



December 6, 2013

Laura Cali
Insurance Commissioner
Oregon Department of Consumer Business Services
350 Winter St NE
Salem, OR 97301-3883

Re: Proposed Rule OAR 836-053-0008; Request for Comments on Provisions in Health Reform
Proposed Rule Regarding 24-Month Transplant Waiting Period

Dear Commissioner Cali:

On behalf of the American Society of Transplant Surgeons (ASTS) and American Society of Transplantation (AST), representing the majority of professionals caring for people awaiting or receiving lifesaving organ transplants, we appreciate this opportunity to respond to your request for comments on the provision in the Oregon Insurance Division's proposed rule that would establish a benchmark plan for purposes of defining essential health benefits (EHB) under the Affordable Care Act (ACA). This proposed rule includes a 24-month waiting period for organ transplantation. We agree with concerns stated in the proposed rule that this policy violates the essential health benefit protections of the Affordable Care Act. As such, we recommend that the Oregon Insurance Division strike the two-year waiting period for organ transplantation from its essential health benefits package.

ASTS is a medical specialty society comprising more than 2,000 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. The efforts of ASTS members save lives and enhance the quality of life of patients with end stage organ failure. AST is an international organization of transplant professionals who are dedicated to advancing the field of transplantation and improving patient care by promoting research, education, advocacy, and organ donation. The Society comprises nearly 3,200 transplant physicians, surgeons, scientists, and allied health professionals. Both organizations seek to ensure that life-saving benefits of organ transplantation are available to those who need them.

ASTS and AST have worked hard at every stage of the enactment and implementation of the ACA to ensure that organ transplantation is considered a covered essential health benefit. This included working with the Congress to enact the ACA and 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 federal EHB rulemaking and submitted comments to HHS urging that methods for defining essential health benefits include organ transplantation.

For that reason, we are dismayed to see that Oregon is considering adopting regulations that would identify as its “benchmark plan” a plan that permits a 24-month waiting period for organ transplantation. As set forth in more detail below, we believe this is squarely at odds with the requirements of the ACA. If Oregon finalizes selection of this plan as the state’s benchmark plan without amendment of this provision, qualified health plans (QHPs) offered through the Oregon exchange will be permitted to impose this discriminatory waiting period. Further, the fact that the benchmark plan would offer credit toward the waiting period for prior coverage does not cure its discriminatory design. Individuals who did not have prior qualifying coverage because they were unable to obtain health insurance in the past—the very individuals the ACA is designed to help—would still be faced with the 24-month waiting period. And even those individuals who had coverage in the past might still have to wait, depending on the length of their prior coverage.

A. The Proposed Rule Violates the ACA’s Scope of EHB Coverage

When Congress enacted the ACA, it identified by statute ten “essential health benefit” categories that all QHPs must provide. Organ transplantation coverage can be considered across a wide spectrum of these categories, including ambulatory services, hospitalization, chronic disease management, and prescription drugs. In addition, Section 1302 of the ACA directs the Secretary of Health and Human Services (“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.” [Emphasis added.]

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.)

Thus, organ transplantation is a benefit specifically identified by the Secretary of Labor as typically covered by employer plans 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.

B. The Proposed Rule Violates ACA’s EHB Non-discrimination Protections

In addition to requiring that plans cover specific EHBs, Congress enacted additional protections to prevent discrimination in benefit design. Once a benchmark plan is selected from one of several plan options already functioning in the state, the federal EHB guidance and regulations require the state to assess whether the benchmark plan complies with the benefit category mandates in the statute and the non-discrimination protections below. If the benchmark plan fails either of these tests, it must be modified to bring the benchmark plan into compliance with federal law.

The non-discrimination protections require regulators to 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; and,
- (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 and 45 C.F.R. § 156.125)

In addition to the fact that typical employer plans do not routinely impose lengthy waiting periods for organ transplantation, a 24-month waiting period for an organ transplant violates a number of these non-discrimination protections. It potentially 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 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, degree of medical dependency, or quality of life.

CMS subsequently clarified, in a letter to issuers, how it would evaluate QHP benefit designs for discrimination when certifying plans in the federal exchange.¹ 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 24 months 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 24-month waiting period for organ transplant 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 24-month wait or, in fact, any waiting period at all.

Federal regulations at 45 CFR § 156.110, which sets forth standards that EHB-benchmark plans must meet, prohibits a plan from including “discriminatory benefit designs that contravene the non-discrimination standards defined in §156.125.” The benchmark plan at issue is clearly in contravention of this regulation. Imposing a 24-month waiting period on organ transplantation therefore violates the ACA’s essential health benefits requirement.

C. The Proposed Rule Would Violate the ACA’s Ban on Pre-Existing Condition Exclusions

The 24-month 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 markets 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 key reforms enacted as part of the ACA.

The impact of the proposed 24-month waiting period would be felt most severely by 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 24 months for a transplant, especially if a suitable donor organ becomes available. Many patients with liver disease present for medical attention at advanced stages, with high short-term mortality. If a 24-month waiting period were imposed, many of these patients would die before they

¹ See http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf

had an opportunity to undergo liver transplantation. Similarly, patients in need of a heart or heart/lung transplant cannot afford to wait 24 months before eligibility.

Organ transplantation is often the only life-saving treatment available for patients with end stage organ failure. And even where alternative therapies are available, transplantation is often the most cost-effective because it restores patients to healthy and productive lives.

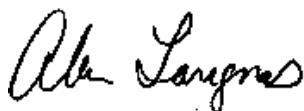
Conclusion

Based on the foregoing arguments, it is clear that adopting a benchmark plan that would require individuals to wait 24 months before being eligible for an organ transplant would:

- 1) Violate the scope of the EHB requirements for coverage;
- 2) Violate the prohibition against use of a discriminatory benefit design in 45 CFR § 156.125;
- 3) Cause Oregon to fail to meet the requirement that its benchmark plan provide for EHBs;
- 4) Violate the ACA's ban on pre-existing condition exclusions; and,
- 5) Would delay, and effectively deny, life-saving treatments to individuals in critical need.

For these reasons, we strongly urge the State of Oregon to strike the discriminatory 24-month waiting period within the benchmark plan and that it immediately require QHPs in the Oregon exchange to eliminate the waiting period for organ transplantation effective January 1, 2014. Thank you for your consideration of our views.

Sincerely,



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