



American Society of Transplant Surgeons

July 5, 2012

VIA ELECTRONIC SUBMISSION

Adam Block
Team Lead on Essential Health Benefits and Actuarial Value
Center for Consumer Information and Insurance Oversight
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

RE: *The Impact of Proposed Rule CMS-9965-P on Organ Donation & Transplantation*

Dear Mr. Block:

The American Society of Transplant Surgeons (ASTS) respectfully submits these comments on the proposed rule “**Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans**” [CMS-9965-P] and the corresponding materials in the Paperwork Reduction Act (PRA) notice issued on June 1, 2012 by the Centers for Medicare and Medicaid Services (CMS).

ASTS is a medical specialty society comprised of over 1900 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals. ASTS is 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.

ASTS submits these comments for your consideration as you draft and issue a final rule on essential health benefits (EHB) data collection in order to ensure that all aspects of organ transplantation are covered in states’ EHB benchmark benefit packages in a comprehensive and non-discriminatory manner.

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In its statutorily mandated report to the Secretary of Health and Human Services (HHS), the Department of Labor specifically investigated – and found widespread employer coverage of – organ transplantation and related services in the “typical employer plan.” Additionally, in the Essential Health Benefits Bulletin issued by HHS in December 2011, the Secretary recognized 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, December 16, 2011, Page 5]

There is a wide range of required medical services throughout the organ transplant process, including ambulatory services, hospitalization services, chronic disease management services, dialysis (in the case of kidney transplantation), mental health services, rehabilitative services and prescription drugs. All of these treatments fall under one or more categories of essential health benefits.

There is widespread coverage in the employer health plan market of transplantation of solid organs as routine care, including kidney, liver, heart, pancreas, intestine, lung, bone marrow and heart-lung transplants. Because of this, and because of the statutory requirement that essential benefits include those covered in the typical employer plan, these services should be considered part of the essential health benefits package. Organ transplantation, in most instances, means the difference between life and death. In this respect, they are clearly essential health benefits and should be covered in every benchmark benefits plan.

Data Collection of Transplant Services in the Small Group Market

In section 156.120(b) of the proposed rule, CMS requires that the three largest small group plan issuers in each state submit “certain benefit and enrollment information” to HHS that will be used by States, Exchanges and insurers to “define, evaluate and provide the EHB.” This information includes coverage of benefits, limits, and exclusions. ASTS believes this data collection must encompass all services to be covered in the EHB packages, including all services related to the transplantation process, in order to ensure states can make fully-informed decisions about their benchmark plan as well as how to enhance this benchmark plan to cover all categories of care and meet non-discrimination standards set forth in the ACA.

ASTS agrees that data submission on benefit coverage from potential benchmark plans in each state is critical to developing appropriate EHB benefit packages at the state level. We are concerned, however, that the level of detail and specificity necessary for states to make decisions regarding their benchmark plan will not be collected—especially in regard to organ transplant services—since the Department has limited itself to collecting information on only 45 benefit

categories. **ASTS strongly recommends that CMS modify the EHB package template (Appendix H3 in the PRA notice) to specifically include “transplant services” to ensure adequate data collection for both states and stakeholders to assess coverage in the benchmark plans.**

Other disease progression can lead to the need of organ transplantation, such as End Stage Renal Disease (ESRD) that affects over 350,000 Americans who require either routine dialysis or a kidney transplant to sustain their lives. These services should also be considered when determining the EHB package. 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. Therefore, **ASTS also strongly recommends that “kidney dialysis and kidney related services” be specifically delineated in Appendix H4 and that coverage, limitation, and exclusion data from each small group plan be collected.**

In the event that a small group market product cannot provide details on coverage, limitations, and exclusions of transplant services, **ASTS suggests that CMS instruct states to look to other benchmark options, such as the national Federal Employees Health Benefits (FEHB) plans which provide extensive detail on which transplant services are covered, excluded and limited, as a basis for comparison of EHB and to ensure that benefits reflect those provided under a “typical employer plan.”** The FEHB plans can help inform states of what appropriate transplantation coverage looks like and how to enhance their benchmark plan to meet ACA standards that require an appropriate balance among the essential benefit categories.

Data Collection Should Not Limit EHB

The data collection process outlined by CMS in the proposed regulation is limited to a relatively short list of benefits that are listed in a previous HHS publication, the Summary of Benefits and Coverage (SBC) regulation, which was never intended to serve as the contents of the essential health benefits package. The ten categories of benefits specified in the ACA encompass more services than are detailed in the benefits template (Appendix H3) under this proposed rule and PRA notice and yet this proposed rule (i.e., the data collection proposed rule) would not even collect data on these statutorily mandated EHB categories.

ASTS acknowledges that there are certain practical limits on the collection of comprehensive data on benefit design in the small group market in each state. Therefore, while it is critical that the final rule expand the list of benefits on which data is collected to include organ transplantation and related services, **ASTS asks CMS to clarify in the final regulation that the benefits template (Appendix H3) in no way defines the EHB package for each state and that states should not narrow coverage to only this list of 45 benefits.** If HHS does not prohibit narrowing of the EHB, it is possible that small group and individual plans in the reformed market could provide less comprehensive coverage than is available today, which would be contrary to the explicit intent, the letter, and the spirit of the Affordable Care Act.

Federal Oversight of the EHB Process

ASTS believes HHS must establish a primary role for the federal government in the oversight and enforcement of the EHB packages across the states, especially with respect to coverage of benefits for high-risk patients such as those in need of organ transplantation and related services. Without such a federal role, ASTS has serious concerns that the benchmark plans will not meet the needs of the most costly and vulnerable populations.

ASTS applauds CMS for requiring states to submit to them the EHB benchmark plans and their details using Appendix H4 of the PRA notice. ASTS believes HHS should assess the adequacy of plan coverage for all benefit categories listed in the ACA and ensure that the plan complies with the non-discrimination provisions of ACA Section 1302(b). **ASTS recommends that CMS state in the final regulation the process it will use if it finds plans to be out of compliance with statutory requirements.**

Organ transplants are a life-saving and well established treatment that many in the transplant community refer to as the “Gift of Life.” We must respect this gift by ensuring that organ transplantation is a treatment option for patients with end stage organ failure. Without appropriate coverage of organ donation and transplantation services, chronic kidney disease and end-stage renal disease services, as well as coverage of the immunosuppressive drug regimen necessary to prevent organ rejection, patients will be at risk of being without life sustaining treatments at a time when they need it most.

Please do not hesitate to contact us with any questions. We look forward to an opportunity to discuss these issues with you further and partner with you as HHS moves forward with implementing these and other EHB provisions.

Sincerely,

A handwritten signature in blue ink, appearing to read "Kim Olthoff", with a stylized flourish at the end.

Kim M. Olthoff, MD
President