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hiv medicine association

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December 19, 2012

Maryilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-9980-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: CMS-9980-P

Dear Ms. Tavenner:

The HIV Medicine Association (HIVMA) appreciates the opportunity to comment on the proposed federal rule that will set the standard for essential health benefits (EHB) as required under the Affordable Care Act (ACA). The EHB standard is critical to ensuring meaningful access to health care under the ACA's health care coverage expansion. HIVMA represents nearly 5,000 HIV clinicians and researchers working on the frontlines of the HIV epidemic in communities across the country.

We are excited by the opportunity that the ACA provides to dramatically improve access to health care coverage for people with HIV across our country. Nationally – fewer than 20 percent of people with HIV infection have private insurance coverage. For those HIV-infected patients with private insurance coverage, gaps in coverage for services such as care coordination, quantitative service limits and high cost sharing can poses serious barriers to the effective care and treatment required to optimize health outcomes.

We strongly urge you to keep the medical needs of our patients with HIV infection in mind as you finalize the EHB rule. We appreciate the need to balance affordability for the general population with the generosity of benefits, but focusing on population-level costs does not reflect the cost to individuals with HIV and other chronic conditions. These costs can be high in terms of health outcomes and quality of life as well as increased health care expenditures. Patients with HIV who are unable to regularly access providers, services and treatment frequently become sicker and require more costly interventions, such as hospitalization and an increased number of medications.

HIVMA has submitted detailed comments in collaboration with other HIV organizations regarding the proposed EHB rule.

We highlight in this submission issues of particular concern from the HIV medical provider perspective and urge you to give serious consideration to the recommendations that follow.

State Selection of Benchmark Plans (§ 156.100)

We are concerned by the lack of detailed information available on the benchmark selections and the missing, incomplete or inaccurate data available for some states, e.g., the state benchmark data for Pennsylvania suggests that no anti-HIV antivirals are covered. We recommend making publicly available the plan formularies, benefit exclusions, and utilization management techniques and service limits. The lack of detailed benefits information and questions regarding the reliability of the information raise serious questions regarding how the benchmark plan will set an appropriate coverage standard that can be replicated by other plans for the 10 EHB categories.

Poor health care coverage contributes to late diagnosis of HIV, premature progression to AIDS and development of serious co-occurring conditions, including opportunistic infections. We strongly urge HHS to closely monitor implementation of the benchmark approach across states and reevaluate the process for determining the EHB standard for 2016 with consideration to setting a higher national standard across states. We are deeply concerned that under the current approach we will continue to see geographic disparities in HIV-related health outcomes that are driven in part by state variability in health care coverage levels.

Please consider the specific recommendations noted below in revising the proposed rule.

EHB Category Definition and Process for Supplementing Deficient Coverage (§156.110)

SUPPLEMENTAL COVERAGE

We are concerned with the flexibility granted to plans with regard to supplementing categories when coverage is insufficient. This is particularly important for benefit categories that are not well defined across benchmark plans, such as chronic disease management.

- We urge HHS to define a federal floor for the scope of items and services to be covered within each category.

PRESCRIPTION DRUG COVERAGE

Coverage of Anti-HIV Antivirals

According to the data included in the proposed rule, most of the benchmark plans appear to cover approximately 70 percent of the 36 antiretroviral drugs approved by the Food and Drug Administration for HIV treatment.[1] However, coverage in at least five states (Maryland, North Carolina, New Mexico, Wisconsin and Pennsylvania) appears to be well below the level necessary to

[1] See *Antiretroviral Drugs Used in the Treatment of HIV Infection* at http://www.fda.gov/ForConsumers/byAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm118915.htm. Accessed 12.14.12.

support access to the standard of care set by the federal HIV treatment guidelines that are maintained by the National Institutes of Health.[2] To ensure appropriate access to antiretrovirals and medications from other drug classes across states and plans, we strongly urge HHS to:

- Adopt the successful Medicare Part D policy that requires coverage of all or substantially all of the drugs available in six drug classes, including antiretrovirals. At a minimum, we urge HHS to set a consistent standard across states reflecting typical coverage of the HIV drug classes across all of the benchmark plans.
- Adopt a higher baseline standard that at a minimum requires at least two drugs per drug class for all drug classes as required under Medicare Part D (in the case where a benchmark plan does not cover any drugs in a given class).

Coverage of Anti-Hepatitis Antivirals and Specialty Drugs

An even greater number of states offer subpar coverage within the anti-hepatitis antiviral drug class. Based on the information posted by Center for Consumer Information and Insurance Oversight (CCIIO),[3] 10 state benchmark plans (Colorado, the District of Columbia Hawaii, Iowa, Maryland, New Mexico, North Carolina, Pennsylvania, South Dakota, Tennessee and Utah) offer limited coverage within the anti-hepatitis drug class. In some states, the hepatitis medications may be covered as a "specialty" drug, but it is unclear from the proposed rule how "specialty" medications will be reflected in the drug coverage standard set by the state benchmark.

Access to the best available treatment options is critical for the estimated 30 to 40 percent of people living with HIV who are co-infected with hepatitis C (HCV). HCV treatment is on the verge of being revolutionized with the anticipated availability of new and improved therapeutics that have higher cure rates, and are more tolerable due to shorter treatment regimens and fewer side effects. People living with HIV and others who gain coverage through the 2014 coverage expansion should have the opportunity to benefit from these treatment advances. We urge HHS to:

- Require coverage of the benchmark "specialty drugs" and ensure that these drugs are reflected in the appropriate drug class to ensure appropriate coverage levels within the respective drug class.
- Designate anti-hepatitis drugs as a protected drug class requiring coverage of all or nearly all of the drugs available, or at a minimum set a higher baseline coverage relative to the typical coverage provided across benchmark plans.

Policies to Support Access to the HIV Standard of Care

Please consider the policy recommendations below to bring the EHB prescription drug coverage standard in line with the medication needs of people living with HIV.

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[2] See *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* at http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0/. Accessed 12.17.12.

[3] Available at http://cciio.cms.gov/resources/data/ehb.htm. Accessed 12.14.12.

- It is imperative for our treatment-experienced patients to have timely access to new therapeutic agents as they become available. We urge HHS to:

    - Emphasize in the final rule that the minimum coverage requirement of the greater of one drug in a class or the number of drugs covered in a class by the benchmark plan is a floor, not a ceiling.
    - Require plans to be responsive to treatment advances by having a mechanism to review and consider coverage of new drugs upon approval by the Food and Drug Administration (FDA).

- A fair and reasonable process for individuals to appeal for access to non-formulary medications and lower cost-sharing should be specified in the regulation as a mechanism to mitigate potential harm due to restrictive formulary coverage. We urge HHS to:

    - Adopt the Medicare Part D exceptions and appeals process, including the provisions allowing the process to be initiated by the provider or an authorized representative.
    - Allow for enrollees to file an appeal to obtain a medication at a lower cost sharing tier as allowed under Part D.

- The US Pharmacopia (USP) categorizes the antiretroviral medications into four broad classes of drugs while the federal HIV treatment guidelines and the FDA group antiretrovirals into seven drug classes, reflecting the unique mechanisms by which the therapeutic agents suppress the virus.[4] We urge HHS to:

    - Reconsider the USP formulary guidelines for determining the EHB drug classes.
    - Update the USP classes to reflect widely recognized standards of care, such as the federal HIV treatment guidelines and develop a mechanism to add new drug classes upon approval by the FDA.

- Monthly medication limits can impede access to medically appropriate treatment and discriminate against people with HIV and others who rely on regular access to multiple prescription drugs per month to stay healthy. If any plans impose monthly drug limits, we urge HHS to:

    - Waive any monthly drug limits for people with HIV and others with chronic and/or life-threatening conditions; or
    - Require plans to allow the prescribing medical provider or pharmacist to override any limits on the number of prescription drugs covered per month.

[4] See *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. Available at http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/0/. Accessed 12.14.12.

- Disruptions in treatment have been avoided under Medicare Part D due to a transition policy requiring drug plans to provide a temporary supply of a non-formulary medication upon first presentation at the pharmacy. We urge HHS to:

    - Implement a transition policy that requires coverage of a one time 90-day supply of a non-formulary medication to prevent dangerous treatment interruptions in 2014 and beyond when individuals may transition between private plans or between Medicaid and private insurance coverage.

CHRONIC DISEASE MANAGEMENT

Many of our patients with HIV infection have multiple co-occurring conditions, in addition to socioeconomic and psychosocial barriers that complicate care and treatment adherence. For them, access to an effective chronic disease management benefit is a central component of care. We are very concerned with the lack of information provided on the chronic disease management benefit either by the benchmark plans or within the proposed rule.

If the chronic disease management benefit is not identified or clearly defined within the benchmark or the EHB rule, there will not be a standard for health plans to base their coverage and it will be difficult to monitor coverage across plans. Failure to cover or market this important benefit is another way to discourage individuals with chronic conditions from plan enrollment.

We also are concerned that given the latitude to substitute services within the 10 EHB categories, that plans may substitute coverage for preventive services over chronic disease management services. In the final rule, we urge HHS to:

- Set a minimum standard for chronic disease management that is patient-centered and supports care coordination and case management along with the flexibility to cover support services as medically indicated. See the elements identified in *Essential Components of Effective HIV Care*.[5]
- Specify that chronic disease management must remain a distinct benefit that cannot be replaced by preventive services.
- Specify that HIV infection qualifies an individual for chronic disease management.

MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES

Access to the continuum of services effective at treating mental illness and substance use disorders is critical to the nearly 50 percent of HIV-infected patients in the United States also have a mental health or substance use diagnosis. In practice, one of our biggest challenges can be helping our patients access effective mental health and substance use services due to poor coverage and a lack of qualified providers.

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[5] Gallant, JE et al. *Essential Components of Effective HIV Care*. Clin Infect Dis (2011). Online at http://cid.oxfordjournals.org/content/early/2011/10/20/cid.cir689.full. Accessed 12.18.12.

We look to the ACA to help address these disparities and fully support the proposed rule's inclusion of the Mental Health Parity and Addiction Equity Act (MHPAEA) requirements into the EHB. However, given the challenges with implementing the MHPAEA within the employer-sponsored market, we strongly recommend providing greater guidance to states for this important benefit. We urge HHS to:

- Clarify how states will monitor and enforce the parity requirements and specify how substance abuse and mental health benefits packages found to be non-compliant will be supplemented.
- Provide explicit clarification that a range of both mental health and substance abuse services must be covered.

PREVENTIVE SERVICES

We encourage HHS to explicitly restate that the preventive services coverage requirement applies to the Medicaid expansion population in future rulemaking on the Medicaid benchmark.

Substitution of Benefits (§ 156.110(b)(1))

We are concerned that the proposed rule would allow plans substantial flexibility to substitute benefits *within* EHB categories. This flexibility could result in plan designs that limit access to essential services for people living with HIV, such as chronic disease management. We urge HHS to:

- Not allow substitution within categories, a practice that could discriminate against certain populations, e.g., substituting mental health services for substance use services, and
- Place additional protections and limits on substitution by providing a list of allowable plan substitutions if substitution within categories is allowed.

Non-discrimination (§ 156.125)

The practices historically employed by insurers to avoid covering the HIV patient population have contributed to fewer than 20 percent of our patients having private insurance coverage. While important protections will no longer allow plans to deny or rescind coverage based on health status, we are concerned that some insurers will employ other tactics to avoid covering this patient population. The ACA includes explicit protections to safeguard against discriminatory insurance practices that we believe must be defined and enforced to the greatest extent possible – particularly in the absence of a higher national benefits floor. We recommend greater clarity and guidance to states regarding discriminatory plan designs to ensure that the ACA mandates are met to address the issues noted below.

- Physician network size and composition must be evaluated to ensure that plan networks include providers that are able to provide quality care for people living with HIV and other chronic and complex conditions. Excluding HIV providers from a plan network should be highlighted as a discriminatory plan design that hinders access to EHB services.

- Utilization management techniques, exclusions, and service limits must be closely monitored to ensure that plans have not created barriers to services or excluded services to discourage enrollment of people with chronic and complex health conditions or to deny or delay access to medically appropriate care for people with HIV infection.

- Enrollment across plans should be monitored to ensure that plans are not excluding people with HIV. Under Medicare Part D, plans dropped people with HIV from coverage or failed to comply with the "six protected classes" policy that requires coverage of all antiretrovirals to discourage enrollment of people with HIV.

- The use of cost-sharing, in the form of co-payments, deductibles, and coinsurance, must be closely evaluated to ensure that cost-sharing is not used to limit access to medically appropriate care and treatment for people living with HIV and other chronic conditions. As an example, placing HIV or viral hepatitis medications on specialty tiers that require 25 or 30 percent coinsurance can leave lifesaving medications out of reach for some patients. In cases where cost-sharing prohibits access to care for people with HIV infection, we urge HHS to delineate medical override provisions or exception processes that can be initiated by the enrollee, an authorized representative or the medical provider (similar to the current process used in Medicare Part D).

- EHB coverage should support widely accepted standards for HIV care. Clinical guidelines and recommendations are available at http://aidsinfo.nih.gov/ and http://www.hivma.org/Guidelines_and_Patient_Care.aspx.

Cost-sharing and Actuarial Value

Accurately estimating out-of-pocket costs and the underlying value of the coverage will be a key factor for our patients to consider in making plan selections. We highlight a few key recommendations below to improve the proposed approach in these areas.

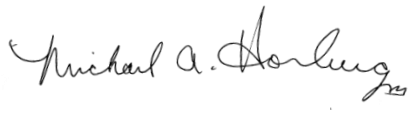
- The data used to set the standard for the AV calculator should be streamlined to represent a single, standard population to more accurately compare coverage and out-of- pocket costs across the four "metal" levels of coverage options (bronze, silver, gold and platinum).

- The single, standard population should reflect the usage associated with a generous plan design to properly value the more generous plan and allow for a more accurate comparison of less generous plans.

- The AV calculator must be structured to take into account service limits as well as dollar denominated forms of cost-sharing. Service limits contribute to higher out-of-pocket costs for individuals with HIV and other chronic conditions and must be reflected in the AV.

Thank you for the opportunity to comment on this important rule that will play a large role in determining the success of the ACA for many of our patients and people with HIV across the country. We would be pleased to discuss our recommendations with you, and can be reached through the HIVMA executive director Andrea Weddle at (703) 299-0915 or aweddle@hivma.org.

Sincerely,



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