December 24, 2012

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: November 26, 2012 Proposed Rule: Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation

Dear Secretary Sebelius:

On behalf of the leading healthcare professional and patient organizations whose members are directly affected by obesity – either as an affected individual or as a healthcare professional or researcher who treats or examines this serious chronic disease, we urge the Department of Health and Human Services (HHS) to protect patient access to medically necessary obesity prevention and treatment services. Specifically, we request that HHS define management of obesity and metabolic disorders as part of "chronic disease management" within Item #9 *Preventive and wellness services and chronic disease management*. (Section §156.110 EHB-benchmark plan standards, page 95: http://www.ofr.gov/OFRUpload/OFRData/2012-28362_PI.pdf))

Obesity *is* a Chronic Disease

Similar to many other medical conditions, obesity is a complex, multifactorial chronic disease, which requires a multidisciplinary treatment approach. This approach must encompass the best standards of care, both in terms of the treatments chosen, and the care coordination and clinical environment in which they are delivered.

Just as those affected by heart disease receive their care through a coordinated multidisciplinary treatment team, those affected by obesity should also follow a similar continuum of coordinated care. Because of the complex nature of obesity and its variety of impacts on both physical and mental health, effective treatment requires the coordinated services of providers from several disciplines and professions (both physician and non-physician) within both of these treatment areas.

Treating Obesity *is* Chronic Disease Management

Numerous healthcare professional organizations, such as the American Heart Association, American Diabetes Association, and the American Association of Clinical Endocrinologists define obesity as a

chronic disease. Additionally, over 40 healthcare professional and patient organizations recently cited obesity as a serious medical condition that needs to be treated with respect, urgency and action. These groups included the American College of Cardiology, the American Cancer Society Cancer Action Network, the Arthritis Foundation, the American College of Surgeons, Mental Health America, Trust for America's Health, the American College of Preventive Medicine, the American Academy of Nurse Practitioners, and the American Academy of Pediatrics.

While HHS may be reluctant to explicitly mandate coverage of obesity treatment services as part of a state EHB benchmark plan, we believe that, at a minimum, HHS should clarify whether management of obesity and metabolic disorders are chronic disease management services – and therefore covered services under the "Preventive and Wellness Services and Chronic Disease Management" category of the essential health benefits package. This clarification is critical given the ambiguity of health plan coverage policies surrounding obesity treatment services, which are either silent on coverage or outright exclude obesity treatment services.

Too often, for too long, private health plans have excluded coverage for obesity treatment services -- partly due to shortsighted cost savings efforts and partly due to the false assumption that these services are either not medically necessary, or not in line with generally accepted standards of medical care despite scientific evidence to the contrary.

Should HHS be unwilling to explicitly define obesity as a disease, we believe that the Department must clearly recognize that obesity is a serious medical condition, and as such, an area for protection under the Department's proposed regulations regarding discriminatory benefit designs. Under the proposed rule, HHS states that an:

"EHB-benchmark plan must not include discriminatory benefit designs. As set forth in §156.125, those standards would prohibit benefit and network designs that discriminate on the basis of an individual's medical condition, or against specific populations as described in the statute. This proposed standard would apply both to benefit designs that limit enrollment, and those that prohibit access to care for enrollees. While we believe that it is unlikely that an EHB-benchmark plan will include discriminatory benefit offerings, this section proposes that any EHB-benchmark plan that does include discriminatory benefit designs must be adjusted to eliminate such discrimination in benefit design."

Status of Coverage of Obesity Treatment Services

Intensive, Multi-Component Behavioral Interventions

We have been pleased how certain provisions of the Affordable Care Act (ACA) would appear to protect patient access to, and coverage of, obesity treatment services. For example, individuals affected by obesity will now have access to covered obesity screening and referral to intensive, multi-component behavioral interventions, as these "preventive" services are recommended by the United States Preventive Services Task Force *and* mandated under the ACA.

While we applaud both the Task Force for its recommendations and the Administration for its efforts surrounding prevention and screening for chronic disease, we remain concerned over the lack of specificity surrounding the definition of intensive, multi-component behavioral interventions. As we've stated before, effective treatment requires the coordinated services of providers from several disciplines and professions (both physician and non-physician). Will HHS enact protections, or exercise vigorous oversight, to ensure that individuals screened for obesity have access to a robust

behavioral intervention beyond being handed a patient brochure on diet and exercise as part of a routine office visit?

Coverage of FDA-Approved Obesity Drugs – a Major Treatment Gap in the Care Continuum

We note that in the proposed regulations HHS recommends *"that the state's benchmark plan selection in 2012 would be applicable for the 2014 and 2015 benefit years, and be based on plan benefits offered by the selected benchmark at the time of selection, including any applicable state-required benefits enacted prior to December 31, 2011. We intend to revisit this policy for subsequent years. We chose this approach for establishing a consistent set of benefits for two years in order to directly reflect current market offerings and limit market disruption in the first years of the Exchanges."*

We are curious as to how this provision would affect new safe, effective, and evidence-based obesity treatments, such as obesity drugs, which either are available or will soon be available to those Americans whose overweight or obesity require medical intervention. These medications present exciting new options for medical therapy, particularly for those who do not respond to behavioral intervention or those patients who may not yet be ready for bariatric surgery.

The weight loss accompanying these medications has been shown to prevent progression to diabetes in high-risk patients, and to reduce the need for medications used to treat diabetes and hypertension. In addition, the newly established American Board of Obesity Medicine is currently certifying obesity medicine specialists who will be able to safely and effectively administer these new obesity drugs.

Does HHS intend to place a freeze on any newly approved FDA drugs from entering state exchange health plan formularies until 2016? We raise this issue, because we are concerned about the impact of such a policy on obesity drugs – especially those that have been recently approved by the FDA, or are in the final stages of the agency's approval process.

We would also alert HHS to possible questionable coverage policies that private plans might utilize to expand coverage of obesity drugs. For example, a major insurance carrier recently announced coverage of FDA-approved obesity drugs as a "new medical benefit" in plans that do not specifically exclude coverage for obesity treatment services. By categorizing a prescription drug as a medical benefit, carriers would then be allowed to possibly attach overly restrictive coverage policies, or excessive patient cost sharing, beyond what is usually required of other drugs included in their formularies for other chronic disease states.

Metabolic & Bariatric Surgery

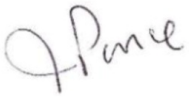
At the other end of the care continuum, individuals affected by severe obesity must have access to bariatric surgery. In reviewing state benchmark plan selections, HHS must recognize that bariatric surgery is already widely covered by Medicare, TRICARE, 47 State Medicaid plans and 44 State employee plans. In addition, Mercer's 2010 National Survey of Employer-Sponsored Health Plans show that bariatric surgery is covered by 40% of plans with <500 employees AND also that the fastest growth in coverage is in small employers (<500) which is growing at 8% annually. Allowing states to ignore a widely covered treatment avenue for this serious chronic disease would both disadvantage, and discriminate against, a significant portion of Americans who would clearly benefit from this medically necessary intervention.

Let's Treat Obesity with the Respect, Urgency, and Action it Deserves!

Just like many other serious medical conditions, obesity is a complex, multifactorial chronic disease, which requires a multidisciplinary treatment approach. This approach must encompass the best standards of care, both in terms of the treatments chosen, and the care coordination and clinical environment in which they are delivered. Finally, physicians and other qualified healthcare providers should be appropriately reimbursed for all evidence-based evaluation and treatments for obesity, as are evaluation and treatments for any other disease state.

As HHS moves forward during the review and oversight process of state benchmark plan implementation, the obesity community urges the Secretary to recognize that obesity is a serious chronic disease and deserves to be treated seriously in the same fashion as diabetes, heart disease or cancer. Therefore, as your department guides states through this critical phase of state health exchange development, please afford those affected by obesity with the same medically necessary treatment avenues afforded to all others who suffer from chronic disease.

Sincerely,



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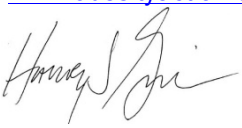

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