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Donald Berwick, MD, MPP
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Proposed Rule 76 Federal Register 136 (July 15, 2011).

Dear Dr. Berwick:

The HIV Medicine Association (HIVMA) appreciates the opportunity to comment on the federal rules that will govern the state-based exchanges. The regulations will establish an important standard for ensuring the exchanges serve as a fair marketplace for health coverage options that provide meaningful access to health care, including for people with HIV infection. HIVMA represents more than 4,500 HIV clinicians and researchers working on the frontlines of the HIV epidemic in communities across the country.

There are many important issues for the Centers for Medicare and Medicaid Services (CMS) to consider in issuing exchange rules that offer states appropriate levels of flexibility while maintaining critical protections for people with HIV infection and others with chronic conditions. We will focus our comments on the provider network issues because of their critical role in supporting access to quality HIV care, but strongly urge you to consider the recommendations that we have endorsed in the HIV Health Care Access Working Group's comment letter related to:

- Stakeholder involvement that ensures inclusion of advocates and providers of "hard to reach populations" to ensure seamless access to HIV care that includes safety-net Ryan White providers.
- A navigator program that includes at least one option that is a community and consumer focused non-profit.
- A simple streamlined, one application process for exchange plan enrollment, premium tax credit, cost sharing subsidies, Medicaid, and the Basic Health Plan.
- Extended enrollment periods that ensure seamless coverage for people with HIV infection, including if they are auto-enrolled the flexibility to change to a plan with benefits and provider coverage that meets their needs.
- Standardized transparency and "plain language" standards across the insurance market that include information on out-of-network coverage and cost sharing that can be compared across health plans.
- Reimbursement levels for federally qualified health centers (FQHCs) that are no less than the FQHC Medicaid payment level to ensure FQHCs have the ability to meet the higher medical and psychosocial needs of the populations that they serve, including people with HIV infection.

- **Establishment of Exchange Network Adequacy Standards (§155.1050)**

Inclusion of HIV Medical Providers

HIV patients with early and reliable access to care and treatment can live healthy lives with near normal life spans thanks to the remarkable advances in HIV care and treatment. Effective care management requires a hybrid of specialty and primary care—particularly for patients diagnosed late (as are nearly a third of HIV patients) and after damage to the immune system has occurred. The complexity of HIV care is compounded by the high rates of serious comorbidities among people with HIV, including hepatitis C, serious mental illness, substance use disorders, diabetes and heart disease.

HIV medicine does not fall under the purview of any one medical specialty, but it is well documented that higher quality and more cost effective care is delivered by physicians with experience and expertise in treating HIV, regardless of specialty training. Experience is generally defined according to patient management in addition to ongoing learning through HIV-related continuing medical education. HIVMA developed guidance in 2002, updated in 2010, that has been adopted by the State of California, health plans and institutions to identify qualified HIV physicians for provider networks. Please find a summary of the definition in the box below.

HIVMA Definition of a Qualified HIV Physician

HIV physicians should demonstrate continuous professional development by meeting the following qualifications:

- In the immediately preceding 36 months, provided continuous and direct medical care, or direct supervision of medical care, to a minimum of 25 patients with HIV;

AND

- In the immediately preceding 36 months has successfully completed a minimum of 40 hours of Category 1 continuing medical education addressing diagnosis of HIV infection, treatment for HIV disease and co-morbidities, and/or the epidemiology of HIV disease, and earning a minimum of 10 hours per year;

AND

- Be board certified or equivalent in one or more medical specialties or subspecialties recognized by the American Board of Medical Specialties or the American Osteopathic Association.

OR

- In the immediately preceding 12 months, completed recertification in the subspecialty of infectious diseases with self-evaluation activities focused on HIV or initial board certification in infectious diseases. In the 36 months immediately following certification, newly certified infectious diseases fellows should be managing a minimum of 25 patients with HIV and earning a minimum of 10 hours of category 1 HIV-related CME per year.

We urge CMS to require plans to include HIV medical providers in their networks and to provide guidance for identifying qualified HIV medical providers, such as the HIVMA definition. It also will be important to clearly identify HIV medical providers in plan network directories.

Access Standards

We strongly support the provider access standards below and urge you to ensure that they apply to HIV medical providers and others who provide specialized care.

- Plans must maintain sufficient types of providers to ensure service accessibility.
- Plans must ensure enrollees are not required to travel unreasonable distances or times to access services.
- Plans must monitor the adequacy of the provider network.
- Plans must ensure out-of-network care is available at no additional cost to the enrollee when network providers are not reasonably accessible.
- Plans must be required to ensure care for ALL enrollees, including those with conditions requiring unique expertise, such as people living with HIV disease.
- Plans should define primary care providers as including Nurse Practitioners (NP) and Physician Assistants (PA), as they play an important and growing role in the HIV care system.

Quality Monitoring

Exchanges should be required to monitor and evaluate the quality of care offered by their network providers. We urge you to offer guidance to the exchanges on the importance of monitoring the quality of care to improve health outcomes and deliver more cost effective care. In addition, exchanges should be encouraged to employ the quality measures adopted by other federal programs, such as the Physician Quality Reporting System, including the HIV-specific measures developed by the National Committee for Quality Assurance and endorsed by a consortium of organizations, including the American Medical Association and HIVMA.

- **Essential Community Providers (§156.235)**

Ryan White providers are covered under the provision in the Patient Protection and Affordable Care Act (ACA) that requires plans within the health insurance exchanges to contract with “essential community providers where available, that serve predominately low-income, medically-underserved individuals, such as health care providers defined in section 340B(a)(4) of the Public Health Service Act.” We are concerned by any proposal to weaken this provision and urge CMS to offer a robust definition for evaluating the sufficiency of the provider network that requires inclusion of providers with expertise caring for underserved populations that rely on specialized care, such as HIV patients. **Specifically, we urge you to require plans to contract with “any willing” Ryan White provider to ensure this standard is met.**

Since 1990, the Ryan White program has supported the delivery of HIV care to uninsured and underinsured populations and in doing so created a network of nearly 400 clinical programs dispersed throughout the country that are Centers of Excellence for HIV care. The programs are a blend of academic health centers, FQHCs and other community-based organizations that have developed unique expertise in delivering high quality HIV care and in meeting the medical, psychosocial and daily living needs of a medically underserved patient population.

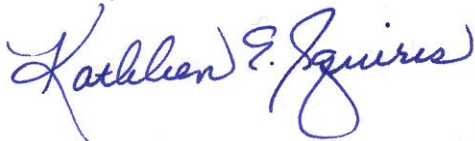
Many of the individuals with HIV who gain access to coverage through the state-based exchanges or the Medicaid expansion are currently receiving primary care at Ryan White-funded clinical sites. It is critical for them to have the option to stay with their HIV medical providers to maintain continuity of care and ensure access to the providers with the appropriate level of HIV expertise. As an example, enrollment in the Pre-existing Condition Insurance Plan (PCIP) has been limited for people with HIV, despite un-insurance levels as high as 30% among HIV patients, because Ryan White providers were not included in some state provider networks. In these states, patients elected to stay with their HIV medical provider rather than enrolling in the PCIP to avoid jeopardizing their health with a new and unknown medical provider.

For these reasons, we strongly recommend that you require plans to contract with the HIV clinics and programs currently funded by the Ryan White program to provide comprehensive HIV care. We are concerned based on prior experience with private insurers barring contracts with “public health” clinics and by the disincentive plans may have to contract with Ryan White-funded programs because of the populations that they serve. To avoid serious disruptions in care and to ensure access to qualified HIV providers, we urge you to require plans to contract with “any willing” Ryan white-funded medical provider.

The ACA’s health coverage expansion in 2014 will be the first opportunity for many of our patients to access any type of health care coverage before they become sick and disabled. Our comments are offered based on our experience with the current health care system and with the hope that the coverage expansion will provide meaningful access to lifesaving care to our HIV patients and to the nearly 50 percent of people with HIV in the U.S. not in regular care.

Thank you for the opportunity to share our views. Please do not hesitate to contact us with questions through the HIVMA executive director Andrea Weddle at (703) 299-0915 or aweddle@hivma.org.

Sincerely,

A handwritten signature in blue ink that reads "Kathleen E. Squires". The signature is fluid and cursive, with the first name being the most prominent.

Kathleen E. Squires, MD

Chair, HIV Medicine Association