



American Society of Transplant Surgeons

February 27, 2012

Steve Larsen, Director
Center for Consumer Information and Insurance Oversight
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Impact of Essential Health Benefits Bulletin on Organ Donation & Transplantation

Dear Director Larsen:

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to comment on the *Essential Health Benefits Bulletin* issued on December 16, 2011 by the Center for Consumer Information and Insurance Oversight (CCIIO). ASTS is a national trade association comprised of over 1900 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals dedicated to excellence in transplant surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

The Bulletin lays out a regulatory framework for states to select amongst four benchmark plans to meet the EHB statutory standards in the Patient Protection and Affordable Care Act (ACA). ASTS is concerned that the proposed framework provides too much flexibility and could create significant coverage variation between states. However, ASTS also believes that comprehensive federal oversight of the essential health benefit package process can alleviate wide variation in the coverage of transplant benefits and effectively eliminate discriminatory insurance practices that fail to adequately cover essential transplant benefits.

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Federal Oversight of EHB Process

ASTS believes HHS must establish a primary role for the federal government in the oversight and enforcement of the EHB package, especially as pertains to categories of services for high-risk patients such as those who need organ transplant benefits. Without such a federal role, ASTS has serious concerns that the benchmark plans may not meet the needs of the most costly and vulnerable patients.

Specifically, the federal government should be required to assess the adequacy of coverage in all benefit categories listed in the ACA to ensure that the benchmark plan coverage is meaningful in each state. HHS must review states analyses showing their benchmark plan option covers all ACA-mandated benefit categories and complies with the non-discrimination provisions of ACA Section 1302(b). If HHS finds plans out of compliance with statutory requirements, the federal government should withhold subsidies until plans make the appropriate changes and meet HHS approval. ASTS also supports the creation of a federal advisory board to assist the Secretary in refining and updating the essential benefits package in future years.

Transplant Services as Essential Benefits under 10 categories

In its report on the typical employer plan, the Department of Labor specifically searched for and found wide coverage of transplant and organ services. The HHS Bulletin also recognizes that organ transplant services are consistently covered across markets (and are expected to be included in benchmark plans):

“... across the markets and plans examined, it appears that the following benefits are consistently covered: physician and specialist office visits, inpatient and outpatient surgery, hospitalization, organ transplants...” [See Essential Health Benefits Bulletin, Page 5]

There are a wide range of required medical services at different points of the transplant process, including ambulatory services, hospitalization services, chronic disease management services, mental health services, rehabilitative services and prescription drugs. All of these treatments fall under one or more categories of essential health benefits.

In our preliminary review of small employer plans identified as benchmark options, we found that plans identified transplant services as covered with a variation in cost-sharing arrangements. However, the small group plans did not provide details of the benefits covered under the transplant category. The national FEHBP plans, however, provided extensive detail on which transplant services are covered, excluded and limited. All benchmark plan options should reveal

as much detail as possible to HHS and on www.Healthcare.gov so that stakeholders can examine plan coverage for themselves in a transparent process.

HHS should assess the proposed essential health benefits packages by reviewing extensive plan detail for compliance with the non-discriminatory provisions of the ACA (e.g., the EHB benchmark plan cannot make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life). Many benchmark options outlined in the HHS release of plan listings will not automatically meet these new requirements under the ACA.

For example, plans are not currently required to reflect an appropriate balance among the essential benefit categories so that benefits are not unduly weighted toward any one category. This new ACA requirement is critical and must be enforced by HHS, who should review plans in detail to ensure that essential services like transplant services are appropriately covered. If HHS finds plans out of compliance with the ACA requirements, the federal government should withhold federal subsidies until such plans make needed changes and HHS approves the changes. In addition, in our review of plan coverage we have found that most insurers provide coverage for traditional organ transplant procedures. The medical procedures involved with extracting an organ from a donor for transplantation is considered part of the recipient's overall procedure and is covered as such. Yet, we have still run across some small plans that refuse to pay for the standard acquisition costs for deceased donor organs or the cost of working up living donors. We suggest that HHS should ensure coverage of such costs for all organ donor patients under the essential health benefits package.

Limitations for Essential Organ Transplant Benefits

In the EHB Bulletin, HHS recognizes that there is widespread coverage of transplantation of solid organs as routine care, including kidney, liver, heart, pancreas, intestine, lung, bone marrow and heart-lung transplants. Because of this, these services should be considered part of the essential health benefits package. Organ transplantation, in most instances, means the difference between life and death. The ACA mandates that plans cannot set annual and lifetime caps on essential health benefits. Consistent with the ACA, medically necessary essential benefits related to organ transplants should not be subject to annual and lifetime limits.

Immunosuppressive Drug Coverage and Kidney Dialysis Coverage

Prescription drug coverage under the EHB packages should recognize that transplant recipients are required to take immunosuppressive medications for their entire lives to prevent rejection of the transplanted organ. Any interruption of this drug regimen risks rejection of that organ with

dire consequences. Indeed, 70% of U.S. kidney transplant programs report patient deaths and failed kidney transplants attributable to unaffordable medications. It is essential that physicians be able to prescribe medications that are best for the patient, based on independent clinical judgment, and that patients are afforded access to these medications as part of the EHB and any state's benchmark plan.

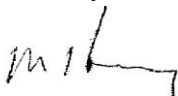
Protected Six Classes of Drugs: ASTS urges HHS to include the long-standing, important protections that require plans to cover “all or substantially all drugs” in six critical lifesaving drug classes for patients with certain serious and often life-threatening conditions, such as cancer, HIV/AIDS, schizophrenia, epilepsy, and organ transplant recipients. This policy has successfully protected vulnerable patients under Medicare Part D who need access to biocompatible medications. The HHS Bulletin also proposes an EHB coverage standard of only one single drug per therapeutic class—a dramatically lower standard that could result in 50% fewer covered drugs on plan formularies relative to Medicare Part D. We, therefore, recommend that an EHB standard of two drugs per Therapeutic Class be established by HHS in proposed and final regulations, consistent with the standard present in Medicare Part D.

Dialysis Coverage: End Stage Renal Disease affects over 350,000 Americans who require either routine dialysis or a kidney transplant to sustain their lives. In the case of kidney transplant recipients who may survive even if the transplant fails, a return to dialysis sessions is medically necessary. This renal replacement therapy is essentially withheld from no individual in the United States and should be considered an essential benefit as well.

In closing, transplants are a life-saving and well established treatment that transplant recipients often refer to as the “Gift of Life.” There is no better way to respect this gift than by ensuring coverage of organ transplantation as well as related services such as dialysis and medications to prolong the life of the donated organ for as long as possible. Such a result is consistent with the goals of the EHB package, and the broader goals of health care reform.

Thank you for the opportunity to provide ASTS's perspective on the EHB issue. We look forward to an opportunity to discuss these issues with you further and partner with you as HHS moves forward with implementing these provisions. Thank you.

Sincerely,



Mitchell L. Henry, M.D.
President
American Society of Transplant Surgeons