December 26, 2012

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: (CMS-9980-P) ACA Standards Related to Essential Health Benefits, Actuarial Value and Accreditation of Qualified Health Plans

Dear Administrator Tavenner:

The American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) appreciate the opportunity to comment on the proposed rule *ACA Standards Related to Essential Health Benefits, Actuarial Value and Accreditation of Qualified Health Plans*. The ASTS and AST represent the majority of healthcare professionals caring for people awaiting or receiving lifesaving organ transplants in the United States. ASTS and AST members are dedicated to excellence in transplantation through education and research with respect to all aspects of organ donation and transplantation. The efforts of our members save lives and enhance the quality of life of patients with end stage organ failure.

We believe strongly that comprehensive oversight and enforcement of the essential health benefits (EHB) and nondiscrimination standards at the state and federal level will help ensure consistent coverage of transplant benefits and effectively eliminate discriminatory insurance practices.

Toward that end, HHS must continue to play a primary role in the oversight and enforcement of the EHB package, especially for categories of services for high-risk patients such as organ transplant recipients. Without such a federal role, we have serious concerns that the benchmark plans may not meet the needs of the most costly and vulnerable patients.

If plans are out of compliance with statutory requirements and federal regulatory requirements, HHS should withhold subsidies until plans make the appropriate changes to meet with HHS approval. We also support the creation of a federal advisory board to assist the Secretary in refining and updating the essential benefits package in future years.

Organ Transplant Services as Essential Benefits

We can think of no more essential benefit to preserving a patient's life than organ transplantation and related transplant care. In its report on the typical employer plan, the Department of Labor specifically searched for and found widespread coverage of organ transplant services. The December 16, 2011 Bulletin issued by HHS also 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, 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.

Standards For and Approval of EHB-Benchmark Plans

We recommend that HHS specify in the final rule that EHB base-benchmark plans:

- Must cover, at a minimum, benefits routinely covered by the benchmark plan that reasonably fall within one of the 10 statutory categories, regardless of whether those benefits are all listed in the data collection template used by states to report to HHS on their base-benchmark plan; and
- Must provide clarity around benefits that are truly essential. For example, organ transplant benefits are not listed in the data collection template used by states to submit details of their base-benchmark plans, nor do several state base benchmark plans clarify whether organ transplantation is or is not a covered benefit. However, organ transplantation is routinely covered by these types of plans and is certainly covered by the typical employer plan. This lack of clarity on the coverage status of organ transplantation is unacceptable for such a life or death benefit.

We recommend that HHS specify in the final rule that statutory requirements for "appropriate balance" in benefit design require EHB benchmark plans to, at a minimum:

- Cover EHB benefits across the continuum of care and at the recognized standard of care;
- Prohibit substitution between categories of EHB. (For example, plans should be prohibited from substituting coverage of kidney dialysis indefinitely in lieu of kidney transplantation); and
- Protect participant access to appropriate and medically necessary care when allowing substitution within benefit categories. (For example, substituting a generic immunosuppressive drug for a brand name drug, or switching between generics without notifying the patient or health care provider can cause complications and even organ graft failure if the patient is sensitive to this drug substitution).

We recommend that HHS specify in the final rule that non-discriminatory plan design standards:

- Prohibit higher cost-sharing for participants on some benefits than others;
- Prohibit unreasonable and arbitrary coverage limits;
- Prohibit the targeted use of utilization management techniques for some benefits, and not others; and
- Prohibit defining the benefits so as to exclude coverage for those services based on a patient's (e.g., an organ recipient) age, disability or expected length of life. While these factors are considered in terms of organ allocation, they should be expressly prohibited for purposes of coverage and payment of organ transplant services.

In order to meet the health care needs of diverse segments of the population (as required by the statute), ASTS and AST recommend that HHS specify in the final rule that EHB-benchmark plans must:

- Provide a process for participants to request and receive clinically appropriate benefits not routinely covered by the plan;
- Provide a process for participants to request and receive coverage for benefits beyond the limits set by the plan where extraordinary circumstances exist; and
- Provide a process for participants to request and receive coverage of specialty care not routinely covered by the plan when medically necessary and appropriate.

Immunosuppressive Drug Coverage

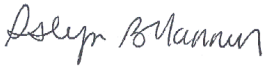
Prescription drug coverage under the EHB packages should recognize that transplant recipients are required to take immunosuppressive medications for their entire lives to prevent rejection of the transplanted organ. Any interruption of this drug regimen risks rejection of that organ with dire consequences.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

In closing, organ 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 living donor candidate evaluation, organ acquisition costs, dialysis and medications to prolong the life—and enhance the quality of life—of the organ recipient are included under EHB. Such a result is consistent with the goals of the EHB package, and the broader goals of health care reform.

Thank you for your consideration of our comments. Please feel free to contact us if we can further assist CMS in its deliberations of these important issues.

Sincerely,



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