



American Society of Transplant Surgeons

April 21, 2014

Mike Kreidler, OD  
Washington State Insurance Commissioner  
302 Sid Snyder Avenue SW  
Olympia, WA 98501

**Re: Comments of the American Society of Transplant Surgeons with respect to Rule 2014-03 regarding the EHB requirements for Transplant Waiting Periods**

Dear Commissioner Kreidler:

The American Society of Transplant Surgeons (ASTS) appreciates this opportunity to respond to your request for comments on Rule 2014-03, which requires the commissioner to review the waiting period for transplant services, supplies, and treatment currently permitted as an optional limitation under the state's rules implementing the Essential Health Benefits (EHB) in WAC 284-43-878 to ensure conformance with applicable federal law for plan years on or after January 1, 2015. WAC 284-43-878 provides that the transplant waiting period must not be longer than ninety days, inclusive of prior creditable coverage, if an issuer elects to apply a limitation to the benefit.

The ASTS is a medical specialty society comprised of over 1800 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 state organ failure.

Part of ASTS' mission is to ensure that life-saving benefits of organ transplantation are available to those who need them. In that regard, ASTS has worked tirelessly, at every stage of the enactment and implementation of the Affordable Care Act (ACA), to ensure that organ transplantation would be a covered essential health benefit. This included working with the Center for Consumer Information and Insurance Oversight (CCIIO) on its Essential Health Benefits Bulletin which laid out the framework for states to select benchmark plans. We also participated in the EHB rulemaking and submitted comments to HHS urging that methods for defining essential health benefits included organ transplantation.

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For that reason, we are delighted to see that Washington is reviewing its current rules related to the optional 90 day waiting period for transplant services. As set forth in more detail below, we believe the waiting period for transplant services is squarely at odds with the requirements of the ACA and urge the removal of this optional waiting period for qualified health plans (QHPs) offered in the state of Washington.

#### **A. The Proposed Rule Violates the ACA's Anti-Discrimination Provisions**

When Congress enacted the ACA it identified ten "essential health benefits" that QHPs must provide. Organ transplantation services cut across a wide range of those EHBs including ambulatory services, hospitalization, chronic disease management, mental health services, rehabilitative services and prescription drugs. Thus, organ transplantation services are clearly within the types of services QHPs are required to cover.

In addition to requiring that plans cover specific EHBs, Congress built in additional protections to prevent discrimination in benefit designs.

Those protections specify that regulators certify that QHPs:

- A. Ensure that such essential health benefits reflect an appropriate balance among the categories described in such subsection, so that benefits are not unduly weighted toward any category;
- B. Not 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;
- C. Take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups;
- D. Ensure that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life. (Section 1302 of the ACA)

A 90 day waiting period for an organ transplant is inconsistent with a number of these protections. It violates the prohibition on discrimination based on disability or expected length of life in subparagraph B. It also violates the protections in subparagraph D in that it individuals in need of organ transplants would be denied coverage "against their wishes" for reasons that may be tied to their present or predicted disability or quality of life.

Regulations implementing the ACA's essential health benefits provision at 45 C.F.R. § 156.125 state provide further clarification:

*An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.*

CMS subsequently clarified, in a letter to issuers, how it would evaluate QHP benefit designs for discrimination when certifying plans in the federal exchange.<sup>1</sup> It stated

*As part of this review, CMS expects to flag any language that indicates a reduction in the generosity of a benefit in some manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices. . .”*

Requiring individuals in need of an organ transplant to wait 90 days for coverage when individuals with other diseases are not subject to similar waiting periods clearly discriminates based on an individual's "health condition" in violation of 45 C.F.R. § 156.125. For example, individuals in need of other life-saving treatments such as heart bypass surgery or chemotherapy would experience no such waiting period and would have access to immediate coverage whereas individuals in need of life-saving organ transplantation would not. It is difficult to imagine a more clear cut case of discrimination than this. Nor is there any clinically indicated reasonable medical management justification for requiring a 90 day wait for coverage. On the contrary, appropriate clinical guidelines and medical management practices support immediate access to organ transplantation. There is no clinically defensible reason for requiring a 90 day wait or, in fact, any waiting period.

45 CFR § 156.110, which sets forth standards EHB-benchmark plans must meet, prohibits a plan from including "discriminatory benefit designs that contravene the non-discrimination standards defined in §156.125." WAC 284-43-878 is clearly inconsistent with this regulation.

#### **B. Plans that Include the Waiting Period are not in Compliance with Essential Health Benefits Requirements**

Imposing a 90 day waiting period on organ transplantation does not meet the ACA's essential health benefits requirement. Section 1302 of the ACA directs the Secretary of HHS to ensure that "the scope of essential health benefits . . . is equal to the scope of benefits provided under a typical employer plan as determined by the Secretary." To assist in this determination, Congress directed the Secretary of Labor to conduct a survey of employer-sponsored coverage to determine benefits typically covered by employers. In its Report to Congress the Department of Labor specifically searched for and found wide coverage of transplant and organ services. The HHS Essential Health Benefits Bulletin, issued December 16, 2011 by CCIIO specifically states:

*"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 . . ." (emphasis added)*

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<sup>1</sup> See [http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014\\_letter\\_to\\_issuers\\_04052013.pdf](http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf)

Thus, organ transplantation is a benefit specifically identified by the Secretary of Labor as typically covered by employers and, as such, must be included in any plan purporting to offer essential health benefits in compliance with federal law. In fact, we can think of no more obvious definition of the term “essential” than services and treatments that interrupt a downward spiral of a disease headed toward certain death and that restore productive, high quality and sustainable life to a patient. As such, plans must cover organ transplantation if they are to meet the requirement that they provide essential health benefits.

**C. The Condition-specific waiting period violates the ACA’s Ban on Pre-Existing Condition Exclusions**

The 90 day waiting period for transplant also violates the ACA’s ban on pre-existing condition exclusions. Section 2704 of the Public Health Service Act, as amended by Section 1201(2)(A) of the ACA, prohibits plans offered in the individual and group market from limiting or excluding benefits for pre-existing conditions. Thus individuals with organ failure or with conditions that are likely to lead to organ failure would be denied coverage based on pre-existing conditions. This is in direct contravention of one of the most important reforms enacted as part of the ACA.

The impact of the proposed 90 day waiting period would be felt most severely on patients in need of heart, lung and liver transplants since most candidates for kidney transplants are covered under the Medicare end-stage renal disease benefit. However, regardless of the type of organ needed, these patients cannot wait 90 days for a transplant. Many patients with liver disease present for medical attention at advanced stages, with high short-term mortality. If a 90 day waiting period were imposed many of these patients would die before they would have an opportunity to undergo liver transplantation. Further, the costs of a liver transplant are less than caring for patients with end-stage liver disease over time.

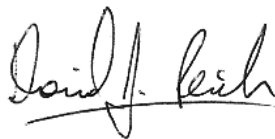
**Conclusion**

Based on the above, it is clear that authorizing a special 90 day waiting period for transplants 1) violates the prohibition against use of a discriminatory benefit design in 45 CFR § 156.125; 2) causes Washington to fail to meet the requirement that its benchmark plan provide for EHBs; 3) violates the ACA’s ban on pre-existing condition exclusion; and 4) would delay, and effectively deny life-saving treatments to individuals in critical need. For these reasons, we strongly urge that Washington amend its regulations to eliminate WAC 284-43-878.

Sincerely,



Alan N. Langnas, DO  
President



David J. Reich, MD  
Chair, Legislative Committee