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MEMORANDUM

To: **ASTS Council**
From: Peter W. Thomas; Adam Renfro Chrisney
Date: December 18, 2009
Re: **Council Report – Legislative Committee**

This memorandum reviews the status of various ASTS Legislative Committee priorities and makes recommendations for the Council's consideration.

EXECUTIVE SUMMARY:

- ASTS advocacy results in Congress providing increased funding for HRSA organ donation and transplantation programs.
- Senate endgame on overall health care reform includes several ASTS legislative priorities including an amendment offered by Sen. Durbin (D-IL) to extend Medicare immunosuppressive drug coverage. Priorities include:
 - Medicare Immunosuppressive drug extension provisions (in House healthcare reform bill; amendment offered to Senate bill);
 - Elimination of living organ donor status as a pre-existing condition exclusion or as a factor in setting premiums or guaranteeing issue of insurance policies;
 - House passed separate bill to reform SGR payment system; Senate so far only includes another temporary delay;
 - Reliance on Comparative Effectiveness Research, recognizing that such research should not inappropriately or prematurely impact coverage decisions by payers.
- Second ASTS meeting with HRSA Administrator Mary Wakefield, Ph.D., R.N planned for early 2010 to follow up on paired and live organ donation and transplantation generally.

LEGISLATIVE UPDATE:

Funding for HRSA Division of Transplantation Programs

Congress finally passed most remaining appropriations bills, with the exception of the bill covering the programs of the Department of Defense, the week of December 7th. This “omnibus” appropriations bill included the Labor/HHS Appropriations bill that contained a \$2 million increase (for a total just over \$26 million) to the Division of Transplantation (DoT) programs with the Health Resources and Services Administration (HRSA). DoT oversees the Organ Procurement and Transplantation Network and runs the organ donation and transplantation programs authorized by the Organ Donation and Recovery Improvement Act of 2004.

This increase was the culmination of efforts that began as an amendment to increase DoT funding by \$10 million championed by Senator Dorgan (D-ND) and adopted by the Senate Budget Committee. While this amendment was non-binding, it set the stage for the final \$2 million increase. ASTS led the external advocacy effort for this increased funding all year long.

Immunosuppressive Drug “Coverage Extension” Bill

November and December have seen intensive activity focused on passage of this long-time priority for ASTS. Provisions related to H.R.1458 and S.565, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2007, were previously included in Section 1232 of the House health care reform bill but no provision has been included in the Senate version currently being debated.

35 Senate offices were engaged by ASTS leadership and members; they were asked to offer S.565 as an amendment to the Senate health reform bill. The lead Senate sponsor of S.565, Sen. Durbin, offered the amendment in mid-December. Amendment cosponsors include Sens. Levin (MI), Casey (PA), Schumer (NY), and Burris (IL). All are Democrats. ASTS has been in close contact with Senator Durbin’s office and sent a letter of support for the amendment to him, as well as Majority Leader Reid, both of whom are working tirelessly to have their bill included in the final health reform bill currently set to pass the Senate by the end of the month. Attaining this goal will smooth inclusion of the provision during later negotiation between the House and the Senate over a final health reform bill.

Under all versions of this legislation, transplant recipients would pay the Part B premium, and Medicare coverage of immunosuppressive drugs would be extended beyond 36 months only for recipients who lack access to other health care coverage. All other health care needs for transplant recipients who are not Medicare aged or disabled would remain subject to the current ESRD 36-month coverage limit. Only immunosuppressive drugs would be covered for the life of the transplant under this legislation. These limitations were necessary to reduce the cost of the legislation.

Pre-Existing Condition Exclusions and other Coverage Standards

All of the health care reform bills pending in Congress would achieve a major goal of the ASTS; prohibition of the use of living donor status as a pre-existing condition in the private health

insurance market. In fact, not only living donor status, but all health conditions, claims experience, and disabilities would be prohibited from being used in the issuance or premium rating of health insurance. For living organ donors, these provisions would eliminate the problem that some live organ donors face when trying to access affordable private health care insurance after they have donated an organ. This would be a significant advance for live donors and remove this disincentive to live donation. ASTS strongly supports the elimination of organ donor status as a pre-existing condition and will work to ensure that the final health care reform legislation contains this protection for living donors.

In addition, the bills create a “Health Insurance Exchange” where private plans would compete for individuals and small businesses in the insurance market. A whole new set of insurance market rules would be established including a requirement that every health plan offer a set of “essential benefits.” The bills prohibit any cost-sharing for preventive benefits and limits annual out-of-pocket spending (House bill only). They also prohibit annual and lifetime caps in benefits which could have a significant impact on transplant recipients.

Physician SGR Payment Changes

Due to a cost of approximately \$245 billion over ten years, a permanent physician payment fix has been stripped from the House health reform legislation to keep the cost of the reform bill under \$900 million, President Obama’s stated goal. Instead, House Democrats passed separate legislation to fix the physician fee schedule.

Under the new physician payment legislation, H.R. 3961, the Medicare Physician Payment Reform Act of 2009, the sustainable growth rate (SGR) formula of Medicare's physician payment system would be replaced with a new formula comprised of two new growth rates that remove certain items, such as drugs and laboratory services not paid directly to practitioners, from spending targets. The two new growth rates would allow the volume of primary and preventive care services to grow at the same rate as the Gross Domestic Product (GDP) plus 2% per year while allowing the volume of most other physician services to grow at the rate of GDP plus 1% per year. This bill only passed when paired with “PAYGO” legislation – a bill important to fiscally concerned moderate Democrats which mandates that all future entitlement spending would be fully budgeted for by Congress.

The House bill was developed after the Senate in October resoundingly failed to pass an unpaid-for bill sponsored by Sen. Stabenow (D-MI) that would have cancelled a 21 percent Medicare payment cut for physicians in 2010, replacing it with a freeze for 10 years. After this failure, Senate Majority Leader Harry Reid (D-Nev.) said the Senate will only readdress overall physician payment reform after health care reform legislation is finished. In the meantime, the Senate health care reform bill would implement another 1-year delay that increases doctors’ pay by 0.5 percent in 2010 at a cost of \$10.9 billion, with a 25% cut to the fee schedule in 2011. The House hopes its separate physician payment bill will be considered in final deliberations between the two chambers once the Senate finalizes its version of health reform.

Of note, due to continuing Senate delays in finalizing its health reform bill, it is anticipated that final action will not be taken by the end of the year and prompting Congress to postpone consideration of a number of legislative priorities. One of the delayed items under consideration

is a patch to cover physician claims for the first two months of 2010 until either another 1-year fix or overall SGR reform can be negotiated and passed early next year.

Comparative Effectiveness Research

A new Center for Comparative Effectiveness Research would be established through the health reform bills to conduct, support and synthesize research relevant to the comparative effectiveness of the full spectrum of health care items, services, and systems. Also established is a public/private stakeholder commission known as the “Comparative Effectiveness Research Commission” to oversee the Center, identify national research priorities, methods and standards of evidence, etc. Clinical perspective advisory panels will provide advice on specific research questions, methods and gaps in evidence in terms of clinical outcomes for priorities identified by the Commission in order to ensure that the research is clinically relevant. One key provision for ASTS included in the health reform bills is that the Center and the Commission are prohibited from mandating coverage, reimbursement or other policies to any public or private payer.

ASTS Outreach to HRSA Administrator

A surprising development emerged during the summer months after a successful meeting on August 12, 2009 between ASTS leadership, including ASTS President Robert M. Merion, MD, the American Society of Transplantation (AST) and the new HRSA Administrator, Mary Wakefield, Ph.D., R.N. In November, an agency-wide postponement of the Kidney Paired Donation Pilot Project (“KPDPP”) and review of live organ donation was implemented by the overall Department of Health and Human Services, HRSA’ umbrella agency, as a result of concerns related to three deaths over the past couple of years directly associated with live organ donation.

This agency runs the Division of Transplantation (DoT) which administers a \$25 million budget that funds various organ donation and transplantation programs, including the OPTN. This also includes the National Living Donor Assistance Center (NLDAC), a nationwide system to provide reimbursement of travel and subsistence expenses to living donors with low incomes, most of whom cannot otherwise afford the expenses. This program is run by HRSA DoT through a cooperative agreement with the University of Michigan (UM) and the American Society of Transplant Surgeons (ASTS).

The discussion focused on the need for the Department of Health and Human Services to highlight organ donation and transplantation programs as a national priority. Administrator Wakefield made it clear that she understands the importance of transplantation and donation issues. She committed to follow up with her staff to further consider the recommendations discussed at the meeting and volunteered to take a personal role in breaking down barriers between HRSA and CMS, particularly on matters of regulatory consistency.

Given the promise that kidney paired donation holds to increase the supply of organs available for transplantation, and the broader potential implications of the agency’s recent interest in the safety of kidney paired donation, ASTS expects to place great emphasis on assisting the HHS Secretary to resolve her concerns and press forward with the kidney paired donation project. ASTS will use the upcoming meeting with HRSA to address these concerns and present data on the safety and efficacy of live donation.