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CHIMERA

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ASTS 30TH ANNIVERSARY

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AMERICAN SOCIETY OF TRANSPLANT SURGEONS

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LETTER FROM THE p r e s i d e n t



Dear Friends,

As my term as President of ASTS comes to an end I can not believe how quickly the time has gone by but appreciate the fact that this is due to the many programs and activities ASTS has initiated and been involved with over the past months. I am truly appreciative of the hard work and dedication of my fellow ASTS colleagues who have made this year as successful for the Society as it has been. The ASTS Council, Committee Chairs and Committee Members along with the ASTS Membership are to be congratulated.

Since I last wrote to you we have completed our 4th Annual State of the Art ASTS Winter Symposium on “Surgical Challenges in Transplantation.” This was our best attended winter symposium ever. Adding to success of this program was the Fundamentals in Clinical Research in Transplantation Course held immediately prior to the Symposium. Over ninety of our newer Members and Fellows attended this course and benefited from the knowledge and experience of the presenters.

ASTS also had a very important meeting with staff of the CMS this year. You can read more about this meeting in the Washington Update in this issue of the *Chimera*. Nine Members of ASTS took the time to travel to Baltimore and meet with members of the CMS to discuss transplantation issues mainly involving standards for transplantation programs. It is very important to the transplantation community that government entities such as CMS are educated and aware of our programs and issues so that we can all work together for the benefit of our patients.

ASTS continues to work with the RUC and ACS to get more transplantation CPT codes added. This is a very tedious but beneficial process we must pursue. Again, the results of all our hard work will benefit our patients.

As we quickly approach the American Transplant Congress (ATC) I can not help but reflect on how this meeting has grown and become such an important part of the transplantation community. Again, I am proud of the hard work and efforts so many ASTS Members have contributed with our colleagues to allow the ATC to reach the level it has in such a short period of time.

I look forward to seeing you all at the ATC in Boston in May. It has been a pleasure and an honor to serve as your President this past year and I thank you for all your support, time and input.

Best Regards,

Abraham Shaked, MD, PhD
President

CHIMERA

The ASTS Council met on January 22, 2004 at Scottsdale, AZ. The following are from reports given at that meeting.

Standards for Transplantation Committee: This committee, chaired by Richard Freeman, has sent a survey on professional standards to ASTS Members. The rationale for the survey is: Multiple organizations have responsibility for development and promulgation of transplant surgeon and transplant program standards. In the past, the ASTS has participated in these processes in a reactive manner. At the ASTS strategic planning retreat and Council meeting in September, 2003, the Council voiced the opinion that the ASTS, in representing its membership, should take a more active role in the process. The survey is designed to ascertain the ASTS Membership's opinion regarding current standards, standard-setting entities, and whether and to what extent ASTS should involve itself in the development and implementation of transplant surgeon and/or transplant program standards.

Thoracic Committee Report: Mark Barr reported:

1. The Thoracic Committee worked 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. All speakers are Members of both the ASTS and the STS. As in the past, the meeting will be an opportunity to increase thoracic surgical membership to the ASTS.
2. The Thoracic Committee worked 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. The Thoracic Committee unanimously agreed to change the wording of the existing donor codes and to have a new set of CPT codes, including add-on codes that were submitted by Dr. Abecassis along with the other proposed changes.
3. The Thoracic Committee will be working with JCAHO on development of Medicare standards for facilities doing destination ventricular assist device implants. Becky has contacted JCAHO and they are pleased to work with ASTS.

Vanguard Committee: Sandy Feng reported on work in progress that included

The Database Project: Work of the Ad Hoc Database Workgroup Phase 1: Completed: Design and implementation of an electronic membership application to enable easy transfer of demographic and research activities / interests / expertise into a database.

Phase 2: Create mechanism to enable pre-existing members to UPDATE their personal profile. For those who do not update, their profile will be updated manually. Anticipate implementation Spring 2004


Phase 3: Create "ASTS-PUBMED" search capability to enable members to identify other members with specific expertise. Research Phase: Fall-Winter 2003; Implementation: Spring-Summer 2004

Transplant Fellowship Match: Joint venture with the ASTS Education Committee

Vanguard Prospectus The third issue of the Vanguard Newsletter, the Vanguard Prospectus, was distributed in September 2003. We anticipate the fourth issue to be distributed in February 2004.

New Initiatives will include:

Develop a Vanguard Page on the Website: Features could include:

- “Mentor Match”
Create an interface for Junior ASTS members to access mentorship or advice. Ultimately, the Vanguard Committee would like to identify senior ASTS members willing to interact with Candidate or Junior Members. Using information, much of which will be collected via the Database project, profiles detailing their professional status and research interests would be provided so that junior members can then select those whose they think may be best able to answer their specific query. Alternatively, junior members may pose their question to the Vanguard Committee who can then “direct” the question to appropriate senior ASTS members.
- “Fellowship News”
Post information regarding ASTS-certified fellowship programs
 - i. Details of ASTS certification
 - ii. Description of fellowship solicited from programs
 - iii. Openings
- “Chat Room”
Provide an informal venue for junior members to communicate
- Resource Links
 - i. Career Development
 - ii. Educational Materials 

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The flurry of legislative activity in late 2003 has given way to a relative period of calm in early 2004. Still, a number of developments important to ASTS members have occurred that are worthy of note. The final enactment of a landmark Medicare reform and prescription drug bill, which included a physician payment increase of 1.5% and a new Medicare drug benefit, could reveal many new implications for the practice of transplantation as the regulations implementing this legislation are drafted.

With Medicare legislation completed, Congress appears to be taking greater steps in 2004 to reform the Medicaid program. Although Medicaid reform is not expected to be enacted this year, efforts underway by Congress and the Bush Administration are certain to alter the future of the program. President Bush mentioned Medicaid reform in his January 20, 2004, State of the Union address and included several controversial proposals in his Fiscal Year 2005 budget that could impact Medicaid throughout the country. In addition to implementation of the Medicare bill and Medicaid reforms, ASTS is also actively engaged on securing final passage of the organ donation legislation. With passage expected soon, ASTS is mounting a proactive strategy to secure Congressional appropriations funding for the organ donation bill's programs.

The last issue of the Chimera featured a detailed description of the major provisions in the Medicare bill impacting ASTS members, such as the physician fee schedule increase. A separate article describing the implications of the bill on immunosuppressive drug coverage is included in this issue.

ASTS Sets 2004 Priorities

At the ASTS Winter Meeting, ASTS approved an action plan to implement the policy objectives outlined by the Legislative Committee and ASTS Council in 2004. Action on the items described below is well underway:

Organ Donation Bill—The organ bill is currently awaiting final passage in the House of Representatives. The ASTS-supported bill passed the Senate on November 25, 2003. Absent addition-

al procedural delays, which may in fact occur, the bill is expected to pass early in the Second Session of the 108th Congress and move to President Bush for his signature. Leading up to and upon enactment, ASTS will press the Bush Administration to hold a high-profile event commemorating passage of the bill. ASTS will also aggressively push for appropriations to fund the new law in Fiscal Year 2005, which begins October 1, 2004. In addition, ASTS will begin to identify, coordinate, and facilitate grant opportunities for funding ASTS-led projects under the bill.

Building Relationships with Policymakers—ASTS will begin to more actively engage its members to develop better relationships with key Washington policymakers. Not only will ASTS need to engage key decision

makers to ensure full funding of the organ donation bill, but other issues impacting transplantation will no doubt necessitate greater involvement of ASTS members directly with their representatives. ASTS will implement a plan of action designed to familiarize select ASTS members with the legislative process, the relevant legislative and regulatory priorities of the society, and the relevant policymakers that address these issues.

The ASTS Legislative Committee is planning to develop a survey of ASTS members to assess the level of interest in creating a Legislative Education Network and/or “Fly-In” Legislative Conference at some point in the future. If significant interest exists, ASTS would use the network or conference to further educate ASTS and Congressional members on transplant policy issues.

Medicare Prescription Drug and Reform Law—ASTS will continue its proactive strategy of education and advocacy on the implementation of the Medicare Reform and Prescription Drug legislation enacted in December 2003. This priority includes continuing to seek out legislative opportunities to improve the recently-enacted Medicare law, for instance, in the area of Part B immunosuppressive drug coverage. (See related story for an explanation of coverage for immunosuppressive drugs under the Medicare law.)

As part of the ongoing implementation of the law, ASTS will closely monitor federal regulations and submit written comments as appropriate. For policy issues that directly and seriously impact transplant surgeons, ASTS will develop a specific strategy and engage ASTS members to advance ASTS’s position proactively in Congress and/or the Administration.

The Administration’s Health Care Agenda for 2004

In addition to Medicare reform implementation, the President’s State of the Union Address outlined many of the Administration’s other health policy priorities, particularly addressing Medicaid reform, the approximately 44 million uninsured Americans, and medical malpractice reform.

Medicaid Reform in 2004—While the overall consensus on Capitol Hill is that Medicaid reform legislation is not likely to be enacted this year, consideration of a wide-ranging Administration-endorsed reform proposal will likely occur later this year. As evidenced in the State of the Union speech and in the past two budget proposals, the Administration continues to express its concern over the rising costs of the Medicaid program and seems to be making both behind the scenes and public moves toward the highly controversial system of “block grants” and consolidated Medicaid funding streams.

These initiatives, if successful, would eliminate the entitlement under the current system for states to receive federal matching funds for all or most of the states’ Medicaid expenditures. Although low Medicaid reimbursement is often a reality in current state Medicaid systems, a consolidated block grant system could potentially require states to fund more of the cost of providing Medicaid services and thus cut benefits and reimbursement further.

Rumors that now appear valid, have floated around for months that New Hampshire, likely followed by Florida and possibly Colorado, have made agreements with the Federal government involving forgiveness of

Medicaid debts in exchange for agreeing to what amounts to a block grant system in future years. This type of “back-door” approach bypasses Congress and often state legislatures, allowing the Bush Administration to negotiate directly with the governors and state Medicaid directors.

Further Medicaid controversy has surfaced as CMS has signaled an interest in “predetermining” states’ Medicaid budgets. The new policy, if implemented, would require states to receive prior federal approval for each source of revenue that would be used to cover the states’ share of Medicaid costs. Currently, states collect federal matching funds for Medicaid costs after their budget has been established. Health care observers have speculated that additional administrative burdens associated with the potential CMS predetermination policy could be used as an effort to frustrate states to the point of agreeing to limits on federal Medicaid funding; i.e. block grants. Over the short term, the policy could also place states in the position of potentially receiving less Medicaid matching funds than they would otherwise receive under the current budget reporting policy.

Health Savings Accounts—During his January 20th speech, President Bush called for expansion of the Health Savings Accounts, enacted within the context of the Medicare bill, to all Americans. Health Savings Accounts would allow individuals to set aside savings, tax-free, to help pay for medical expenses out-of-pocket until such time as a high-deductible health plan would apply.

President Bush demonstrated his faith in the program by proposing that individuals be able to deduct the full cost of their high deductible or cata-

At the ASTS Winter Meeting, ASTS approved an action plan to implement the policy objectives outlined by the Legislative Committee and ASTS Council in 2004.

strophic health insurance policy from their individual HSA. Supporters believe that such an expansion would make coverage more affordable for those who do not receive coverage through their workplace.

Opponents fear that such a policy could prove to be ineffective for low-income patients by favoring higher initial out-of-pocket costs in addition to insurance premiums for high-deductible policies. Furthermore, the proliferation of such health insurance policies could potentially cause other traditional health insurance providers to increase their coverage deductibles and/or employers to drop existing low-deductible coverage.

Health Insurance Tax Credits—The president has proposed a refundable tax credit for low-income workers in order to help them purchase health insurance. These tax credits, which have been proposed at up to \$3000 per family, enjoy bipartisan support; however, efforts to enact them have proven unsuccessful to date.

In a recent hearing, House Ways and Means Committee Chairman William Thomas (R-CA) stated that these health care tax credits might not be appropriate due to the current budget deficit and the potential drain an effective program would have on the government. Critics of these tax credits claim the amount of the credit is insuf-

ficient to purchase adequate health insurance coverage.

Association Health Plans—The President has also asked Congress to support legislation that would permit Association Health Plans (AHP), which would provide small and medium sized businesses the opportunity to join with other similar businesses under umbrella, group health plans.

Ideally, AHPs would increase coverage and lower health insurance costs to employers who might not otherwise be able to purchase coverage. However, negative reaction to this legislation points to the possibility that without state insurance regulation, AHPs would be free to exercise risk selection, thereby leaving high-risk individuals with exorbitant premiums and deductibles.

Medical Malpractice Reform—Resurrecting the issue of medical malpractice reform, which stalled in the Senate last year, President Bush and many in Congress continue to blame rising health care costs, in part, on “wasteful and frivolous” lawsuits against physicians. While medical malpractice legislation is high on the priority list for many physician groups, including ASTS, many, including trial lawyers and consumer groups, aim to oppose the bill. Despite significant support for such legislation, which

would cap non-economic damages at \$250,000, Senate leaders do not anticipate passage of a bill this year.

Fiscal Year 2004 Appropriations and the President's 2005 Budget Proposal:

On February 2, 2004, President Bush released his FY 2005 budget proposal that established funding levels for all federal government programs. This came very soon after the final appropriations bills for FY 2004 were enacted on January 27, 2004.

The total FY 2005 Administration request is for \$2.4 trillion. Not counting mandatory spending such as Medicare, Medicaid, and Social Security, the portion of the budget which is subject to annual appropriations totals \$818 billion, an increase of 4.1 percent over FY 2004. This, however, does not include the costs for ongoing operations in Afghanistan and Iraq. If the 2005 budget is adjusted for those additional factors, the Administration is actually proposing a 6.3 percent cut in discretionary spending. Further, the FY 2005 request does not include the incremental amounts generally expected to be required for Middle East conflicts.

Total spending for the Department of Health and Human Services would increase 5.8 percent to \$580 billion under the FY 2005 budget

ASTS is engaged on multiple fronts in 2004 with the implementation of the Medicare bill, Medicaid reform, and securing passage and funding for the organ donation legislation.

proposal. Although the budget does not officially mention a Medicaid reform plan, the one described in last year's budget is still up for consideration this year. The Bush proposal would generally offer greater "flexibility" and cap federal funding to states. The Budget does propose this year to end Medicaid's "upper-payment limit," or the maximum amount that states may pay local government-owned hospitals through Medicaid.

National Institutes of Health Budget—Under the 2005 budget, the National Institutes of Health (NIH) would receive a 2.7 percent increase, which is much lower than 6 to 7 percent increases in previous years. The NIH was funded at \$28.044 billion in FY 2004 and the FY 2005 budget proposes funding at \$28.773 billion. Within the NIH budget, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) received a 2.96 percent increase from \$1.822 billion in FY 2004 to \$1.876 billion in FY 2005. Funding for CDC would drop to \$4.1 billion from \$4.5 billion, but with an increase in biodefense spending.

Health Resources and Services Administration Budget—HRSA funding took a major overall cut from \$6.7 billion to \$6.0 billion, mostly from health professions and public health

improvement programs. HRSA's Division of Transplantation, however, received level-funding of \$25 million in FY 2004 and in the President's FY 2005 Budget. ASTS will be making a major effort to increase this level given the expected enactment of the organ donation legislation.

Agency for Healthcare Research and Quality Budget—The Agency for Healthcare Research and Quality (AHRQ) is proposed to receive level funding at \$327 million in the President's FY 2005 Budget. Although AHRQ is slated to receive level funding, funding for projects related to the Medicare bill has lowered the budgets for other AHRQ programs in general. The Agency was established in 1990 to promote improvements in clinical practice and patient outcomes, promote improvements in the financing, organization, and delivery of health care services, and increase access to quality care. AHRQ is slated in the organ bill to research translating organ recovery research into practice.

Over the past several appropriations cycles, only Defense and Military Construction appropriations bills have typically been approved under regular Congressional rules. Given that 2004 is an election year and that the Bush budget calls for many cuts in popular programs, it is unlikely that enactment of FY 2005 appropriations will occur

prior to the election and could possibly stretch into calendar year 2005. In this event, Congress will be required to enact continuing resolutions (CR's) to keep government agencies from shutting down.

Conclusion

ASTS is engaged on multiple fronts in 2004 with the implementation of the Medicare bill, Medicaid reform, and securing passage and funding for the organ donation legislation. Although the Medicare law is in the process of implementation, many new Medicare regulations are likely to impact transplantation in the future, including coverage of immunosuppressive drugs. ASTS will continue to monitor Congress and federal agencies and engage ASTS members as appropriate to ensure that transplant surgeons and their patients are not negatively impacted by the new Medicare law or other legislative activity in the future. ✎

Prepared by Peter W. Thomas, Esq., ASTS Legislative Counsel; and Dustin W.C. May, Legislative Director, Powers, Pyles, Sutter, and Verville, PC.

Spotlight on Immunosuppressive Drug Coverage under Medicare: Frequently Asked Questions

Immunosuppressive drugs are currently covered under Medicare Part B for most, but not all Medicare beneficiaries. Coverage is complex and depends on many factors, including but not limited to Medicare eligibility (ESRD or aged/disabled), Medicare eligibility at the time of transplant, and/or whether the transplant was performed in a Medicare-approved facility.

Immunosuppressive drug coverage under the new Medicare law becomes even more complex with the implementation of a drug discount card in June 2004 and the Medicare drug benefit in January 2006. In addition to the discount card and the drug benefit, changes in reimbursement for immunosuppressive drugs may cause access problems for some Medicare beneficiaries whose pharmacies and/or hospitals elect not to dispense immunosuppressive drugs.

The following is a series of major questions about the Medicare law, immunosuppressive drug coverage, and how the new drug benefit will impact transplant recipients.

Does the Medicare reform law change current Part B immunosuppressive drug coverage?

No, Medicare Part B coverage for immunosuppressive drugs will stay the same for all transplant recipients. ESRD beneficiaries receiving a kidney transplant are still limited to 36 months of Medicare coverage and all other transplants will not see Part B coverage change.

The new Medicare drug benefit is separate from Medicare Part B coverage and will cover some costs of drugs not covered through Part B.

What is a transplant recipient's financial responsibility for immunosuppressive drugs under Medicare Part B?

Under current law, during implementation of the new law, and after its implementation, Medicare Part B will pay for 80 percent of the cost of immunosuppressive drugs for beneficiaries eligible for coverage.

Immunosuppressive drugs can exceed \$10,000 to \$20,000 per year for a transplant recipient and unless the recipient is on Medicaid or has supplemental insurance, the beneficiary is still responsible for \$2,000 to \$4,000 per year in coinsurance. Despite the high cost of coinsurance for some, Medicare coverage is essential to ensuring full patient compliance with immunosuppressive therapy, thus preventing rejection episodes, additional hospitalization, and the need for retransplantation.

Which drugs are eligible for immunosuppressive drug coverage under Medicare?

Part B coverage is limited to the following specifically labeled immunosuppressive drugs that the FDA has identified and approved for marketing: Sandimmune

(cyclosporine), (oral or parenteral form); Imuran (azathioprine) (oral); Atgam (antithymocyte/globuline) (parenteral); Orthoclone (OKT3 (muromonab-CD3), (parenteral)); Prograf (tacrolimus), Cellcept (mycophenolate mofetil), Daclizumab (Zenapax), Cyclophosphamide (Cytoxan), Prednisone, and Prednisolone.

Does Medicare currently cover any other outpatient drugs commonly used by transplant recipients?

All other drugs commonly prescribed post-transplant to treat pain or co-morbidities are not currently covered by Medicare Part B.

These drugs will receive some discounts under the drug discount card beginning in June 2004 and limited Medicare coverage under the new Part D drug benefit in January 2006.

Under what conditions are transplant patients excluded from coverage?

Some potential transplant recipients may be unaware that they can receive Medicare coverage for their immunosuppressive drugs or they may mistakenly assume that they will be covered. For many middle- or low-income patients, the prospect of paying out-of-pocket for these drugs can mean the difference between moving forward with a transplant, declining an available organ, facing increased chances of rejection due to non-compliance, or simply managing their condition without a transplant.

For renal transplant patients (and pancreas transplants performed concurrent or subsequent to renal transplants) whose Medicare status is based solely on their ESRD status, Medicare coverage—including immunosuppressive drugs—will last only 36 months from the date of transplant.

Patients unable to afford immunosuppressive drugs after their Medicare drug coverage expires potentially face rejection or retransplantation. After 36 months, these ESRD beneficiaries are not eligible for any new benefits enacted under the Medicare reform law and will not receive any coverage from Medicare unless they qualify for Medicare due to age or disability subsequent to the transplant.

For pancreas, heart, liver, and lung transplants, a patient can be excluded from Medicare coverage for immunosuppressive drugs if one or more of the following conditions are met:

- The transplant was performed when the recipient was not eligible for Medicare (ESRD, age, or disability).
- Regardless of whether the recipient was Medicare eligible at the time of transplant, the beneficiary will be excluded if the transplant was performed in a non-Medicare-approved facility.
- If a pancreas transplant is performed prior to a kidney transplant while this person is ESRD-eligible, Part B coverage for immunosuppressive drugs will not be available until discharge following the kidney transplant.
- Pancreas-only transplants are excluded from coverage under Medicare and, therefore, beneficiaries are not eligible for immunosuppressive coverage.

Why are some transplant recipients excluded from coverage for immunosuppressive drugs or have their coverage expire?

Medicare first recognized the need to cover immunosuppressive drugs in 1986 with a one-year coverage period of cyclosporine for kidney transplants. Medicare has subsequently expanded coverage over time to cover immunosuppressives for successively longer periods of time and for additional types of transplants. Most recently, Congress recognized the need to fill some gaps in coverage for immunosuppressive coverage with enactment of the Balanced Budget Refinement Act of 1999 and the Benefits Improvement and Protection Act of 2000. These laws removed the 36 month time limit on immunosuppressive coverage for all transplants.

Congress failed, however, to ameliorate all Medicare coverage limitations in the 1999 and 2000 bills and did not include ASTS-supported language in the 2003 Medicare

reform law that would have provided coverage for all medically necessary immunosuppressive drugs. As a result, Medicare continues its policy of covering immunosuppressive drugs only for patients who had their transplant reimbursed for by Medicare. Generally, if Medicare did not cover the transplant, immunosuppressive drugs will not be covered. In the case of ESRD Medicare patients, their immunosuppressive coverage expires along with their Medicare coverage after 36 months.

Immunosuppressive drug coverage under the new Medicare law becomes even more complex with the implementation of a drug discount card in June 2004 and the Medicare drug benefit in January 2006.

What is the transitional Medicare drug discount card?

Until the implementation of a full Medicare drug benefit for beneficiaries in 2006, Medicare will administer a drug discount card program to provide discounts of approximately 10-20% to all Medicare beneficiaries who enroll in a card program. The enrollment process will begin in May of 2004 and the card program will last until the prescription drug benefit becomes available in January 2006. Subsidies up to \$600 per year are available for beneficiaries under 135% of the poverty line.

How will the discount card impact transplant recipients eligible for Part B immunosuppressive drug coverage?

For transplant recipients *eligible* for immunosuppressive coverage under Part B, the discount card will not apply to Part B-covered drugs, but will provide 10-20% off retail prices

for outpatient drugs prescribed for pain or co-morbidities. The discount card is intended to “wrap around” Part B immunosuppressive coverage.

It should be noted, however, the discount cards will achieve discounts by limiting access to drugs specifically on a formulary, thereby driving consumers to a select number of alternatives at reduced prices. Thus, transplant recipients should review the different versions of these cards that become available to see which one provides the greatest discount on their non-covered outpatient drugs.

How will the discount card impact transplant recipients *NOT eligible* for Part B immunosuppressive drug coverage?

Transplant recipients *not eligible* for immunosuppressive coverage under Part B (because of coverage exclusions) can use the Medicare discount card for discounts on most pain/co-morbidity medications, but they will not likely receive discounts on many immunosuppressive drugs.

Although discount card formularies are required to include at least one or more immunosuppressive drugs in this therapeutic class, the formulary is not likely to include immunosuppressive drugs covered by Part B unless they are commonly used to provide non-transplant related immunosuppression. This is due to the fact that the discount card statute specifically states that the discount card is intended to “wrap around” existing Medicare Part B coverage. In its haste to publish a regulation following the passage of the Medicare law, CMS did not recognize the fact that some Medicare eligible transplant recipients do not have coverage for immunosuppressive drugs under Part B. ASTS will work with CMS in the future to insure that they are aware of and fill gaps in coverage.

Will immunosuppressive coverage change in 2006 when the Medicare drug benefit is implemented?

No, Part B immunosuppressive coverage will remain distinct from the Medicare drug benefit.

However, CMS is required to study the implications of moving existing coverage of all drugs covered under Part B into the new Part D drug benefit and make recommendations to Congress. While this study required monitoring, it will still require a Congressionally-mandated change in Medicare benefits to incorporate current Part B immunosuppressive drug coverage into Part D.

What is the new Medicare drug benefit?

Beginning in 2006, all Medicare beneficiaries (including beneficiaries with End Stage Renal Disease) will have the

option to purchase private, “stand alone” drug coverage at the following benefit levels:

- Separate from Part B immunosuppressive drug coverage
- A new “Part D” Benefit
- With monthly premiums of approximately \$35 per person
- With a \$250 annual deductible
- With 75% coverage from \$251 to \$2,250 in combined total drug costs
- \$3,600 in out-of-pocket catastrophic coverage
- A “gap” in coverage—\$750 in out-of-pocket costs up to the \$2,250 benefit limit, the beneficiary must spend an additional \$2,850 on drugs before reaching the out-of-pocket limit
- 5% coinsurance on all drug costs after the \$3,600 limit is reached
- Coverage limits start new every year

How will the Part D drug benefit impact transplant recipients *eligible* for Part B immunosuppressive drug coverage?

For transplant recipients *eligible* for immunosuppressive coverage under Part B, the drug benefit will provide some coverage for outpatient drugs prescribed for pain or co-morbidities.

It should be noted, however, that the drug benefit will limit access to these drugs specifically based on a formulary. Thus, transplant recipients should closely review the drug benefit plans available to them to see which one provides the best coverage for their particular drugs.

How will the drug benefit impact transplant recipients *NOT eligible* for Part B immunosuppressive drug coverage?

Transplant recipients *not eligible* for immunosuppressive coverage under Part B (because of coverage exclusions) are likely to receive some coverage for immunosuppressive drugs and coverage of most pain/co-morbidity medications.

Since regulations have not yet been published on the drug benefit, the impact on transplant recipients is unclear at this time. However, ASTS will work to ensure that the drug benefit covers as many medically necessary immunosuppressive drugs as possible. In addition, the use of formularies and generic substitution will likely become a major issue as the drug benefit is implemented.

ASTS will work to ensure that the drug benefit covers as many medically necessary immunosuppressive drugs as possible.

Will out-of-pocket spending for Part B-covered immunosuppressive drugs count toward the Part D drug benefit cost-sharing or catastrophic limit?

No, transplant recipients receiving Part B coverage for immunosuppressive drugs will not be able to count their 20% coinsurance toward their Part D benefit spending.

Will immunosuppressive drugs be subject to a formulary under the new drug benefit in 2006?

Part B coverage will not be subject to a formulary.

Only Medicare beneficiaries not eligible for Part B immunosuppressive drug coverage are subject to a formulary for coverage of immunosuppressive and other outpatient medication. It is unclear at this point which specific drugs the Part D benefit formularies will cover.

Are there changes to reimbursement for immunosuppressive drugs under Medicare Part B that can cause access problems to these drugs?

Due to changes in reimbursement for Part B immunosuppressive drugs, some transplant recipients may encounter difficulty receiving access to their immunosuppressive drugs from a particular pharmacy. This situation will likely be temporary, though, and will be offset slightly by savings on patient coinsurance.

Currently immunosuppressive drugs are reimbursed based on the Average Wholesale Price (AWP) system. Under the Medicare reform law, reimbursement under the AWP system was reformed in several ways that generally lower reimbursement for the drugs themselves and lower dispensing fees for pharmacists, at least temporarily. Generally, this may cause some temporary access problems for patients seeking immunosuppressive drugs from some pharmacies, usually non-chain pharmacies. However, there are other

impacts from AWP reform, such as lower coinsurance for beneficiaries that can be viewed as “positive” developments, especially by patients.

In 2004, reimbursement for immunosuppressive drugs was lowered to 85% of AWP from the previous 95%. (This is for brand name, sole source drugs. But all drugs, both multiple source brand and generic, are similarly reduced). As a consequence of lower reimbursement and a decision by CMS in 2004 to “bundle” pharmacy dispensing fees into AWP reimbursement, pharmacies may opt to stop providing access to immunosuppressive drugs (and other drugs provided through Part B as well). CMS may change the bundling policy over the summer of 2004, but it is unclear if and/or when this will occur.

Furthermore, under the Medicare bill, the current 2004 AWP reimbursement structure will change again in 2005 with a move to a new pricing structure based on “average sales price.” Overall, this will mean further cuts in reimbursement for Part B drugs, but since CMS should have adequate dispensing fee data to unbundle pharmacy payments by then, access problems should be ameliorated.

Although AWP reform could mean temporary access problems for some transplant beneficiaries requiring immunosuppressive drugs, the lower reimbursement for such drugs will also mean lower coinsurance for transplant recipients since they pay a percentage of the total cost of the drug. ❧

For more information Please visit the ASTS website at <http://www.asts.org> to view a chart detailing new immunosuppressive drug coverage under the Medicare bill.

Prepared by Peter W. Thomas and Dustin W.C. May at Powers, Pyles, Sutter & Verville P.C.

Regulatory and Reimbursement Update

Over the past several months, ASTS has continued to be involved in a number of initiatives to improve reimbursement for transplant and related services. These include efforts to improve payment for transplant surgeons' professional services as well as hospital services. In addition, ASTS has engaged the Centers for Medicare and Medicaid Services (CMS) in ongoing discussions about upcoming government activities related to transplant reimbursement and coverage.

Medicare Payment for Professional Services

In the Fall Chimera Update we reported that ASTS was successful in convincing CMS that the use of standardized clinical labor time (e.g. nurse time) that is applied to other surgical procedures was not appropriate for transplant services and that increased staff time was necessary because of the special needs of transplant patients and living donors. In addition, CMS also agreed with the ASTS position that the appropriate physician clinical staff to deliver services to transplant patients was an RN. As a result, some of the payment reductions that had been proposed earlier in the year were rescinded in the final 2004 Physician Fee Schedule.

This year, ASTS is continuing to pursue increased Medicare payment for transplant surgeons' practice expenses for both pre and post-surgical non-physician staff services. ASTS's request for increased staff time will be considered at the PEAC's April, 2004 meeting.

Medicare Payment for Immunosuppressive Drugs

The good news is that Medicare payment for immunosuppressive drugs furnished in hospital outpatient departments increased significantly as the result of the Medicare Prescription Drug, Improvement and Modernization Act (the Act). The bad news is that Medicare payment for the cost of immunosuppressive drugs furnished in physicians' offices and clinics will decrease as the result of different provisions of the same Act.

With respect to drugs furnished in hospital outpatient departments, Section 621 of the Act requires that, during CY 2004, certain sole source drugs, including many injectable and intravenous immunosuppressive drugs, be reimbursed at no less than 88 percent and no more than 95 percent of the average wholesale price (AWP). Previously, reimbursement was based on historic hospital charges, which generally did not capture the full cost of the drugs involved. These underpayments had long been a source of concern to ASTS, which submitted comments to CMS in 2002 and 2003 urging that payment for these drugs be increased. Congress apparently agreed with ASTS' position and has done what CMS failed to do.

The following table illustrates the dramatic increases in reimbursement between 2003 and 2004 for selected immunosuppressive drugs.

Drug/Code	2003 Payment Rate	2004 Payment Rate
Muromonab-CD3 OKT3: J7505 (5 mg)	\$362.82	\$792.33
Antithymocyte immune globulin Atgam (equine): J7504 250 mg	\$174.34	\$258.17
Antithymocyte immune globulin (Thymoglobulin) (rabbit) (25 mg): J 7511	\$137.45	\$331.23
Cytomegalovirus immune globulin Cytogam: J0850 (per 2.5 g. vial)	\$247.11	\$659.60
Filgastrin 300mcg GCSF: J1440	\$109.66	\$172.20
Filgastrin 480mcg GCSF: J 1441	\$168.28	\$290.93

In 2005, reimbursement will decrease but cannot go below 83% of AWP. Beginning in 2006, there will be a new reimbursement schedule for drugs administered in the hospital outpatient department that will be based on acquisition costs as determined by a Government Accounting Office (GAO) study. ASTS will discuss with the GAO the need to ensure that immunosuppressive drugs are properly reimbursed, to ensure that the GAO report ultimately does not result in reinstatement of the inadequate payment rates in effect in 2003 and earlier.

At the same time that payment to hospitals for immunosuppressive drugs has increased, payment to physicians who administer the same drugs in their offices is being reduced. The Act requires that most drugs furnished in the office be paid at 85% of the average wholesale price (AWP) during 2004—down from 95% of AWP in previous years. Some drugs that GAO has identified as overpaid in the past—including Filgastrin—are now paid at an even lower percentage of AWP though payment cannot go below 80% of AWP. The table below shows 2004 allowable rates for selected immunosuppressive drugs. These amounts include the required 20% copayment.

Drug/Code	2004 Payment Rate	% of AWP
Antithymocyte immune globulin Atgam (equine): J7504 250 mg	\$249.36	85%
Antithymocyte immune globulin (Thymoglobulin) (rabbit) (25 mg): J 7511	\$319.94	85%
Cytomegalovirus immune globulin Cytogam: J0850 (per 2.5 g. vial)	\$637.12	85%
Filgastrin 300mcg GCSF: J1440	\$158.50	81%
Filgastrin 480mcg GCSF: J 1441	\$267.95	81%

ASTS has submitted written comments to CMS expressing its concern with the sudden decrease in payment to physicians who provide immunosuppressive drugs to patients in the office, raising significant concerns about patient access, especially for those who reside outside of large metropolitan areas.

In 2005 and beyond, Medicare payment reimbursement will be based on the average sales price (ASP) plus 6%. The calculation of ASP is subject to significant agency discretion and will be the subject of upcoming proposed rules. ASTS will continue to monitor this issue closely and will be submitting comments to CMS as appropriate.

Transplant Center Regulations

On February 9, 2004 ASTS leadership met with Sean Tunis, M.D., Director of CMS' Office of Clinical Standards and Quality and several other CMS staff members to discuss the development of new conditions of participation for Medicare-certified transplant centers. Also in attendance was James Bowman, M.D., a CMS physician advisor and a transplant surgeon. The meeting presented an excellent opportunity for ASTS leadership to become acquainted with high-level CMS staff and to engage in a discussion of current issues in transplant policy.

Although CMS staff was not permitted to discuss the specific content of the transplant center regulations that are under development, ASTS did learn that new conditions of participation for Medicare certified transplant centers likely will be published in proposed form in May of this year. When finalized, these conditions of participation will replace the current standards for transplant center certification, which for the most part have not been codified in regulations.

CMS is also developing new standards for organ procurement organizations and ESRD facilities. The agency expects that all three proposed rules will be issued around the same time followed by a public comment period. CMS staff expressed interest in meeting again with ASTS after publication of these proposed rules to engage in a more substantive discussion of the rule's content and to obtain ASTS' recommendations. ASTS will be monitoring the development of these three rules and, once they are published, will be analyzing their effect and responding appropriately.

OIG Transplant Center Audits

In its 2004 Work Plan, the Office of the Inspector General (OIG) announced its intent to target hospitals' organ acquisition centers for audit. ASTS has learned that the audits are being coordinated by the OIG's California office. While the OIG is prohibited from engaging in discussions about any particular audit, ASTS did learn that OIG intends to audit at least two transplant centers in each of the OIG's ten regions around the country. Some transplant centers may first be "surveyed" by the OIG and, if no problems are identified, the audit will not proceed any further. As of January, 2004, eleven centers were undergoing audits or surveys and additional centers were in the process of being identified. If a center undergoes a formal OIG audit, it is given an opportunity to respond to the audit findings in writing. The OIG's report and the facility's response are then posted on the OIG website.

OIG staff stated that the audits are focusing primarily on the appropriateness of hospital allocation of personnel and overhead (e.g. G & A costs) to the organ acquisition cost center. However, OIG also noted that if the auditors find problems in transplant center relationships with physicians, these will be fully investigated. (In this regard, it is important to keep in mind that the 2003 San Diego Hospital Association and Sharp Memorial Hospital settlement of allegations of False Claims Act violations involved improper payments by the hospital to transplant center physicians. Therefore, it would not be surprising if transplant center relationships with physicians come under scrutiny during the audit process.)

If the OIG determines that organ acquisition costs were improperly stated on the hospital's cost report and that overpayments were made, the OIG likely will refer the case to the fiscal intermediary for determination of the overpayment amount and recoupment. However, if there is evidence of fraud, the OIG may step up its investigation or even refer the matter to the U.S. Attorney's office.

ASTS will continue to monitor OIG activity in this area and will keep members informed of any developments. ✎

Prepared by Diane Millman, Esq., and Rebecca Burke, Esq., Powers, Pyles, Sutter, and Verville, PC.

Transplant Centers Receive OIG Scrutiny

By Rebecca L. Burke, Esq.

Powers Pyles Sutter & Verville, P.C. Washington D.C.

The Office of Inspector General (OIG)'s 2004 Work Plan announced an audit of organ acquisition costs as reported in hospital cost reports. This audit is already well underway and is focusing on transplant centers in each region of the country. The OIG's California office is coordinating the audit which is focusing on whether hospitals are properly classifying costs to the organ acquisition cost center. Although OIG staff stated that physician compensation relationships with transplant centers are not receiving particular scrutiny in the audit, the recent settlement in the case of Sharp Memorial Hospital and the San Diego Hospital Association (discussed below) indicates the OIG is certainly aware of the fraud and abuse issues surrounding physician relationships with transplant centers.

Discussed below are the basic rules of Medicare reimbursement for organ transplants as well as some of the more complex issues that arise in reporting of hospital organ acquisition costs. Also discussed are some of the recent government initiatives in the area of organ transplantation.

Organ Transplantation is Big Business

The U.S. organ transplantation market was approximately \$4.2 billion in 2002 and is expected to reach \$5.4 billion by 2007. Last year 24,833 solid organ transplants were performed at over 250 transplant centers. Meanwhile, thousands of patients remain on waiting lists for organ transplants. Kidney transplants represent about 59% of solid organ transplant procedures most of which are paid for by Medicare under the End-Stage Renal Disease (ESRD) benefit. Considering the number of transplants that are paid with federal healthcare dollars, it is no wonder that organ transplantation reimbursement has the OIG's attention.

Reporting of Organ Acquisition Costs

When Medicare began paying hospitals for inpatient services on a prospective payment system (PPS) through the use of diagnosis-related groups or DRGs, organ acquisition costs were one of the few areas to be excluded from the PPS payment and continue to be reimbursed on a reasonable cost basis. Consequently there is an incentive for a hospital to maximize its costs in this area. As a result, Medicare has adopted regulations and issued guidance which is intended to define and narrow the types of costs that can be allocated to the organ acquisition cost center. For example, only costs associated with activities that take

place before a transplant are includible in organ acquisition costs. Costs associated with the actual transplant, including post-transplant services, are intended to be paid through the applicable DRG. The OIG audit is examining whether hospitals have improperly allocated costs to the organ acquisition cost center which should be paid under the DRG payment.

What Costs Are Considered Organ Acquisition Costs?

Medicare will make Part A payments for both direct and indirect costs of organ acquisition. Direct costs, which are accumulated in the organ acquisition cost center on Worksheet A of the Medicare cost report, are those costs directly related to organ acquisition. Indirect costs, which are transplant center overhead costs, are accumulated in the general service cost centers and allocated through the cost report "stepdown" process on Worksheet B.

What types of costs are considered "direct costs?"

Direct costs that can be allocated to the organ acquisition cost center are:

- ◆ Personnel costs (e.g. salaries) for procurement coordinators, nurses, administrative and support staff, medical directors and social workers/financial coordinators and others;
- ◆ Costs associated with the operating room and other inpatient ancillary services for a living donor, including anesthesia and post operative services;
- ◆ Costs of hospital outpatient services furnished to donors and recipients prior to admission (including lab tests and general medical evaluations);
- ◆ Costs of registration fees paid to the United Network of Organ Sharing (UNOS);
- ◆ Costs of tissue typing, including when done by an independent laboratory;
- ◆ Costs of cadaver organs obtained from organ procurement organizations;
- ◆ Transportation and preservation of organs; and
- ◆ Postoperative hospital services provided to live donors for complications from donation.

How Should Personnel Costs be Allocated?

This is one of the more complicated areas of cost reporting, partly because it requires detailed documentation. It is also an area that the OIG is focusing on in its audits of transplant centers. First, separate cost centers must be maintained for each type of organ. If part of an employee's time is spent providing services to, for example, the kidney transplant cen-

ter and part to the cardiac transplant center, the salary of that employee must be allocated to each cost center in proportion to the employee's time spent providing services to each. Time records or studies must support the hospital's allocation. Sometimes a number of organs are procured at the same time from a single cadaver which makes allocation to the proper organ transplant center especially complicated. Unfortunately, Medicare has not issued instructions or guidance on how to treat such situations.

Second, where an employee's time is split between organ acquisition services and other services, time records must establish what part of the employee's time is devoted to organ acquisition. For example, if an employee's job description involves services that are provided both before and after transplant, the hospital must keep time records to justify its allocations. This area of cost allocation is a focus of the current OIG audit and was also an issue in the OIG's recent audit of Tampa General Hospital in Florida and in the settlement with Sharp Memorial Hospital.

What rules apply to physician services?

Physician costs that can be included in organ acquisition costs include:

- ◆ all donor and recipient preadmission physician transplant evaluation services;
- ◆ laboratory services such as tissue typing;
- ◆ the surgeon's professional fees for excision of an organ from a cadaver;
- ◆ pre-admission laboratory and electroencephalography services;
- ◆ services of residents and interns not in approved teaching programs.

Medicare rules provide that the reasonable cost of a cadaver kidney excision is \$1250; however Medicare has not established any limits on reasonable costs for excision of other cadaver organs.

It is important to remember those physician services that may **not** be included in organ acquisition costs. They include transplant and post-transplant services for the recipient, medical evaluations occurring during the same inpatient stay as the transplant, excision of an organ from a **live donor** and postoperative physician services for the live donor. The physician can bill for these services under the Medicare Part B physician fee schedule.

What Indirect Costs Are Included in Organ Acquisition?

Indirect costs include overhead costs such as staff fringe benefits based on salaries, space costs (depreciation, plant

operations, utilities, etc.) based on square feet, equipment depreciation (if not directly assigned), social services (if not directly assigned) and other general costs such as administration, data processing, insurance and other costs as appropriate and consistent with the overall allocation process. The OIG audit is looking carefully at the allocation hospital space assigned to the transplant center as a basis for allocation of indirect costs.

How is Medicare's Share of Costs Calculated?

Medicare determines its share of organ acquisition costs based on the ratio of Medicare usable organs to total usable organs. Medicare usable organs include organs transplanted into Medicare beneficiaries and organs excised at the transplant center and furnished to organ procurement organizations (OPOs) and organs for which a primary insurance payer made a partial payment and Medicare, as the secondary payer, pays more than the primary payer for organ acquisition. Therefore, transplant centers can usually include in the count of Medicare-usable organs, those transplanted into patients who have Medicare as a secondary payer.

The denominator of the ratio—total usable organs—includes the total number of organs transplanted into all patients and the number of organs excised at the transplant center and furnished to organ procurement organizations.

The Medicare share is calculated by multiplying organ acquisition costs for each organ cost center by the Medicare ratio. Revenue obtained from the provision of organs to OPOs and any revenues received from other primary payers for Medicare patients is treated as an offset. CMS recently issued a clarification that transplant centers may charge an OPO either a standard acquisition charge or the departmental charges actually incurred for the organ retrieval services.

Are physicians at risk in the OIG audits of transplant centers?

According to OIG staff, transplant center arrangements with physicians are not the focus of the OIG audits. However, if the audit reveals evidence of fraud and abuse in the transplant center's arrangements with its physicians, the OIG will pursue the issue.

It is important to remember that it was excessive compensation paid to physicians that was the primary basis for the suit brought by the government against Sharp Memorial Hospital. In March of 2003 the defendants agreed to pay \$6.2 million to settle Civil False Claims Act allegations. The Complaint, brought by a former employee turned *qui tam* relator, alleged that the hos-

pital had knowingly claimed costs as organ acquisition costs on its Medicare cost report that it knew were not attributable to organ acquisition. Among these costs were excessive fees paid to referring physicians for medical director duties, including a contract for \$350,000 per year paid to a physician for administrative services. The government alleged that the physician performed little or no services in return for his fee and that therefore the fees were not reasonable, thus making the cost report a false claim. The government's complaint also included allegations that a number of similar, though less lucrative, arrangements existed between the hospital and transplant surgeons, all of whom were in a position to refer to the hospital. The government also had evidence that the hospital had rented space to physicians at below market rate. Although the government's case was brought under the False Claims Act, the arrangements between the hospital and the referring physicians also implicate the anti-kickback law.

Compliance Tips

1. Review Hospital/Physician arrangements:

Compensation arrangements between Transplant Centers and physicians should be carefully reviewed by legal counsel to ensure compliance with the Stark and federal anti-kickback laws. This includes compensation paid to physicians for medical director duties, leases of office space, and any other financial arrangements. The parties may want to consider having the compensation reviewed by an outside third party such as an independent auditing firm to determine if it reflects fair market value. In addition, payments to physicians for organ donor excision must be reasonable. Although there is a cap of \$1250 for kidney excision, no cap applies to other organs.

Nevertheless, the amount paid the physician and the amount charged to organ acquisition must be consistent with fair market value. Excessive payment by the hospital could be viewed as a disguised kickback to the physician for his or her referrals.

2. Ensure Proper Allocation of Employee Salaries to Organ Acquisition:

The *Sharp* complaint and the Tampa General audit both involved improper classification of employee salary costs to the organ acquisition cost center. OIG staff also indicated that this was an area they were focusing on in their Work Plan audits of transplant centers. Documentation should support allocation of employee costs to organ acquisition. That means that if an employee's time is split between pre-transplant and post-transplant functions, only the pre-transplant time (and cost) can be allocated to organ acquisition. Although

ongoing time reports are preferable, time studies are allowed if they encompass at least one full week per month of the cost reporting period.

If an institution has more than one organ transplant program and an employee's time is split between different programs, the institution must have documents to support its allocation of the employee's time among each organ-specific cost center.

Finally, the transplant center should check time reports or time studies to make sure they do not contain errors or are internally inconsistent.

3. Ensure that Patient Charts Support Medical Necessity:

Patient charts should be reviewed to ensure that the need for the transplant and related services is adequately documented and that patients' status levels conform to United Network for Organ Sharing (UNOS) criteria. A recent case brought by a *qui tam* relator against the University of Illinois and other hospitals in the Chicago area alleged that transplant patients did not meet the criteria for a transplant and the hospital was performing unnecessary transplants in order to maintain Medicare volume requirements. This case was settled with no admission of culpability by any of the hospitals.

4. Review Compliance with Transplant Center Criteria:

To be a Medicare certified transplant center, the center must meet Medicare requirements related to, among other things, volume and survival rates. Failure to meet these standards could result in suspension or termination from the Medicare program. In addition, transplant centers are expected to notify CMS if their survival or volume rates drop below the specified level. Failure to provide such notice could also be grounds for sanctions.

New transplant center regulations are expected to be issued, in proposed form, later this year and may impose more stringent requirements.

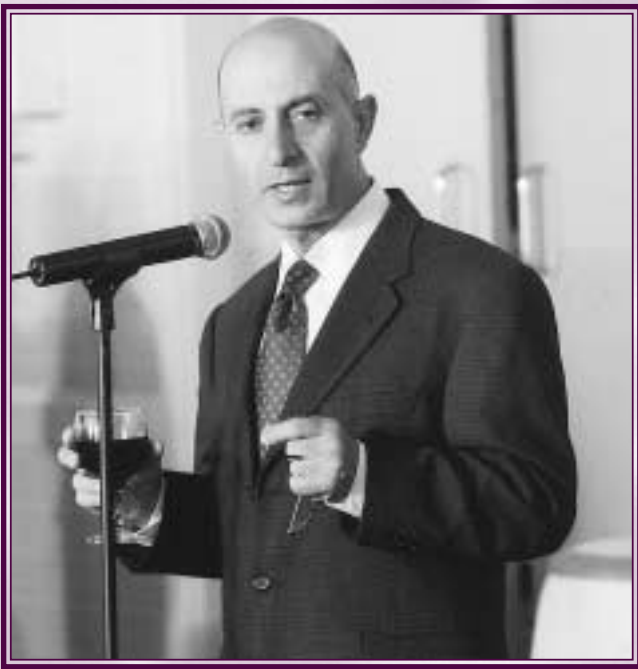
Conclusion

Hospital reporting of organ acquisition costs is a relatively new area of concern to the OIG. Transplant centers can reduce their risk, in the event of an audit, by reviewing their systems and making sure that organ acquisition costs are correctly classified and that the classification is supported by documentation. Transplant surgeons who have financial relationships with transplant centers should carefully review those arrangements for compliance with federal fraud and abuse laws. ❖

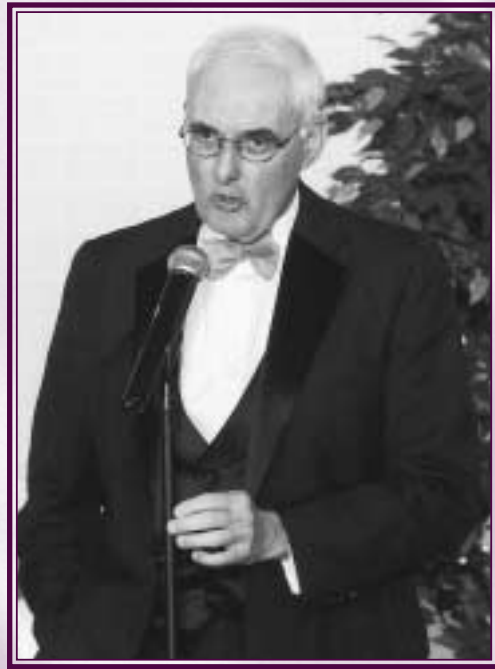
THE ASTS 30TH

OVER TWO-HUNDRED AND SIXTY PEOPLE attended the ASTS 30th Anniversary Dinner held on January 23, 2004 at the Marriott Mountain Shadows Resort and Country Club in Scottsdale, AZ.

ASTS President, Dr. Abraham Shaked, told the participants how honored ASTS was to have sixteen of its Past Presidents attend the gala event. Dr. Marc



ASTS President, Abraham Shaked, begins the ASTS 30th Anniversary Dinner with a toast.



Nicholas Tilney gave some opening remarks about the history of ASTS.



Sir Roy Calne is introduced to the participants of the dinner.



ASTS Past President, Marc Lorber, asks guests at the ASTS 30th Anniversary to "share a moment" about ASTS with everyone.

ANNIVERSARY

Lorber lead the group in a “Share an ASTS Moment.” Many of the Past President’s and Members took turns telling of their favorite ASTS moments in the thirty year history of the Society. Many expressed their appreciation for the hard work of so many which has made the Society the success it is today and who are providing a future of continued growth and success.

Some of the individuals “sharing ASTS moments” with guests included:



Joshua Miller



J. Wesley Alexander



Nancy Ascher



Ronald Busuttil



David Sutherland



Frank Merkel

THE ASTS 30TH ANNIVERSARY

Other attendees “sharing ASTS moments” with guests:



Frank Stuart



Anthony Monaco



Clyde Barker



John Najarian



James Schulak, President of the ASTS Foundation, told the guests about the Foundation and its future goals.



ASTS President Elect, Richard Howard, gave closing remarks for the evening.

ASTS 5TH ANNUAL STATE OF THE ART SYMPOSIUM

The Science and Art of
Immunosuppression



January 21-23, 2005
Eden Roc Resort and Spa
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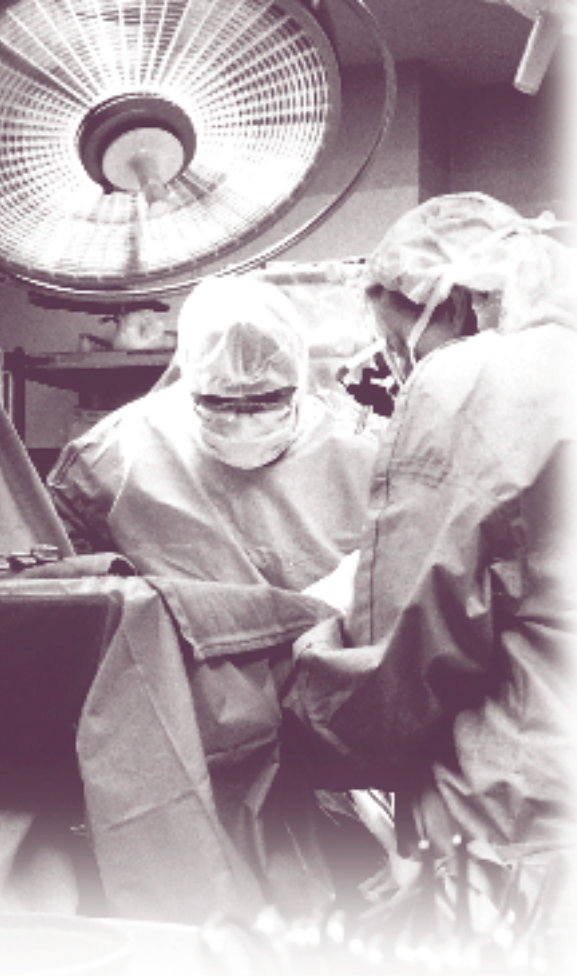
To Register:

Call 1.800.314.1921

or go to www.asts.org

Abstracts will be accepted.






ASTS 2004 Winter Symposium

“Surgical Challenges in Transplantation”

ASTS held its 4th Annual State of the Art Winter Symposium on January 23-25, 2004 at the Marriott Mountain Shadows Resort and Golf Club in Scottsdale, Arizona. Over 270 registrants participated in the symposium in addition to over ninety registrants for the pre-symposium course held January 22-23 on the “Fundamentals of Clinical Research in Transplantation.”

The symposium on “Surgical Challenges in Transplantation.” was arranged by the ASTS planning committee: Sandy Feng, Osama Gaber, Elizabeth Pomfret, Thomas Fishbein and Abhinav Humar.

The Marriott Mountain Shadow Resort and Golf Club, set on seventy acres of desert paradise, with picturesque gardens, lush fairways was the setting for this year’s meeting. In addition to the meeting registrants participated in a family bar-b-que and a golf event.

A webcast of the meeting appears on the ASTS website at www.astsonline.org 



ASTS President, Abraham Shaked, and Past President, Nancy Ascher moderate a session of selected abstracts at the ASTS Winter Symposium on Surgical Challenges in Transplantation.



Dr. Nancy Bridges, Chief, Clinical Transplantation Section of the NIAID, NIH, gives a presentation at the ASTS Fundamentals of Clinical Research in Transplantation Course on January 22, 2004.



Dr. James Burdick, Director, Department of Transplantation, HRSA discusses HRSA grants.

ASTS wishes to **THANK** the following sponsors of the
2004 ASTS Winter Symposium and the Clinical Research Course:

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Pfizer • Barr Laboratories, Inc. • United Resources Network**

Welcome to the American Transplant Congress

It is with great pleasure that the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) invite you to attend ATC 2004, the Fifth Joint American Transplant Meeting. The continuing enormous success and overwhelming attendance of the first four joint meetings confirms that this educational event is the premier annual meeting in the fields of basic and clinical transplantation science and medicine. This year the Congress moves to Boston, Massachusetts where we will hold the meeting in the Hynes Convention Center. The center is conveniently located to a number of hotels that have easy access to the venue. With the move to a larger facility, we have more room overall for the sessions, posters, exhibits and general meeting events. It is particularly appropriate that this meeting is taking place in Boston, where the first successful solid organ transplant was performed 50 years ago.

New to the meeting this year are changes in the pre-meeting symposia. There will be five separate programs on Saturday, May 15th, which will offer a variety of focused learning for everyone attending the ATC. Three of these meetings are co-sponsored with several partnering societies, the American Society for Histocompatibility & Immunogenetics (ASHI), the International Pediatric Transplant Association (IPTA), the International Transplant Nurses Society (ITNS) and the North American Transplant Coordinators Organization (NATCO). We thank our co-sponsors for their assistance in developing these educational events.

On Sunday, Monday and Tuesday, invited experts will present in-depth reviews and scientific symposia for both the clinician and basic scientist. The ever popular, "What's Hot, What's New" will be the feature presentation on Wednesday, the final day of the meeting. On all days of the meeting, controversial topics and new developments will be the focus of the sunrise symposia. Mini-oral presentations, which continue to be so popular, are presented again this year.

The American Transplant Congress is the meeting to attend for the widest range of educational opportunities in the specialized field of transplantation science and medicine. Do not miss the educational and networking experience in the historic and charming city of Boston. Join the ASTS and AST in celebrating 50 years of transplantation.

Donald E. Hricik, MD

MDStuart J. Knechtle, MD

Mark D. Pescovitz, MD

Hugo R. Rosen, MD

American Trans

May 14 - 19, 2004 • Hynes Auditorium • Boston, MA

Tentative Schedule at a Glance

Saturday, May 15

Pre Meeting Symposia

Symposium #1: *Complications of Transplantation and Infections*

Session II: Strategies to Minimize Complications of Immunosuppression

Session III: Infection in Transplantation: State-of-the-Art and Future Challenges

Symposium #2: *Immunology Update 2004*

Session I: The Basics of Transplant Immunology for the Clinician

Session II: Update in Transplantation Biology

Symposium #3: *Tissue Typing Laboratory and Its Clinical Applications*

Cosponsored by the American Transplant Congress and the American Society for Histocompatibility & Immunogenetics

Session 1: Antibodies and Crossmatch: Past, Present and Future

Session II: Clinical Desensitization Protocols

Symposium #4: *Pediatric Symposium*

Cosponsored by the American Transplant Congress and the International Pediatric Transplant Society

Session 1: Transplantation of the Adolescent

Session II: Use of Newer Immunosuppressive Drugs in Pediatric Recipients

Symposium #5: *Transplant Nurses and Coordinators Program*

Cosponsored by the American Transplant Congress, International Transplant Nurses and National Association for Transplant Coordinators

5:00 pm – 7:00 pm Opening Reception with Exhibits

Sunday, May 16

Annual Meeting

7:00 am – 8:15 am Sunrise Symposia

8:30 am – 9:30 am Joint Plenary

9:45 am – 11:15 am Basic Science Symposium

Genomics and Proteomics in Transplantation

9:45 am - 11:15 am Clinical Science Symposium

An Overview of the UNOS and SRTR

11:30 am – 12:00 pm Awards

12:00 pm – 12:30 pm State of the Art Address:

“Advances in Drug Delivery and Tissue Engineering”

Robert Langer

12:30 pm – 2:00 pm Poster Session I and Mini-Oral Sessions

2:00 pm – 5:30 pm Concurrent Sessions

plantCongress

Monday, May 17

7:00 am – 8:15 am	<i>Sunrise Symposia</i>
8:30 am – 9:30 am	Dual Plenaries
9:45 am – 11:15 am	<i>Basic Science Symposium</i> The Science of Complex Systems as it Relates to Transplantation
9:45 am -11:15 am	<i>Clinical Science Symposium</i> Pre-transplant Risk Factors and Effect on Post-transplantation Outcomes
11:30 am – 12:30 pm	In-depth Reviews: Clinical: Use of Registry-Based Evidence for Clinicians and Policy Makers
12:30 pm – 2:00 pm	Poster Session II and Mini-Oral Sessions
2:00 pm – 5:30 pm	Concurrent Sessions

Tuesday, May 18

7:00 am – 8:15 am	<i>Sunrise Symposia</i>
8:30 am – 10:00 am	<i>Basic Science Symposium</i> Regulatory T Cells in Their Role in the Control of Counter-adaptive Immunity
8:30 am -10:00 am	<i>Clinical Science Symposium</i> Campath
10:15 am – 12:00	Presidential Addresses
12:30 pm – 2:00 pm	Poster Session II and Mini-oral Sessions
2:00 pm – 5:30 pm	Concurrent Sessions

Wednesday, May 19

7:00 am – 8:15 am	<i>Sunrise Symposia</i>
8:30 am – 9:30 am	Dual Plenaries
9:45 am – 11:15 am	Concurrent Sessions
11:30 am – 12:30 pm	What's Hot; What's New

ASTS NEW members

David M. Briscoe, MD MB BCh
Children's Hospital Boston

Eric A. Elster, MD
Organ Transplant Service (NIH/NIDDK)

Sander S. Florman, MD
Tulane University

William C. Goggins, MD
Indiana University Hospital

Alihan Gurkan, MD
Akdeniz Universitesi Tip Fakultesi (Turkey)

James Ting-Chih Huang, MD
LifeLink Transplant Institute

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Beth Israel Deaconess Medical Center

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Rabin Medical Center (Israel)

Michael S. Mulligan, MD
University of Washington Medical Center

Hemangshu Podder, MD PhD
University of Texas Houston

William P. Stamford, MD
Real Hospital Portugues (Brazil)

APRIL 2004

April 29 - May 2, 2004

NATIONAL KIDNEY FOUNDATION 2004 CLINICAL MEETINGS

Specialty Courses offered

April 28, 2004

Hyatt Regency

Chicago, IL

Contact Phone: 800-622-9010

Contact Website: www.nkfclinicalmeetings.org

MAY 2004

May 15-19, 2004

AMERICAN TRANSPLANT CONGRESS

John B. Hynes Convention Center
Boston, MA

Contact Phone: 856-439-0880

Contact Website:

www.atcmeeting.org

JUNE 2004

June 19 - 24, 2004

FASEB SUMMER RESEARCH CONFERENCE ON TRANSPLAN- TATION IMMUNOLOGY

Snowmass Village, CO

Contact Website: <http://src.faseb.org>

Contact Email: jlevin@faseb.org

SEPTEMBER 2004

September 5-10, 2004

XX INTERNATIONAL CON- GRESS OF THE TRANSPLANTA- TION SOCIETY

Vienna, Austria

www.transplantation2004.at

DECEMBER 2004

December 8 - 11, 2004

THE 3RD INTERNATIONAL CONGRESS ON IMMUNOSUP- PRESSION

Manchester Grand Hyatt San

Diego

San Diego, CA

Contact Website: www.icicongress.org

Contact Phone: 201-271-6142

Contact Fax: 201-430-1400

JANUARY 2005

January 21-23, 2005

AST 5TH ANNUAL STATE OF THE ART WINTER SYMPOSIUM

"The Science and Art of

Immunosuppression"

Eden Roc Resort and Spa

Miami Beach, FL

ASTS calendar

ASTS Research Bulletin Board

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.astts.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. 

JOB BOARD

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 the www.asts.org, log into the Members Only section and click on Upload/download files.

TRANSPLANT SURGEON The Section of Transplantation, Division of General Surgery, at the Albany Medical Center Hospital is recruiting for a position in Transplant Surgery at the Assistant or Associate Professor level. Duties involve clinical responsibilities in all aspects of kidney and pancreas transplantation, as well as multi-organ donor procurement. Interested parties should forward a CV to David Conti, M.D., Chief of General Surgery, Director -Abdominal Organ Transplant Program. Fax: (518) 262-5571, email: contid@mail.amc.edu, mail: Albany Medical College, MC 61GE, 43 New Scotland Avenue, Albany, NY 12208 ☞

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 ☞

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 ☞

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