



American Society of Transplant Surgeons

August 27, 2010

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9994-IFC, RIN 0991-AB69
P.O. Box 8016
Baltimore, Maryland 21244-1850

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration, Room N-5653
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210
Attention: RIN1210-AB43

Internal Revenue Service
CC: PA: LPD: PR, Room 5025
P.O. Box 7604, Ben Franklin Station
Washington, DC 20044
Attention: REG-120399-10

Re: ASTS Comments on Interim Final Rules for Preexisting Condition Exclusions, and Lifetime and Annual Limits in Private Health Insurance (File Codes OCIIO-9994-IFC, RIN 0991-AB69/ RIN 1210-AB43/REG-120399-10)

Dear Sir or Madam:

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to comment on interim final rules that implement provisions of the Patient Protection and Affordable Care Act (Affordable Care Act or “ACA”) regarding preexisting condition exclusions and lifetime and annual limits. We applaud the issuance of these interim final rules because their promulgation is an important step forward in protecting patients, especially transplant recipients and living donors, against some of the most egregious practices within the private health insurance market. ASTS worked hard during the legislative process to ensure that Congress prohibited discrimination in private health insurance based on organ donor status. We, therefore, provide the following comments for your consideration in strengthening the interim final rules.

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The ASTS is comprised of over 1700 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.

Prohibition of Preexisting Condition Exclusions

We strongly support the interim final rules that prohibit preexisting condition exclusions in group health plans and health insurance coverage in the group and individual markets.¹ These rules begin to implement the ACA's prohibition against discrimination based on health or disability status.² Once fully implemented in 2014, this reform will end the disincentive confronting many live organ donors who fear that their donor status will compromise their ability in the future to secure affordable private insurance coverage.

There are currently over 109,000 people on the nation's waiting lists for donor organs and over 6,000 Americans die each year waiting for a donated organ. Living donors, who donate a kidney or a portion of another organ such as the liver, offer an alternative to such waiting lists. But when live organ donation is considered a preexisting condition, altruistic living donors are often confronted with the prospect of dramatically increased costs for health insurance coverage or the prospect of being considered uninsurable altogether. The fear of losing access to affordable private health care insurance can be a major barrier to potential live organ donors when contemplating the gift of life. In fact, the North American Transplant Coordinators Organization (NATCO) reports that 39% of transplant centers "had eligible donors decline donation due to fear of future insurance problems."³

However, live organ donors are, in reality, very low health care risks because each undergoes a rigorous health evaluation before being considered a potential donor. To pass this testing, the donor must be healthy and without diabetes, hypertension, heart disease, or cancer. Since the majority of donors are under age 50, these healthy donors often have low health care costs for many years. Yet, even with these safeguards to ensure healthy donors, private insurance plans often treat an individual's donor status as a preexisting condition. This creates a serious disincentive for living donation.

The promulgation of the interim final rules will remove such barriers for living donors, beginning in 2014. ASTS greatly appreciates these protections and supports their full and effective implementation and enforcement on a timely basis.

¹ The interim final rules are set forth at 26 CFR 54.9815-2704T, 29 CFR 2590.715-2704, 45 CFR 147.108.

² The statutory prohibition is set forth at Sec. 2704 of the Public Health Service Act (PHS Act), which was added by section 1201 of the ACA. Section 2704 broadens current HIPAA provisions, which only apply to group health plans and group health coverage.

³ NATCO. Living Donor Health Care Coverage, Insurability and Follow-up. May 2006. Available at http://www.natco1.org/public_policy/documents/LivingDonorInsurability.pdf.

Lifetime and Annual Limits

We applaud the interim final rules that prohibit health plans from imposing lifetime limits as well as unreasonable annual limits until 2014 when such limits are prohibited all together.⁴ These restrictions on lifetime and annual limits only apply to “essential health benefits,” a term that is defined in the Affordable Care Act to include ten general categories, including hospitalization, physician services, and prescription drugs.⁵ We think the interim final rules could be improved in the following ways:

- Regulations regarding “essential health benefits” should be issued as soon as practicable, but in the interim, according to the preamble of the interim final rules, health plans may use “good faith efforts” to determine the meaning of “essential health benefits.”⁶ This may lead to significant variations in the set of benefits subject to the rule and raises the concern that health plans may unduly narrow the scope of essential health benefits. In addition, the federal government’s definition of “essential health benefits” is, in part, to be based on a survey of what constitutes a “typical employer health plan.”

ASTS is particularly interested in how health plans will define prescription drug coverage, including medications routinely used by organ transplant recipients. We believe that such coverage should be defined to include immunosuppressive drugs, which are necessary to prevent the immune systems of transplant recipients from rejecting donated organs.

- The rules should also provide an objective definition of “good faith efforts” when health plans’ compliance with the lifetime and annual caps provisions is assessed. We also believe it may be helpful for the rules to provide illustrating examples of actions constituting “good faith efforts” for purposes of determining the meaning of essential health benefits.
- The rules should further clarify how lifetime and annual limits will apply to large group and self-insured plans and at what point in time, because such plans will not be required to provide the essential health benefits package. Since the essential benefits package is inextricably linked to the operation of the lifetime and annual caps, the HHS Secretary should issue additional guidance on this important issue.
- The interim final rules allow the HHS Secretary to waive restrictions on annual limits if compliance would result in a significant decrease in access to benefits or a significant increase in premiums. Consumer protections should be included to ensure that waivers do not have a negative, disproportionate effect on specific patient populations, especially those based on diagnosis or health status such as living donors. For example, the rules

⁴ The interim final rules are set forth at 26 CFR 54.9815-2711T, 29 CFR 2590.715-2711, 45 CFR 147.126. The interim final rules explicate the statutory provisions of Sec. 2711 of the PHS Act, which was added by Sec. 1001 of the ACA.

⁵ ACA, § 1302.

⁶ Patient Protection and Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections, 75 Fed. Reg. 37188, 27191(June 28, 2010).

should allow the Secretary to rescind waivers if there is such a negative, disproportionate effect.

ASTS believes that the interim final rules are a major step forward for transplant recipients and living donors, as well as anyone with a health care condition. Nonetheless, we believe that the rules could be strengthened in the manner described in this letter. If you have any questions, please feel free to contact me at 312-695-0359 or mabecass@nmh.org. Alternatively, you may also reach ASTS counsel, Peter W. Thomas, at 202-466-6550 or peter.thomas@ppsv.com.

Thank you for your consideration of these comments.

Yours sincerely,

A handwritten signature in black ink that reads "M. Abecassis". The signature is written in a cursive, flowing style.

Michael M. Abecassis, MD, MBA
President