hivma
hiv medicine association

1300 Wilson Boulevard Suite 300 / Arlington, VA 22209
703-299-1215 / f 703-299-8766 / info@hivma.org / www.hivma.org

January 30, 2012

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

Re: Essential Health Benefits Bulletin

Dear Secretary Sebelius:

On behalf of the HIV Medicine Association (HIVMA), thank you for the opportunity to offer input on the HHS approach to defining the Essential Health Benefits (EHB) standard in advance of issuing regulations. HIVMA represents more than 4,800 medical providers and researchers working on the frontlines of the HIV epidemic across the U.S.

By establishing new federal insurance rules and standards for meaningful health coverage, the Affordable Care Act (ACA) offers great promise to the more than 25 percent of people with HIV who are uninsured and to the estimated 50 percent of people with HIV without regular access to medical care. The basic coverage standard established by the EHB package will be a key factor in determining the success of the ACA in improving access to care and treatment for people with HIV infection. With this in mind, we are concerned that the approach outlined in the Dec. 16th HHS Bulletin does not create a high minimum national standard for the EHB package and that a failure to do so will exacerbate existing HIV-related disparities.

We urge you to consider the following recommendations in developing further EHB guidance or regulations to ensure a basic national coverage level that will meet the medical needs of people with HIV infection and others with chronic conditions who rely on regular access to medical care and treatment to stay healthy and prevent disease progression.

- **Create a higher national floor for the minimum EHB package by defining the benefit categories.**

The high degree of flexibility granted to states in the approach outlined in the Bulletin is likely to contribute to higher rates of new HIV infections, late HIV diagnoses and more rapid disease progression in states with less comprehensive EHB standards. We strongly urge you to define the benefit categories at the national level to ensure a basic coverage level.

This is particularly important given that, as acknowledged in the Bulletin, the benchmark options do not uniformly cover the 10 EHB categories required by the ACA legislation or may use different terms to define the services, e.g., ambulatory care and chronic disease management.

- **Narrow the benchmark options that states can use to set their state EHB standard by dropping the small group plan option and requiring states to identify benchmark plans from within the other plan categories that cover the 10 required service categories identified in the Affordable Care Act and that base coverage decisions on the standards of care.**

In addition to defining the benefit categories at the federal level, we recommend creating a higher baseline EHB standard by eliminating the small group insurance market category. Fewer than 15 percent of people with HIV currently have private insurance coverage of any kind. Many of our HIV patients with private coverage are underinsured due to restrictions on services, high cost sharing and inadequate provider payments that result in limited access to specialists. While many people with HIV infection have been shut out of the insurance market, the fact that small group plans carry increased service limits and higher cost sharing requirements indicates that the coverage will be insufficient for many patients with high cost conditions, such as HIV infection.

We also urge you to require states to identify benchmark plans from within the other three plan categories, i.e., state-employee health plan, federal employee health benefit plan and non-Medicaid health maintenance organization, that cover the 10 service categories mandated by the ACA and that base coverage decisions on standards of care, such as for managing HIV infection[1]. The intent of the ACA was to create greater protections for consumers and in doing so improve access to necessary medical care by mandating coverage for 10 critical service categories. We are concerned that basing the state EHB standard on the largest existing plans in these categories that have historically shut out the individuals who will be gaining coverage through the exchanges will not lead to the reforms promised by the ACA and may not set an appropriate coverage standard in states across the U.S. We are particularly concerned by the flexibility proposed at the plan level to substitute coverage across benefit categories.

Finally, we strongly recommend changing the fall back plan for states that do not identify an EHB benchmark plan to the federal employer health benefits plan to set a standardized coverage level in these states. A failure to adopt a higher floor for the default option will penalize residents in states that fail to define an EHB standard and where residents will not have the opportunity to provide input into their state's EHB benchmark.

- **Establish protections at the national level to ensure that coverage meets the standard of care for HIV disease, including protections to ensure access to prescription drugs for HIV patients and others with conditions at risk for adverse clinical consequences in the absence of effective treatment, such as viral hepatitis.**

The drug coverage requirement outlined in the Bulletin allowing plans to cover one drug for each drug category or class will not support the basic standard for HIV treatment that requires a minimum of three antiretroviral agents prescribed according to factors unique to the individual patient. HIV medicine is an area of rapid scientific discovery, and the development of more effective and less toxic antiretroviral therapies has been critical to our remarkable success in treating HIV infection in patients with access to treatment. Reliable access to the range of medications available to suppress HIV infection under the EHB coverage, regardless of the state HIV patients live in, is critical to avoid a serious public health crisis.

Federal HIV treatment recommendations are written and frequently updated by the National Institutes of Health in recognition of the complexity of HIV treatment and ongoing advances in preferred treatment regimens[2]. Failure to uniformly provide access to the preferred antiretroviral treatment regimens will lead to poor viral suppression and the development of drug resistance. The consequences for HIV-infected individuals will be poorer health outcomes and higher health care expenditures as well[3, 4]. In addition, recent studies show that failure to maintain viral suppression will lead to increased transmission of HIV infection to others[5].

Drug coverage decision-making must be based on empiric evidence of treatment effectiveness and not driven by cost. Protections for certain drug classes, including antiretroviral agents and the newer, more effective viral hepatitis medications, will be vital to ensure meaningful health coverage for HIV patients.

- **Protect against discriminatory service limits, utilization management and cost-sharing practices.**

For our patients with private insurance coverage, service limits and cost sharing can be significant barriers to staying in care and adhering to their daily HIV treatment regimen. Effective HIV treatment requires regular access to a comprehensive set of services, including an HIV medical provider at least three or four times a year; adherence to a daily regimen of multiple drugs to treat HIV infection, treatment of side effects and concomitant conditions; laboratory screening two to four times a year to monitor treatment effectiveness; specialty care for co-occurring conditions, such as viral hepatitis, mental illness, substance use disorders, diabetes and heart disease in addition to a range of other services[6]. The compounded effect of even nominal co-payments has been proven to impede access to necessary medical care and treatments for patients with chronic conditions[7-9], and arbitrary service limits driven by cost rather than care standards can contribute to increased use of more costly health care services, such as emergency room and inpatient care.

Plans also use cost-sharing structures to discourage enrollment by people with HIV infection and others with chronic conditions, particularly in the prescription drug benefit design or in limiting access to specialists, including HIV providers. Plans frequently place the preferred antiretroviral drugs on the highest cost sharing tiers, while placing older, less effective drugs on lower cost sharing tiers. We strongly urge the EHB guidance or regulations to include strong protections to bar these practices by plans.

Setting a high national standard on service limits and cost-sharing is particularly important given the challenges in monitoring plans for discriminatory practices across all 50 states. We also recommend developing standards for the cost-sharing structures at the national level to avoid the confusion and challenges patients with HIV and other conditions face comparing coverage levels across Medicare Part D plans.

Finally, the protections under Medicare Part D barring plans from applying utilization management to the antiretroviral drug class have been critical to maintaining reliable access to HIV therapies. The burdensome prior authorization processes put in place by Medicare Part D plans for non-HIV medications have delayed access to medically necessary drugs and contribute to the cost and workforce inefficiencies of our health care system[10].

- **Establish a process to monitor benchmark plans at the state level to ensure that plans do not discriminate and to require states to have meaningful processes for public input from all stakeholders, including medical providers.**

With significant state variability, it will be critical to ensure regular monitoring of plans at the federal level to ensure that they do not discriminate through benefit design against people with HIV and others with chronic conditions. As recommended by the Institute of Medicine, we urge HHS to outline requirements for public input processes to ensure that stakeholders have the opportunity to respond to the proposed EHB standard and that states respond or incorporate feedback in a meaningful way.

- **Set a federally defined medical necessity standard based on recognized standards of care, best practices and the clinical expertise of the medical provider.**

A standard definition of medical necessity is another critical element to developing an adequate baseline EHB coverage standard at the national level. A federal definition for medical necessity will be an important safeguard to ensure that coverage decisions are grounded in empirical evidence and clinical expertise and to help mitigate discriminatory practices against HIV patients and others with chronic complex conditions.

We greatly appreciate your leadership in implementing the ACA. As the President stated so well on World AIDS Day 2011, we now have the tools to mark the beginning of the end of the AIDS pandemic. The critical ACA decisions being made now, such as the EHB standard, will determine the success of health reform at improving access to HIV prevention and care, and in doing so chart our course for ending AIDS in the U.S.

Please do not hesitate to contact the HIVMA executive director Andrea Weddle at aweddle@hivma.org for additional information regarding our comments.

Sincerely,

Judith A. Aberg, MD, FIDSA
Chair

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