January 31, 2012

The Honorable Kathleen Sebelius
Secretary
The U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on the December 16, 2011 Essential Health Benefits Bulletin

Dear Secretary Sebelius,

The AIDS Institute, a national public policy and advocacy organization, is concerned that the Essential Health Benefits (EHB), as outlined in the Bulletin released on December 16, 2011, will fail to meet the health care needs of patients in the United States, especially people with chronic conditions such as HIV/AIDS. The Essential Health Benefits package, required by the Patient Protection and Affordable Care Act (ACA), must support the provision of high quality, comprehensive and affordable health care for all people who will be affected by it. This is particularly important for those with complex and highly specialized health needs, including people with HIV/AIDS. Thanks to groundbreaking scientific and public health advances, in most instances with access to affordable, quality, coordinated care and treatment, people with HIV/AIDS can manage their condition effectively, leading otherwise healthy lives.

As health reform is implemented, it must meet the needs of those with chronic conditions and those who are most vulnerable. While we believe ACA recognizes this, we worry that the EHB Bulletin does not adequately define the services that must be covered by law and lacks the necessary patient protections.

Health care reform will provide access to care for hundreds of thousands of people with HIV/AIDS and in doing so, can significantly change the course of HIV/AIDS in the U.S. Many will receive coverage through Medicaid, thousands will receive coverage from the exchanges, and many will enter the private insurance market for the first time. It is our hope that the essential health benefits will help ensure that people living with HIV/AIDS have access to the care and treatment they need to prolong their lives. This is a multi-staged process that begins with early diagnosis, and continues with disease control and management.

It is critical that those diagnosed as HIV positive are linked to care and stay in regular care and treatment. We believe that ACA can make this a reality for the large numbers of people with HIV/AIDS who have never accessed care or who have fallen-out of care. Pre-health reform, we know that of every 100 people with HIV only 80 are aware of their infection, 62 of whom are linked to care, 41 of whom stay in care, 36 of whom receive antiretroviral treatment, and only 28 of whom have low levels of the
HIV virus in their blood.\textsuperscript{1} We believe that by guaranteeing the right protections, including providing sufficient access to care, monitoring, and treatment and with limited cost-sharing, HHS can help reverse this cascade effect and more generally, impact the HIV/AIDS epidemic in the United States.

In addition to offering these HIV-specific comments on behalf of The AIDS Institute, we are an active member of the HIV Health Care Access Working Group and fully support the comments submitted by the group on January 17, 2012. We also have been leading efforts with a number of other coalitions, working across many disease groups to support access to comprehensive, quality, and affordable healthcare as the essential health benefit package is developed. We have been spearheaded the” I AM ESSENTIAL” campaign, which sent a letter signed by 28 national patient groups outlining concerns around patient needs to your office on December 7, 2011. In the letter we asked the Secretary to be mindful of what we identified as fundamental principals including, “patients need access to quality medical services and to specialist care...diagnostic tools and state-of-the-art protocols for their utilization...preventive services...ample formularies...(and need to be) protected from utilization management techniques which may penalize the chronically ill.”

The AIDS Institute also organized a patient’s group online petition which has been signed by over 2,600 individuals and groups from across the country urging HHS to consider the needs of patients, particularly those with chronic conditions and disabilities, in the EHB design. Those who signed onto the petition agree the EHB Bulletin does not fulfill the statutory requirements included in ACA nor does it include the necessary patient protections. The petition states, “we are concerned that the approach HHS is taking in defining Essential Health Benefits will not provide the necessary coverage to meet our needs.” The incredible joining of numerous diverse groups points to the common concerns of health consumers, particularly those with significant health care needs.

**Essential Health Benefit Architecture**

We note that the state-based benchmark that HHS has proposed in the Bulletin encourages variability between states and does little to foster a national standard of care. Instead of allowing such great state flexibility, we ask you embrace the ethos of the ACA and create a federal floor that ensures individuals living in Massachusetts are not afforded better care than individuals living in Florida by virtue of where they live and how their states choose to implement health reform. By deferring to state benchmarks, we believe that HHS has failed to adequately define each of the 10 categories of EHB services outlined in the ACA and in so much has not met its statutory requirements.

Proceeding with a highly flexible state-based approach will likely mean that it is more difficult to ensure the necessary patient protections required by ACA, such as prohibiting discrimination, including against those with disabilities, are in place. Specifically, we urge you not to allow states the ability to substitute benefits within, or particularly between, categories. This practice could lead to coverage gaps, to cherry-picking of beneficiaries (by not covering services critical to particular patient groups) and potentially to unlawful discrimination.

We are concerned that proceeding with a flexible state-based approach may allow plans to employ harmful utilization management techniques. We ask that HHS not allow them. This is particularly important if a state selects as its benchmark a small-employer plan. These plans notoriously make use of utilization management techniques that limit visits, treatment and care and sometimes introduce prohibitive cost-sharing. These mechanisms can result in patients being left without access to the care they need.

People with HIV require ongoing access to care to monitor their viral loads, and white blood cell count along with various other laboratory tests. Therefore it important not to limit access to laboratory tests or office visits, which are a fundamental component of care for people living with HIV, allowing them to stay healthy and prevent disease progression.

**Prescription Drug Benefit**

We are deeply concerned with how the Bulletin articulates the prescription drug benefit. By allowing plans to cover only one drug in each category or class covered by the benchmark, the guidance outlined in the bulletin would not meet the needs of those living with HIV/AIDS and other chronic conditions. Access to prescription drugs without quantity limits, specialty tiers, drug class restrictions or excessive cost-sharing is crucial in the treatment of HIV/AIDS and many other chronic conditions.

Thanks to the advent of antiretroviral therapy (ART), most people living with HIV who have access to routine care and treatment can now live with a managed chronic disease. However, to attain the benefits of the medications, patients must have access to the full range of pharmaceuticals on a consistent basis. Most people accessing ART require access to three drugs at a time and because some people experience drug resistance the ability to switch to other drugs within the same class is critical.

To allow plans to limit coverage to one drug per class would be catastrophic to those living with HIV/AIDS and for people with a number of other chronic conditions. With such a low bar, something as benign as a drug allergy could bar someone from the critical care they need. Additionally, because not everyone responds to the same drug in the same way, it is a best practice for patients and physicians to be able to select the most effective drug on an individual basis, without extreme formulary restrictions. Further, because we now know that treatment is prevention, ensuring best quality treatment for those living with HIV/AIDS shows a commitment to public health.

It would be devastating if the EHB package did not support the standard of care set forth by federal HIV treatment guidelines, which make the case for unfettered access to all HIV antiretrovirals. The Medicare Part D drug benefit, as well as many state Medicaid programs and private insurers, have put in place protections and plan requirements to ensure that people living with HIV have unrestricted access to lifesaving medications. These include requirements that all HIV antiretrovirals be included in the drug formularies and prohibitions against any utilization management techniques, such as prior authorization or step therapy. Access to a full range of medications is good for both patient care and enhances market competition. In the forthcoming EHB rule, we urge you to require all plans to include access to all drugs within each class, particularly for HIV drugs.
**Preventative Services**
We urge you to make clear specific preventive services in the upcoming EHB rule. Comprehensive preventative healthcare is indispensable for good individual and population health and for curbing the growing cost of healthcare spending. With approximately 1 in 5 of the 1.2 million people infected with HIV in the U.S unaware of their infection\(^2\), routine and wide access to HIV testing is essential for individual and public health. The groundbreaking HPTN052 Study, named the 2011 breakthrough of the year by the journal *Science*, confirmed that treatment is prevention.\(^3\) HPTN052 found that when those who are HIV positive are under care, on antiretrovirals, and virally suppressed the chance of transmitting HIV to others is reduced by up to 96 percent.\(^4\) However, the first step, and only way to get people into care and treatment, is to identify unknown positives though widespread HIV testing.

We congratulate you for including annual HIV screening and counseling in the women’s preventive service package and in doing so, recognizing the importance of routine HIV testing. However, the EHB must extend this service to everyone, particularly given that men account for 76 percent of all new HIV cases.\(^5\) Screening should not be limited only to “at risk” individuals because we know that risk is difficult to determine and that many people infected with HIV are overlooked.

Routine opt-out testing is widely supported by the scientific-evidence, HIV advocates and the CDC. The CDC recommends voluntary routine opt-out HIV testing for all persons 13-64 years old in healthcare settings. In order to best address the epidemic, it is critical that there is coverage by payers to match the CDC recommendations. Routine testing is also supported by a breadth of major medical associations including American Medical Association, American Academy of Pediatrics, American College of Emergency Physicians, American College of Physicians,, and the HIV Medical Association, among others.\(^6\) Therefore, we ask that routine HIV testing be included within the Essential Health Benefits.

**Preventative Services and Medicaid Expansion**
We understand that the Department will be releasing future guidance on the relationship between Medicaid expansion and the EHB and are looking forward to it. In the interim, we stand behind the National Women’s Law Project letter dated January 19, 2012, of which we are co-signees, urging HHS “to ensure individuals receiving coverage through the Medicaid expansion and Basic Health Plans (BHP) have access to all preventive services that must be covered by group health plans and health insurance issuers.”

We ask that those consumers who will be coming into care through the Medicaid expansion and Basic Health Plans be granted access to the preventative services that private plans in exchanges will be required to cover without cost-sharing, as mandated in Section 2713 of the Affordable Care Act. These

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include those services with an A or B grade rating from the United States Preventative Services Task Force and women’s preventative services, among others.

Medical Necessity
We believe that is critical for the essential health benefits to include that which is medically necessary to care for and treat people with HIV/AIDS. HHS should clearly define the standards plans are permitted to use in determining medical necessity and not leave such a definition to states or insurers, who may have perverse incentives. Medical necessity standards will be used in deciding whether or not a patient is to receive access to a particular treatment or intervention. We urge that these standards be clear and transparent and that determinations be made using objective, evidence-based, and individualized criteria. We urge HHS not to define medical necessity too rigidly and let individual clinical indicators play a role in determining whether particular treatments are covered. We believe determinations will be best made between the patient and their providers. Denials of medically necessary care must be made clear to patients along with a straight-forward roadmap for a timely appeals process.

Cost-sharing
In developing future guidance on cost-sharing we implore the Secretary to consider the affordability of plans and accessing care from the consumer perspective. It is critical that people living with HIV and AIDS and other complex conditions have access to affordable care and treatment and are not faced with being insured but being unable to access care as a result of high out-of-pocket costs. We ask the Secretary to be mindful that often, even a small co-payment acts as a barrier to accessing care, particularly among low-income individuals. This is particularly problematic given that we know when patients avoid care in the short-term, they are likely to become sicker, develop more complicated conditions and require more costly care overall. Reducing use of healthcare in response to cost-sharing requirements is particularly troubling among low-income people, who are more likely to experience negative health outcomes as a result.

We ask that HHS require health plans to make all cost-sharing requirements (including any deductibles, co-payments, coinsurance, and premiums) clear to patients in the initial information consumers will use in selecting a plan in the exchanges. This will allow patients to compare the cost-sharing requirement of plans when selecting a product, find a plan that best meets their needs, and make them more educated health care consumers.

Oversight
We do not believe the Bulletin sufficiently addressed state and federal oversight. Given the considerable flexibility afforded to states, it will be critical for state and federal governments to monitor plans to ensure patient safety and protections, and to make sure that plans are in accordance with state and federal statute. Similarly, there must be a clear appeals process for patients who feel their rights

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have been violated, that they are subject to discrimination or their plans have acted improperly. Oversight will be important during implementation but there will be an ongoing role for oversight throughout the operation of the exchanges, particularly to monitor non-discrimination.

**Discrimination**

We are concerned that the flexible approach taken in developing the Essential Health Benefits may leave significant room for discrimination, particularly against vulnerable populations by both states and insurers. The ACA prohibits against discrimination in multiple places, including in Section 1302, which lays out EHB. This section requires the Secretary “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.”\(^{10}\) The Secretary must also “take into account the health care needs of diverse segments of the population, including women, children and persons with disabilities, and other groups.”\(^{11}\) These protections are particularly important for people living with HIV, many of whom have historically been denied coverage, have quickly reached limits or have encountered other discriminatory utilization management techniques that impede access to high-quality care.

We urge the Secretary to make sure that future guidance on the EHB encompasses these broad and critical protections. We ask that as the degree of flexibility afforded to states and plans is evaluated, the potential for discrimination be carefully considered. We reiterate our concern that flexibility, especially flexibility in benefit design and allowing plans to substitute across and within categories, will allow plans to select healthier enrollees and discriminate against vulnerable groups. We ask that the Secretary is particularly mindful of these anti-discrimination provisions when providing plans guidance and believe that significant oversight will be needed to guard against such unlawful behavior.

Thank you for considering these comments on the Bulletin. We look forward to working with you as you further develop the Essential Health Benefits package and other aspects of health reform implementation. Should you have any questions, please feel free to contact me at cschmid@theaidsinstitute.org or 202/462-3042.

Thank you very much.

Sincerely,

Carl E. Schmid II
Deputy Executive Director

\(^{10}\) ACA (§1302(b)(4)(B))

\(^{11}\) ACA (§1302(b)(4)(C))