discrepancies noted should be investigated and corrected or documented as resolved.

Finally, once the time sheets can be certified as correct, they should be reconciled with what is reported on the actual cost report. Shifting of hours or services for ease in cost reports should be completely avoided. If two employees split their time equally between pre- and post-transplant, their time should be reflected on the cost report worksheet as they actually spent the time. In other words, 1.0 FTE should not be allocated to pre-transplant, while the other staff member is allocated to post-transplant, rather than reporting two halves of each. Reimbursement personnel preparing the cost report often are not aware of the impact such simplification can have. If ever audited, it could appear as if the employee allocated as 1.0 FTE, who only recorded 0.5 FTE on pre-transplant functions was over allocated so as to increase cost-based reimbursement. Again, any discrepancies found must either be corrected or have a reasonable and documented explanation.

2. Do We Monitor Space Usage for the Different Phases of the Transplant Program?

Since the costs associated with the lease of space are also included in the calculation of organ acquisition costs on the cost-report, it is extremely important to know how much time the transplant program’s space is devoted to pre-transplant patients and to post-transplant patients. Furthermore, for patient convenience, different clinic space may not be used for pre- and post-transplant service, which creates a need to track how the common space is being used.

Unfortunately, time tracking is a time-consuming, tedious and generally manual task. The cleanest method of segregating a large portion of the time spent by the staff (collectively) on pre- and post-transplant patients is to designate pre-transplant clinic days and post-transplant clinic days (or mornings versus afternoons) and then allocating the total expenses for those clinics based on the relative number of clinic sessions. This split will help ease the administrative task of time tracking for the clinical employees, but to a lesser extent for the support staff as well. For functions that cannot be so clearly separated, worksheets, time studies, motion reports or other documentation methods (e.g. number of phone calls, number of registrations, etc.) should be used to track time spent on combined activities. Staff should track time ideally one week per month and time should be aggregated on a quarterly basis.

Tracking “by default” may also be an option for staff who spend the great majority of their time on either pre- or post-transplant activities, but may spend a few hours a month on non-related duties, such as separately reimbursable research activities. These staff can document only the time spent on the research or other minority project, and the rest of their time can be reasonably assumed to have been spent on the main duties.

Will this process guarantee that our staff expense reporting is accurate?

To ensure that this tracking effort is not wasted, a couple of important activities must be performed.

First, the tracking documents should be periodically monitored internally or externally audited to ensure that they reflect reality as much as possible and to correct problems identified before they appear on the cost report. Employee time sheets should be reflective of the actual hours worked. For example, while this seems obvious, experience indicates that unless monitored an employee who worked a 45-hour week can have the sum of her time allocated to the different transplant functions add up to 55 hours for that week.

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Which of our staff members should be tracking their time?

If the pre- and post-transplant functions of a program are indeed being performed by the same employees, then any employee who is performing duties for both should be tracking their time for each service. This includes transplant nurse coordinators, financial coordinators, social workers, medical directors, secretaries, receptionists, billing coordinators, home health nurses, dieticians, as well as managers and supervisors.

How should our staff be tracking their time?

Unfortunately, time tracking is a time-consuming, tedious and generally manual task. The cleanest method of segregating a large portion of the time spent by the staff (collectively) on pre- and post-transplant patients is to designate pre-transplant clinic days and post-transplant clinic days (or mornings versus afternoons) and then allocating the total expenses for those clinics based on the relative number of clinic sessions. This split will help ease the administrative task of time tracking for the clinical employees, but to a lesser extent for the support staff as well. For functions that cannot be so clearly separated, worksheets, time studies, motion reports or other documentation methods (e.g. number of phone calls, number of registrations, etc.) should be used to track time spent on combined activities. Staff should track time ideally one week per month and time should be aggregated on a quarterly basis.

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Specifically, what space needs to be tracked?
If the same set of staff is performing functions for pre- and post-transplant patients combined as described above, and the same clinic rooms and reception areas are being used for pre- and post-transplant patients, then all of the space should be reasonably tracked.

If the space is ever used for non-transplant reimbursable activities, such as research, then that time should be documented as well and removed from the cost report.

How can we track space usage?
As in the example of tracking staff time, the cleanest way to track space usage is to segregate pre- and post-transplant to specific days and/or times. Thereby a clinic visit type ratio can be established that can closely estimate the amount of time the space is devoted to pre-transplant and to post-transplant activities. Large variations in the amount of time the space was devoted to pre- or post-transplant should not be seen from month-to-month; however, the ratio should be reviewed and updated from time to time. As an alternative, total space costs can be allocated based as the ratio of pre-transplant visits to post-transplant visits or other such logical metric.

The systematic method that your Center chooses to determine the space allocation through a combination of fixed clinic days and times and clinic visit ratios should be well documented. This documentation must support the building and occupancy expense allocation submitted on the cost report.

3. Do We Have an Effective System for Determining How to Allocate the Various Non-Staff and Space Expenses of the Transplant Process?
For the same reasons that the staff and space time must be tracked carefully for pre- and post-transplant activities, the non-staff/space expenses should be allocated to the appropriate phase of transplant to ensure that claims and cost reporting activities are true reflections of the operations of the transplant program.

Which non-staff expenses need to be tracked?
The main expenses related to providing transplant patient care other than staff and space include: general office supplies, medical supplies, information systems/communications and pharmaceuticals.

4. Have Our Transplant Program Contracts Been Reviewed by an Outside Party?
Any agreements for the provision of services to the transplant program or by the transplant program that are going to end up in whole or in part on the cost report must fall within the fair market value for those services.

Which type of agreements must be reviewed?
Medical Directorship Agreements, Management Services Agreements, Lease Agreements and Service Agreements.

What terms should we be looking for when having our contracts reviewed?
The transplant program should ensure that any compensation paid (particularly to medical directors) or received (e.g. for space leases) falls within the fair market value for those services. Additionally, if the services provided cover both pre-and post-transplant aspects of the program, then the method of invoicing for the services should clearly include a designation of which services were provided for pre-transplant and which were provided for post-transplant so that only services related pre-transplant/organ acquisition end up on the cost report.

Special attention should be paid to medical directors’ compensation based on the qualifications of the director, the level of difficulty of the duties performed, and the actual number of hours actually worked. Specifically, compensation should vary based on the stage of development of the program and the actual duties performed and reported on the monthly logs. Medical directors must track their time. To be safest, typically, medical directorship compensation arrangements should be based on the actual number of hours worked up to a pre-set maximum and documented on logs. Most valuation experts find that medical director compensation tops out at $150 per hour, although some special circumstances can cause it to be higher on an hourly basis. Pay careful attention to the appearance that more than one medical director is being paid for the same programs.

As always, any lease agreements should also be based on fair market value rent for the specific area and any services that are included.

Conclusion
As recent cases illustrate, there are serious risks associated with reimbursement for organ transplant services. The complex layers of pre- and post-transplant services—including allocation of staffing costs, building and occupancy costs, supply and overhead expenses, and physician costs and the varying services reimbursed—make the compliance challenges all the more difficult. The stakes are too high to let another day pass without assessing organizational procedures in these areas and taking appropriate precautions to ensure compliance.

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### ASTS Awards Program

**Deadline for application of 2004 awards is December 12, 2003**

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<tr>
<th>Award</th>
<th>Eligibility</th>
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<td>ASTS-Novartis Fellowship in Transplantation</td>
<td>Qualified surgeon who will have completed an approved ACGME residency program or its foreign equivalent in a major surgical discipline by 7/1/04</td>
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<td>ASTS - Fujisawa, USA Faculty Development Award: 1 recipient</td>
<td>Junior Faculty Member - 0-5 Years Post Fellowship</td>
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<td>Surgical Resident PGY 3</td>
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<td>ASTS - Thoracic Surgery Fellowship</td>
<td>Thoracic Surgical Resident or Fellow</td>
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<td>Assistant or Associate Professor and Attendant Appointment</td>
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<td>Roche Presidential Travel Award: 2 recipients per year</td>
<td>Investigator - 42 years of age or younger</td>
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<td>ASTS Vanguard Prize (4 awards annually)</td>
<td>ASTS Member; Instructor or Assistant Professor</td>
<td>1</td>
<td>$1,000 &amp; Expenses to ASTS Winter Symposium</td>
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<td>ASTS - NKF Folkert Belzer MD Research Award: 1 Recipient</td>
<td>Surgical Resident PGY 3</td>
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<td>$35,000</td>
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ASTS Accredited Training Programs (Alphabetically by state)

QUEEN ELIZABETH II HEALTH SCIENCES CENTRE
Joseph G. Lawen, MD, FRCSC Surgical Director, The Kidney Transplant
Fellowship Program Room 295, Victoria Building 1278 Tower Road
Halifax, Nova Scotia Canada B3H 2Y9
PH: 902-473-4026 FAX: 902-492-2437  Kidney

UNIVERSITY OF WESTERN ONTARIO LONDON HEALTH SCIENCES CENTRE
William Wall MD, FRCSC Program Director, Multi-Organ Transplant
Unit 339 Windermere Road London, Ontario Canada N6A5A5
PH: 519-663-2940 FAX: 519-663-33067  Kidney, Liver

UNIVERSITY OF TORONTO
Paul D. Greig, MD, FRCS(C) Director, GI Transplantation
Toronto General Hospital Norman Urquhart Wing 10-145 621 University
Avenue Toronto, Ontario Canada M5G 2C4

UNIVERSITY OF ALABAMA
Devin E. Eckhoff, MD, Director, Transplant Division LHRB 710 1530
3rd Avenue S Birmingham, AL 35294-0007
PH: 205-934-7714 FAX: 205-934-8378  Kidney

CEDARS-SINAI MEDICAL CENTER LOS ANGELES
Christopher R. Shackleton, MD Director, Multi-Organ Transplant
Program and Center for Liver Diseases & Transplantation, Professor
of Surgery UCLA School of Medicine 8635 W Third Street, Suite
590W Los Angeles, CA 90046
PH: 310-423-2641 FAX: 310-423-0234  Kidney, Liver

ST. VINCENT MEDICAL CENTER
Robert Mendez, MD, FACS Professor of Urology & Surgery Director,
Multi-Organ Transplantation Program 2200 West Third Street, Suite
500 Los Angeles, CA 90057
PH: 213-413-2779 FAX: 213-484-6652  Kidney, Pancreas

UCLA
H. Albin Gritsch, MD Surgical Director, Renal Transplantation UCLA
Medical Center, CHS 63-276 Center for the Health Sciences Box
951738
Los Angeles, CA 90095-1738
PH: 310-794-7152 FAX: 310-206-5343  Kidney

UCLA
Hillel Laks, MD Chief, Professor-Cardiothoracic Surgery 10833 Le
Conte Avenue, Box 951741 Los Angeles, CA 90095
PH: 310-206-8232 FAX: 310-825-7473  Heart

UNIVERSITY OF CALIFORNIA LOS ANGELES (UCLA) MEDICAL CENTER
Ronald W. Busuttil, MD, PhD Professor and Chief, Division of Liver
and Pancreas Transplantation Director, The Dumont-UCLA
Transplant Center UCLA School of Medicine 10833 Le Conte Avenue
Los Angeles, CA 90095
PH: 310-825-5318 FAX: 310-206-7760  Kidney, Liver, Pancreas

STANFORD UNIVERSITY MEDICAL CENTER
Carlos O. Esquivel, MD, PhD Professor of Surgery, Chief, Division of
Transplantation 750 Welch Road, Ste. 319 Palo Alto, CA 94304-1510
PH: 650-498-5689 FAX: 650-498-5690  Kidney, Liver

UCSD CENTER FOR TRANSPLANTATION UNIVERSITY OF CALIFORNIA SAN DIEGO MEDICAL CENTER
John Dunn, MD Director of Kidney Transplant Program 200 W. Arbor
Drive San Diego, CA 92103-8401
PH: 619-543-3493 FAX: 619-543-7785  Kidney

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
John Roberts, MD Professor of Surgery, Chief, Transplant Service 505
Parnassus Avenue, Room M896 San Francisco, CA 94143-0780

STANFORD UNIVERSITY
Robert C. Robbins, MD, Director of Thoracic Transplant Program
300 Pasteur Drive Falk Building, 2nd Floor Stanford, CA 94305-5407
PH: 650-725-3828 FAX: 650-725-6846  Heart, Lung

YALE UNIVERSITY SCHOOL OF MEDICINE
Marc I. Lorber, MD, FACS Chief, Organ Transplantation and
Immunology 333 Cedar Street, FMB112 PO Box 208062
New Haven, CT 06520-8062
PH: 203-785-2565 FAX: 203-785-7162  Kidney

WASHINGTON HOSPITAL CENTER
Jimmy A. Light, MD, FACS Director, Transplantation Services
Transplantation Services 110 Irving Street, NW, Room 3B-1
Washington, DC 20010-2975
PH: 202-877-6029 FAX: 202-877-6581  Kidney, Pancreas

UNIVERSITY OF FLORIDA COLLEGE OF MEDICINE
Richard J. Howard, MD, PhD Professor and Chief, Transplant Surgery
Department of Surgery PO Box 100286 Gainesville, FL 32610-0286
UNIVERSITY OF MIAMI SCHOOL OF MEDICINE  
Joshua Miller, MD Andreas G. Tzakis, MD Co-Directors of the Division of Transplantation  
Jackson Memorial Hospital Medical Center 1611 NW 12th Avenue Miami, FL 33136  
PH: 305-243-6171 (Dr. Miller) FAX: 305-243-6516  
PH 305-243-5288 (Dr. Tzakis) FAX: 305-243-7233

UNIVERSITY OF MIAMI SCHOOL OF MEDICINE  
Si M. Pham, MD, Director, Cardiopulmonary Transplant Program  
1801 NW 9th Avenue Highland Professional Building, 5th Floor Miami, FL 33136  
PH: 305-355-5070 FAX: 305-355-5074

TAMPA GENERAL HOSPITAL/LIFELINK TRANSPLANT INSTITUTE/UNIVERSITY OF SOUTH FLORIDA  
Victor D. Bowers, MD Director, Transplantation Surgery 409 Bayshore Blvd. Tampa, FL 33606  
PH: 813-253-2640 FAX: 813-251-0096

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You Min Wu, MD Director, Transplant Service University of Iowa Hospitals and Clinics 200 Hawkins Drive Iowa City, IA 52242  
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NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE  
Michael Abecassis, MD Chief, Division of Transplantation 675 N. St. Clair Street, SU 17-200 Chicago, IL 60611  
PH: 312-695-0254 Fax 312-695-9194

RUSH-PRESBYTERIAN-ST. LUKES MEDICAL CENTER  
Howard Sankary, MD Program Director 1653 West Congress Parkway Chicago, IL 60612-3833  
PH: 312-942-4827 FAX: 312-942-2867

UNIVERSITY OF CHICAGO  
J. Michael Millis, MD Chief Section of Transplantation University of Chicago Hospitals Department of Surgery 5027 S. Milledge Avenue Chicago, IL 60637-6104  
PH: 773-702-6319 FAX: 773-702-7511

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Robert M. Merion, MD Professor of Surgery 1500 E. Medical Center Drive, 2926 TC Ann Arbor, MI 48109-0331
PH: 734-936-7336 FAX: 734-763-3187  Kidney  Liver  Pancreas

HENRY FORD HOSPITAL
Marwan S. Abouljoud, MD Benson Ford Chair Division of Transplantation 2799 W. Grand Boulevard, K-7
PH: 313-876-2911 FAX: 313-876-9147  Kidney  Liver  Pancreas

UNIVERSITY OF MINNESOTA
David E. R. Sutherland, MD, PhD Head, Division of Transplantation Department of Surgery Box 280 420 Delaware Street, SE Minneapolis, MN 55455
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Mark D. Stegall, MD Director, Abdominal Transplant Surgery Fellowship Program, Consultant, Division of Transplantation Surgery, Department of Surgery, Associate Professor of Surgery, Mayo Medical School, Surgical Director, Kidney and Pancreas Transplantation, Division of Transplantation, Department of Surgery Department of Surgery 200 First Avenue, S.W. Rochester, MN 55905
PH: 507-266-6794 FAX: 507-266-2810  Kidney  Liver  Pancreas

ST. LOUIS UNIVERSITY HOSPITAL
Paul J. Garvin, MD Director of Abdominal Organ Transplant Professor of Surgery St. Louis University Health Science Center 3635 Vista Avenue at Grand Boulevard St. Louis, MO 63110-0250

WASHINGTON UNIVERSITY AT ST. LOUIS
Nader Moazami, MD Division of Cardiothoracic Surgery Queeny Tower, Suite 3108 One Barnes-Jewish Hospital Plaza

WASHINGTON UNIVERSITY SCHOOL OF MEDICINE/BARNES-JEWISH HOSPITAL
William Chapman, MD Department of Surgery Program Director, Transplantation Section One Barnes Hospital Plaza Suite 6107 Queeny Tower Campus Box 8109 St. Louis, MO 63110

UNIVERSITY OF NORTH CAROLINA HOSPITALS
Jeffrey H. Fair, MD Associate Professor of Surgery Director Liver Transplantation Chief Abdominal Transplant Surgery Dept. of Abdominal Transplant Surgery 3010 Old Clinic Building, CB#7210 Chapel Hill, NC 27599-7210
PH: 919-966-8008 FAX: 919-966-6308  Kidney  Liver

DUKE UNIVERSITY MEDICAL CENTER
J. Elizabeth Tuttle-Newhall, MD Director Transplant Fellowship 110 Bell Bldg. DUMC Box 2910 Durham, NC 27710
PH: 919-684-5923 FAX: 919-684-8716  Kidney  Liver  Pancreas

DUKE UNIVERSITY MEDICAL CENTER
R. Duane Davis, Jr. Associates Professor of Surgery Director Cardiopulmonary Transplantation Box 3864, DUMC Durham, NC 27710
PH: 919-681-4760 FAX: 919-681-4797  Heart  Lung

UNIVERSITY OF NEBRASKA MEDICAL CENTER
Alan N. Langas, DO Professor of Surgery Chief of Transplantation 983285 Nebraska Medical Center Omaha, NE 68198-3285
PH: 402-559-4076 FAX: 402-559-3434  Kidney  Liver  Pancreas

UMDNU - UNIVERSITY HOSPITAL
Baburao Koneru, MD, Director, Liver Transplantation Program Stanley S. Bergen Building, Room GA230 65 Bergen Street Newark, NJ 07107  Liver

ALBANY MEDICAL COLLEGE
ALBANY MEDICAL CENTER HOSPITAL
David J. Conti, MD Director of Transplantation 43 New Scotland Avenue, A-61GE Albany, NY 12208-3478
PH: 518-262-5614 FAX: 518-262-5571  Kidney

STATE UNIVERSITY OF NEW YORK HEALTH SCIENCE CENTER AT BROOKLYN (SUNY)
Bruce G. Sommer, MD, FACS Professor and Director Division of Transplantation Department of Surgery 450 Clarkson Avenue, Box 40 Brooklyn, NY 11203-2098
PH: 718-270-1898 FAX: 718-270-4789  Kidney  Liver

MOUNT SINAI MEDICAL CENTER
Charles M. Miller, MD Alfred and Florence Gross, Professor of Surgery, Director, Recanati/Miller Transplantation Institute The Mount Sinai Hospital, Box 1104, One Gustave L. Levy Place New York, NY 10029-6574
PH: 212-241-0106 FAX: 212-996-9688  Kidney  Liver

NEW YORK PRESBYTERIAN HOSPITAL
Milan Kinkhabwala, MD (Liver) Associate Professor Mark Hardy, MD (Kidney) Professor and Director Kinkhabwala: Center for Liver Disease and Transplantation PH 14 622 West 168th Street New York, NY 10032 Hardy: Kidney Transplant Program 177 Fort Washington Avenue New York, NY 10032
PH: 212-305-9381 FAX: 212-305-9139  Kidney
PH: 212-305-5502 FAX: 212-305-6837  Liver
NEW YORK UNIVERSITY MEDICAL CENTER  
Lewis W. Teperman, MD  
Director of Transplantation  
Mary Lea Johnson Richards Transplant Center  
403 E 34th Street, 3rd Floor  
New York, NY 10016  
PH: 212-263-8134  
FAX: 212-263-8157  
Kidney  
Liver

STATE UNIVERSITY OF NEW YORK AT STONY BROOK  
Wayne C. Waltzer, MD, FACS  
Director, Transplantation Services  
University Hospital and Medical Center at Stony Brook  
HSCT-19, Room 040  
Stony Brook, NY 11794-8192  
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FAX: 631-444-3831

UNIVERSITY OF CINCINNATI  
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Director of Transplantation  
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Cincinnati, OH 45267-0538  
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FAX: 513-558-7040

THE CLEVELAND CLINIC FOUNDATION  
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Chairman, Division of Transplantation  
Department of Surgery  
9500 Euclid Avenue  
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FAX: 216-444-9375

THE CLEVELAND CLINIC FOUNDATION  
Delos Cosgrove, MD  
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Cleveland, OH 44195  
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THE OHIO STATE UNIVERSITY HOSPITALS  
Ronald M. Ferguson, MD, PhD  
Director, Division of Transplantation  
Room 363, Means Hall  
1654 Upham Drive  
Columbus, OH 43210-1250  
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FAX: 614-293-4541

ALBERT EINSTEIN MEDICAL CENTER  
Cosme Manzarbeitia, MD, FACS  
Chairman, Division of Transplantation  
5501 Old York Road  
Philadelphia, PA 19141  
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FAX: 215-456-8058

HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA  
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4 Silverstein  
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Philadelphia, PA 19104-4283  
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Director of Heart-Lung Transplantation  
Division of Cardiothoracic Surgery  
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Philadelphia, PA 19104  
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FAX: 215-343-5798

UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE  
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Thomas E. Starzl Transplantation Institute  
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Pittsburgh, PA 15213  
PH: 412-648-3200  
FAX: 412-647-5480

HOSPITAL ESPANOL AUXILIO MUTUO DE PUERTO RICO  
Eduardo A. Santiago-Delphin, MD  
Chairman, Transplant Program  
Box 1227  
San Juan, PR 00919  
PH: 787-765-7650

MEDICAL UNIVERSITY OF SOUTH CAROLINA  
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Associate Professor of Surgery  
171 Ashley Avenue  
Charleston, SC 29425-0777  
PH: 843-792-4003  
FAX: 843-792-3553

BAYLOR UNIVERSITY MEDICAL CENTER  
(see Dallas Liver Transplant Program below)

DALLAS LIVER TRANSPLANT PROGRAM  
BAYLOR UNIVERSITY MEDICAL CENTER  
Goran Klintmalm, MD, PhD  
(Divisional Director)  
Dallas Liver Transplant Program  
Baylor Institute of Transplant Sciences  
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FAX: 214-648-4784

UNIVERSITY OF TEXAS MEDICAL BRANCH GALVESTON  
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BAYLOR COLLEGE OF MEDICINE  
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UNIVERSITY OF TEXAS MEDICAL SCHOOL AT HOUSTON
Barry D. Kahan, PhD, MD Professor and Director Division of Immunology and Organ Transplantation 6431 Fannin, Suite 6240 Houston, TX 77030
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TEXAS TRANSPLANT INSTITUTE METHODIST SPECIALTY AND TRANSPLANT HOSPITAL
Francis H. Wright, MD Director, Organ Transplantation 8201 Ewing Halsell San Antonio, TX 78229
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UNIVERSITY OF VIRGINIA HEALTH SCIENCES CENTER
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MEDICAL COLLEGE OF VIRGINIA
Marc P. Posner, MD, FACS Professor and Chairman Division of Transplantation Surgery Director, MCV Transplant Program PO Box 980057 Richmond, VA 23298
PH: 804-828-9298 FAX: 804-828-4858

UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE (SEATTLE)
James D. Perkins, MD, FACS Professor of Surgery Director, Division of Transplantation Department of Surgery 1959 N.E. Pacific Street Box 356410 Seattle, WA 98195-6410
PH: 206-543-3825 FAX: 206-543-8136

UNIVERSITY OF WISCONSIN-MADISON SCHOOL OF MEDICINE
Hans W. Sollinger, MD, PhD Professor and Chairman Division of Organ Transplantation Department of Surgery 600 Highland Avenue Madison, WI 53792-7375
PH: 608-263-9903 FAX: 608-263-7652

ASTS
“THANKS”
Benefactor’s Circle
Fujisawa Healthcare, Inc.
Founder’s Circle
Novartis Pharmaceuticals Corporation
Roche Laboratories, Inc.
Wyeth Pharmaceuticals
Friend’s Circle
Sangstat
This Mini-Symposium aims to teach fundamental methodology of designing and conducting clinical trials in transplantation. Instruction and interaction will focus on how to
- develop concepts and skills to design and implement clinical research/clinical trials in transplantation;
- assemble the appropriate research components to complete clinical research / clinical trials in transplant-
  plantation
- identify possible and appropriate funding mechanisms;
- disseminate research results through publication.

Specific objectives include:
1) To provide investigators in the field of transplantation with the concepts necessary to develop a pro-
tocol for a clinical trial that is fundable by a peer-reviewed agency;
2) To understand the design and implementation issues unique to performing trials in transplantation;
and
3) To foster collaborative efforts necessary to conduct a clinical trial.

SESSIONS:
- Why Do Clinical Research?
- Overview of Study Design: Strengths and Weaknesses
- Advancing Surgical Techniques
- Clinical Trial Design
- Selecting Endpoints: Critical Choices
- Registry Data: Pros and Cons
- Regulatory Alphabet Soup: IRB, FDA, HIPAA . . .
- Who Might Fund My Study?
- The Anatomy of Funding Proposals
- Successful Trial Administration: From Budget to Personnel
- The NIH
- The Pharma Interaction
- Investigator-Initiated Pharma-Sponsored Research
- Publication / Patents / Proprietary Right
- Ethics of Clinical Research
- Breakout Sessions and Proposal Reviews

For registration information please go to: www.asts.org

The program will be on “Surgical Challenges in Transplantation.” The members of the planning committee are Sandy Feng, Osama Gaber, Elizabeth Pomfret, Thomas Fishbein and Abhinav Humar.

The Marriott Mountain Shadow Resort and Golf Club is set on seventy acres of desert paradise, with picturesque gardens, lush fairways, and endless variety. Tucked away in the pastel-tinted shadows of Arizona’s Camelback Mountain, you’ll discover a relaxed elegance and unparalleled convenience. Luxurious guest rooms with spectacular views, and unlimited recreation. Extraordinary options for indoor and outdoor dining, and so much more - all just minutes from Phoenix, and less than 12 miles from Sky Harbor International Airport. You can view the Marriott Mountain Shadow Resort and Golf Club at www.mountainshadow.com

More detailed information and registration materials will appear on the ASTS website at www.asts.org
ASTS 2004 Winter Symposium

Fundamentals of Clinical Research in Transplantation

Course Description

The course aims to provide an overview of the current state of clinical research in transplantation, focusing on the methodologies and principles that underpin successful studies. Participants will learn about the design, execution, and evaluation of clinical research projects in the field.

Course Objectives

- Understand the ethical considerations in clinical research.
- Learn how to design and conduct clinical trials.
- Gain insight into the regulatory and publication aspects of clinical research.

Course Highlights

- Keynote presentations by leading experts in the field.
- Interactive sessions with case studies.
- Networking opportunities with colleagues.

Schedule

- Thursday, January 28
- Friday, January 29

Venue

Exact location details to be announced.

Conference Logistics

Registration is now open. Early bird rate available until December 31, 2003.

Early Bird Rate: $495

Regular Rate: $595

Contact Information

For more information, please contact:

ASTS Winter Symposium

Phone: 1-800-123-4567

Email: info@astswinter.org

Website: www.astswinter.org

We look forward to welcoming you to the ASTS 2004 Winter Symposium.
Come Celebrate

ASTS’s

30th Anniversary
to take place at the
American Society of Transplant Surgeons’
4th Annual Winter Symposium
“Surgical Challenges in Transplantation”

January 23-25, 2004
Marriott Mountain Shadow Resort and Golf Club
Scottsdale, AZ
ASTS NEW members

Andrey E. Belous, MD PhD
Vanderbilt University School of Medicine

Bradley H. Collins, MD
Duke University Medical Center

Meelie A. Debroy, MD
University of Michigan Health System

Jonathan A. Fridell, MD
Indiana University School of Medicine

Scott R. Johnson, MD
Beth Israel Deaconess Medical Center

Mercedes S. Mandell, MD PhD
University of Colorado Health Sciences Center

Martin A. Marachio, MD
University of Michigan Health System

Alejandro Mejia, MD
University of Nebraska Medical Center

Jang Il Moon, MD
University of Miami School of Medicine

Robert M. Naraghi, MD
Mendez Transplant & Urological Medical Group

Anil S. Paramesh, MD
Saint Luke’s Medical Center

Steven R. Potter, MD
Mendez Transplant & Urological Medical Group

Andrew F. Precht, MD
University of California-San Diego

Sasan Roayaie, MD
Mount Sinai Medical Center

Juan R. Sanabria, MD MSc FRCSC
Medical College of Ohio

Edmund Q. Sanchez, MD
Baylor University Medical Center

Mark J. Walsh, MS MD FRCSC
Toronto General Hospital

John K. Wright, Jr., MD FACS
Vanderbilt University School of Medicine

OCTOBER 2003

October 1 - 4, 2003
TRANSPLANT IMMUNOSUPPRESSION 2003:
The Continuing Challenges
Minneapolis, MN
Contact Phone: 612-626-7600
Contact Fax: 612-626-7766
Contact Email: cmerg@umn.edu
Contact Website: www.med.umn.edu/cme

NOVEMBER 2003

November 4-8, 2003
4TH ANNUAL RACHMIEL LEVINE SYMPOSIUM
Advances in Diabetes Research: From Cell Biology to Cell Therapy
Universal City, CA
Contact Phone: 800-679-4693
Contact Email: kramos@coh.org
Contact Website: http://levine symposium.coh.org

November 27-December 1, 2003
7TH CONGRESS OF INTERNATIONAL SOCIETY FOR ORGAN DONATION AND PROCUREMENT (previous ISOS) & 4TH CONGRESS OF ITCS
Warsaw, Poland
Abstract deadline extended to July 1, 2003
Go to www.isodp2003.com
Contact Phone: +48 22 8244164
Contact Fax: +48 22 8244163
Contact Email: info@isodp2003.org
Contact Website: www.isodp2003.org

DECEMBER 2003

December 4-6, 2003
THE CLINICAL AND BASIC SCIENCE OF ISLET TRANSPLANTATION 2003 AND BEYOND
3rd Annual Symposium
Annenberg Center for Health Sciences
Rancho Mirage, CA
Contact Phone: 760-773-4267
Contact Fax: 760-773-4513
Contact Email: brotterree@annenberg.net

JANUARY 2004

January 22-23, 2004
AMERICAN SOCIETY OF TRANSPLANT SURGEONS
Clinical Research in Transplantation: Getting Started
Marriott Mountain Shadow Resort and Golf Club
Scottsdale, AZ
Contact Website: www.asts.org
Contact Phone: 1-800-736-6261

January 23-25, 2004
ASTS 4TH ANNUAL WINTER SYMPOSIUM
Surgical Challenges in Transplantation
Marriott Mountain Shadow Resort and Golf Club
Scottsdale, AZ
Contact Website: www.asts.org
Contact Phone: 1-800-736-6261
ASTS has developed a “research bulletin board” to enable you to post information about research projects in which you would like additional participants or other input.

The purpose of this bulletin board is to allow investigators to solicit participation from other centers for their clinical trial. It is hoped that this bulletin board will attract enrollment of a sufficient number of patients to statistically power clinical trials.

Please go to www.asts.org and click on to “Members Only” section and then click “ASTS Research Bulletin Board.”

Click into the specific organ where your study better belongs or to see any proposal that has been posted.

We encourage you to utilize this site and refer to it on a regular basis to see what has been added and to post studies for which you are seeking input. We hope this tool will help in developing research studies for which Members would like to find collaborators or receive input and advice from other investigators. Both clinical and basic projects are welcomed.

It should be noted that posting of studies on the trials bulletin board does not in any way denote support or sponsorship of the principal investigator or clinical trial by the American Society of Transplant Surgeons. In addition, the American Society of Transplant Surgeons does not vouch for the scientific validity, clinical efficacy, and/or

The site was developed by the ASTS Scientific Studies Committee.
The ASTS Job Board is enhanced further by the addition to the ASTS website, www.asts.org of CV’s of ASTS Candidate Members. This is in an effort to facilitate the interactions between graduating fellows and transplant programs with junior position openings. To access the CVs go to www.asts.org, log into the Members Only section and click on Upload/download files.

MULTI-ORGAN TRANSPLANT FELLOWSHIP University of Minnesota Medical School Department of Surgery. Applications are now being accepted for two positions for a two-year advanced ASTS-approved training program in multi-organ transplantation at Fairview University Medical Center. Must be board certified, eligible, or equivalent in general surgery, and hold or be eligible to obtain a State of Minnesota medical license. Responsibilities include 24 months of specialty training in kidney, pancreas, and liver transplantation. Successful candidates will be appointed as full-time yearly renewable non-tenure track Instructors in the Department of Surgery. The start dates are January 2005 and July 2005. Candidates are immediately needed and encouraged to apply for the January 2005 opening. The positions will remain open until filled. Applications for future years will also be accepted. To apply, please submit curriculum vitae and bibliography to: Arthur J. Matas, M.D., Professor of Surgery, Director, Transplant Fellowship Program, University of Minnesota Dept. of Surgery, 420 Delaware St. SE, MMC 280, Minneapolis, MN 55455, matas001@umn.edu, The University of Minnesota is an equal opportunity educator and employer.

MULTI-ORGAN TRANSPLANT FELLOWSHIP The Division of Organ Transplantation, Northwestern University Feinberg School of Medicine is seeking highly motivated individuals for its ASTS-approved transplant fellowship beginning July 1, 2004. The fellowship is a two-year program with training in kidney, pancreas, and liver transplantation and multi-organ cadaver procurement. Comprehensive training in adult and pediatric renal and liver transplantation will be provided. Training will also be provided in laparoscopic living-donor nephrectomy, living donor liver transplantation, and dialysis access. Participation in ongoing clinical research projects and translational projects within the Division of Transplantation is encouraged. Fellows should be board eligible or board-certified in general surgery. Interested individuals should contact: Joseph R. Leventhal, MD, PhD, Division of Transplantation, Department of Surgery, 675 N. St. Clair Street, Suite 17-200, Chicago, IL 60611, 312-695-1703 – Phone, 312-695-9194 – Fax, Email: jleventh@nmh.org.

ACADEMIC TRANSPLANT SURGEON Southern Illinois University School of Medicine has a faculty position available for a second transplant surgeon for their longstanding kidney and pancreas transplant program. The successful candidate will be committed to clinical excellence, research and teaching. The opportunity exists to practice general surgery and vascular access in addition to transplantation. The candidate must be board eligible or board certified. Springfield, Illinois is the capital city and offers many of the opportunities associated with a larger city while providing the friendly atmosphere of a small, Midwestern town. This position has been designated security-sensitive, and employment is contingent upon the result of a criminal background investigation. Illinois licensure is a requirement of employment. Send letter of application along with your curriculum vitae to Tim O’Connor, M.D., Department of Surgery, P. O. Box 19638, Springfield, IL 62794-9638. Applications should be received by July 30, 2003 but may be accepted until the position is filled. SIU School of Medicine is an Equal Employment Opportunity/Affirmative Action employer.

THE CENTER FOR SCIENTIFIC REVIEW (CSR) at the NIH is expanding and reorganizing its scientific review structure into four Divisions, including a Division of Clinical and Population-based Studies. CSR is seeking a Director for this division with experience and knowledge in clinical research and/or behavioral and social science, who can serve as an effective liaison with these research communities. This is a senior executive level position. For more information, please see ad at http://www.csr.nih.gov/employment, or contact Ms. Pam Sullivan, SullivanP@csr.nih.gov.

TRANSPLANT SURGEON: The University of Kentucky Transplant Section wishes to recruit a transplant surgeon at the Assistant Professor level with expertise in performing liver, kidney and pancreas transplantation. Candidates with laparoscopic donor nephrectomy experience will be given special consideration. Please contact: Dinesh Ranjan, M.D., Chief—Transplant Section, 859-323-4661 or dranj1@pop.uky.edu. The University of Kentucky is an Equal Opportunity Employer. Minorities and women are encouraged to apply.
Contract Policy: Only the current President and Treasurer of the American Society of Transplant Surgeons is authorized to sign any contract or enter into any obligation of the Society including those with obligation of Society funds. All such contracts and other forms of obligation are to be submitted to the Society headquarters offices with recommendation from submitting person/committee for approval.