



**Center for  
Health Law  
and Policy  
Innovation**

**HARVARD LAW SCHOOL**

**HEALTHCARE REFORM MONITORING PROJECT  
HIV/AIDS COMMUNITY UPDATE  
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The U.S. Supreme Court's long-awaited decision on the Patient Protection and Affordable Care Act (ACA) was handed down in June 2012.<sup>1</sup> The Court largely upheld the law, ruling that:

- (1) the minimum essential coverage provision (the "mandate") was constitutional under Congress' authority to tax and spend;
- (2) the Medicaid expansion provision was constitutional but not enforceable (i.e., the Department of Health and Human Services (HHS) may not revoke existing federal medical funding from states that refuse to expand); and
- (3) the Anti-Injunction Act (AIA) did not bar the law suit challenging the mandate, even though it was deemed a tax that had not yet been collected.

In the wake of the opinion, advocates, policy makers, and health care providers, having long awaited its delivery, have acted rapidly to move forward with the implementation of the law, at both the federal and state level. Over the past several months, HHS has issued several final rules, proposed regulations, and guidance that provide details as to how key pieces of the law – such as state based or federally facilitated exchanges – will work in practice. In addition, states are continuing to move ahead with implementation efforts, including taking advantage of opportunities to encourage collaboration between HIV providers and agencies, state Medicaid offices, and safety net providers as states plan for the ACA's private insurance exchanges and Medicaid expansion in 2014. Below are descriptions of these developments, as well as a discussion of ongoing advocacy efforts.

### **Patient Protection and Affordable Care Act of 2010 (ACA): Implementation Issues**

#### **Federal Regulations and Guidance**

Since the Supreme Court's ruling on the ACA, HHS has published several proposed rules and guidance across a range of its provisions, including:

##### *Exchanges*

In June 2012, the Center for Consumer Information and Insurance Oversight (CCIIO) released a Draft Blueprint for State Exchanges (Blueprint), outlining the requirements for states to indicate when and whether they will develop a state based exchange or a state partnership exchange. The Blueprint includes a roadmap, laying out state requirements for running a state-based exchange or entering into a partnership with a federally facilitated exchange (FFE). A state that submits a declaration of intent to develop an exchange at least 20 days before submitting an exchange Blueprint is entitled to exchange application consultation services from the Centers for Medicare

and Medicaid Services (CMS). States intending to run their own exchanges must have a design prepared by January 1, 2013 (or will be entered into an FFE).

Notably, the Blueprint does not include requirements that states provide attestation and supporting documentation outlining plans to implement and enforce the nondiscrimination requirements that attach to any state or entity receiving federal funds.<sup>2,3,4</sup> These civil rights laws require federally funded states or entities to reduce health disparities and make equitable services available to all demographics, including those with limited English proficiency or disabilities.<sup>5,6</sup>

- Community response: Compliance with these nondiscrimination laws will be paramount; 49 states and the District of Columbia received federal funds to plan and implement exchanges (§ 2.3 of the Blueprint explicitly requires compliance with these laws and HHS released final exchange eligibility and enrollment regulations in March 2012, requiring state exchanges to comply with all applicable nondiscrimination statutes<sup>7</sup>). Patient navigators contracting with Exchanges and Qualified Health Plans (QHPs) sold thereon are also subject to these rules (§§ 2.6 and 4.0, respectively). Unlike exchange applications, QHP certification standards must include verification of compliance with prohibitions against discrimination.

Finally, the Blueprint requires only part of state exchange blueprints be publicly available within ten days of HHS approval or conditional approval. Principles of transparency require that an entire blueprint be made publicly available.

### *Women's Preventive Services*

As of August 1, 2012, the ACA requires most health plans (created or substantially changed after March 23, 2010) to cover evidence-based preventive services without cost-sharing (i.e., free of charge to the patient).<sup>8</sup> Many of these services are relevant to women living with or at risk for HIV. For example, the law requires these plans to cover, in full:

- annual counseling and screening for HIV for all sexually active women;
- all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women of reproductive age;
- annual counseling on sexually transmitted infections for all sexually active women; and
- screening and counseling for interpersonal and domestic violence.

### *Essential Health Benefits*

HHS released a final rule, effective August 12, 2012, governing data collection on plans that will be potential benchmark plans for purposes of defining Essential Health Benefits (EHB).<sup>9</sup> The rule is relevant to patients with HIV in that the data provided to officials will affect the determination of what is considered adequate EHB. In particular, three aspects of the rule are important. First, HHS decided not to collect data on non-quantitative limits in plans (e.g., step therapy or prior authorization requirements). This means that people living with HIV may be required to try the most cost effective drug and establish that it is therapeutically ineffective before being able to access more expensive (brand name) versions. Second, HHS is requiring

that state selected plans be available for public comment before being submitted as a benchmark defining the state's EHB. This is critical to allow advocates to comment on lack of transparency (e.g., regarding non-quantitative limits). Finally, HHS refused to expand data collection as suggested by many health advocates (e.g., to require information on coverage exclusions, medical necessity, habilitative services, cost-sharing, or treatment limits).

- Community response: HIV advocates are concerned that coverage limitations in benchmark plans may be incorporated into EHB definitions. In other words, if a benchmark plan covers only one drug per therapeutic class, and is approved by HHS as defining EHB for plans sold on the state's Exchange, some beneficiaries will lack access to necessary treatment (e.g., individuals living with HIV often require a "cocktail" of drugs falling within the same therapeutic class). Advocates have encouraged HHS to revise its guidance (issued in December 2011) to require plans sold in the individual and small group markets to cover "all or substantially all" medications in major therapeutic classes, including HIV/AIDS.<sup>10</sup> This is the Medicare plan standard, and provides patients with comprehensive access to care. Even Congress has adopted this recommendation: 28 Members of the House have encouraged HHS to adopt Medicare's "all or substantially all" plan rather than the one drug per class in defining EHB.<sup>11</sup> It is important for advocates to note that cutting costs on drug coverage will not ultimately reduce healthcare spending, but rather result in increased morbidity and mortality as patients cannot access the appropriate drug combinations that treatment standards require. As advocates await further guidance regarding EHB definitions, it remains critical to emphasize that federal regulations must meet the non-discrimination provisions of existing laws, that protect the needs of people living with HIV and other chronic conditions.<sup>12</sup>

### *Federally-Facilitated Exchanges*

In May 2012, CCIIO released preliminary guidance on Federally-Facilitated Exchanges (FFE),<sup>13</sup> which will operate in states that have not established a fully operational Exchange by 2014 (enrollment in Exchanges must be open as of October 1, 2013; determination of a state's need for a FFE will be made by January 1, 2013).<sup>13</sup> Because most states have not made substantial progress in creating a state-based exchange, FFEs are likely to be common. There are four guiding principles for FFEs: (1) commitment to consumers; (2) market parity; (3) leveraging the traditional state role; and (4) engagement with states and other stakeholders.

States may opt to enter into a State Partnership model FFE, in which a state would administer plan management functions (QHP certification and oversight, development of QHP standards, data collection) and/or in-person consumer assistance functions (e.g. oversight and management of Navigators, enrollment and comparison assistance) and HHS would manage centralized functions of the FFE (e.g., maintaining an Exchange website and consumer hotline).<sup>13</sup> The ACA provides funding for these activities.<sup>14</sup> Otherwise, HHS will run the FFE in its entirety.

- Community response: Regardless of whether a state opts to participate in the administration of an FFE, robust, meaningful, and ongoing stakeholder engagement will be critical. Indeed, CCIIO's bulletin notes that states must hold implementation sessions

in which community members can provide input into the implementation of FFEs. Also critical is the input of providers, public health professionals, and vulnerable populations, to ensure both the design and implementation of the FFEs meet the needs of people living with HIV and other chronic conditions. For example, plans offered in an FFE will cover visits to “essential community providers.” Without stakeholder input, this could be defined to exclude Ryan White program clinics, which would exclude a large number of HIV providers from a beneficiary’s network of care. Similarly, it will be important that FFEs develop high standards for patient navigators, requiring linguistic and cultural competence to ensure that vulnerable populations are not left behind in states opting into an FFE. Finally, input of state Medicaid administrators will be critical; FFEs will have to coordinate with Medicaid to refer eligible applicants that apply for coverage on the exchange.

Ensuring full participation in FFE design will likely require a mandate that states or HHS create working groups rather than defer to the National Association of Insurance Commissioners or state insurance commissioners (in the case that a state declines to implement an exchange, state leaders are likely to be antagonistic to the process).

Guidance on multistate plans is forthcoming.

#### *Medicaid Payments for Primary Care Physicians*

The ACA increases the rate at which primary care physicians (PCPs), including family practice physicians, general internists, and pediatricians, are reimbursed by Medicaid to at least the rate paid by Medicare for two years (2013-2014).<sup>15, 16</sup> The new rate is designed to improve access to continuous care, preventive care, and to reduce health care costs.

- Community response: the HIV Health Care Access Working Group has emphasized that it will be critical that these payments are administered in a manner that ensures these goals are met (e.g., access to care must be measureable) and that payments are not diverted via managed care overhead costs or otherwise not distributed to PCPs. In short, increased PCP reimbursement rates not paid out to PCPs must be refunded to CMS. Finally, for the purpose of the provision to be realized (i.e., to encourage more physicians to practice primary medicine), the expanded rates must continue beyond 2014.

#### *Basic Health Plans*

The ACA authorizes states to create a state-run basic health plan (BHP) for individuals living between 133-200% FPL, not eligible for Medicaid, Medicare, or affordable employer sponsored coverage, as defined by the Act. These individuals may purchase a subsidized plan, most likely operated under the state’s Medicaid agency. Details regarding state plans to operate BHPs are forthcoming (CMS released a Request for Information Regarding State Flexibility to Establish a BHP in September 2011,<sup>17</sup> and states have yet to make final plans). All BHPs must offer the EHBs required of QHPs sold on the exchanges, and may not impose greater cost sharing requirements.

- Community response: Advocates should educate state Medicaid offices on the options the ACA affords in designing BHPs. For example, subsidized cost sharing is permissible, and is something many states should consider, particularly for low-income groups requiring multiple specialist visits and/or prescription medications. Moreover, states are authorized to create multiple BHPs (e.g., disease specific BHPs that might subsidize cost sharing for a certain demographic).<sup>18</sup> These types of options are particularly important for individuals living between 133-200% FPL who require a multitude of physician visits and prescriptions, and for whom cost sharing can quickly become prohibitive.<sup>19</sup>

### *Expanding Medicaid*

The ACA requires states to expand Medicaid eligibility to all individuals living under 133% FPL, beginning in 2014 (or earlier if states choose). The Supreme Court recently ruled that the Secretary of HHS could not enforce this provision by revoking all existing federal medical funding for failure to comply with the expansion, but could still offer additional federal money (90-100% of the cost of newly eligible beneficiaries) indefinitely.

In the wake of this ruling, HHS has issued new guidance for states, including two letters: one addressed to state Governors from Secretary Sebelius,<sup>20</sup> encouraging them to adopt the expansion provision, and a second to Governor McDonnell (R, VA) from Acting Administrator Tavenner, highlighting the benefits of the expansion.<sup>21</sup> The Congressional Budget Office (CBO) has also released updated estimates on the cost of healthcare reform, given the Court's ruling. The CBO's most recent projections estimate that approximately 4 million more individuals will be uninsured in 2014 than projected before the Court ruled on the law, and an additional 3 million by 2022.<sup>22</sup> This translates into an estimated savings in Medicaid spending of \$288 billion.<sup>22</sup> This number does not account for the cost of uncompensated care.

States are in the process of deciding whether or not to expand programs. States that have already committed to and initiated the expansion process are upgrading information technology systems to increase capacity of enrollment (subject to enhanced federal funding for this purpose from CMS), but require additional guidance on implementing the Modified Adjusted Gross Income methodology (see below).<sup>23</sup>

- Community response: Advocates have been active in encouraging states to take advantage of the ACA's expansion option in the wake of the Court's ruling. There are several arguments supporting expansion, including the improvement of individual and public health as well as fiscal solvency. If all states expand Medicaid eligibility pursuant to the ACA, approximately 17 million uninsured individuals will become newly eligible for coverage. This will expand access to preventive services and early treatment, reducing the incidence and burden of chronic diseases. It will also reduce the spread of existing infectious diseases by reducing contagion levels or providing a cure. Finally, Medicaid expansion will improve fiscal solvency of both hospitals – which rely on disappearing federal supplementary money to offset the cost of serving the uninsured – as well as states, which shoulder the burden of most uncompensated care, particularly for the mentally ill. Net state savings are projected to range between \$12-19 billion in the first five years of implementation.<sup>24</sup> Regardless of a state's current deliberations relating

to expansion, it is important to note that all states remain bound to the maintenance of effort provision of the ACA (maintaining existing eligibility standards until 2014).<sup>25</sup>

### *Dual Eligibles*

The ACA improves coordination and delivery of care for dual eligible beneficiaries (enrolled in both Medicare and Medicaid).<sup>26</sup> In May 2012, CMS release a proposed rule on State Home and Community-Based Services (HCBS)<sup>27</sup> that implement's the ACA's creation of 5 year waivers for dual eligible beneficiaries (allowing the use of managed care as well as long-term or community based care).<sup>28</sup>

- Community response: While renewal or authorization of these waivers is subject to the Secretary's discretion, it is important that consideration of cost-effectiveness or efficiency, as provided by the ACA, not be read to allow for renewal of waivers that reduce services for dual eligibles. See below for more information on coordination of benefits for dual eligibles.

The ACA also gives HHS authority to issue grants for demonstration projects to study new ways of coordinating care. On July 11, 2012, CMS issued guidance to state Medicaid directors outlining a new financial alignment model designed to reduce cost and improve coordination of both managed care and fee-for-service plans.<sup>29</sup> This three year demonstration plan will allow states to experiment with new payment and service delivery models, aiming to reduce spending and improve care. Beneficiaries will receive benefits through the demonstration projects beginning in January 2013.

- Community response: Dual eligible system of coverage is critical to HIV care – CMS is the largest funder of HIV care; nearly 50% of people receiving treatment rely on Medicaid and 30% of these are dual eligibles. Yet one item of concern in the July guidance is that it allows states to pursue passive enrollment into managed care plans, despite caution from Senator Rockefeller (and the HIV Health Care Access Working Group) that dual eligibles must be able to select plans based on individual needs.<sup>30,31</sup> Indeed, the ACA protects dual eligible beneficiaries' right to select a fee for service plan rather than an MCO. This is particularly relevant to individuals living with HIV, who may require a more expansive drug formulary than is available from an MCO. At the very least, beneficiaries must at least not be locked into an automatically assigned plan (i.e., must be able to switch plans without undergoing a waiting period), and must have access to comprehensive education about plan options and beneficiary outreach programs available to support individuals in selecting a plan.

Problematically, the financial alignment model, as outlined to the states, is contingent on realization of cost savings,<sup>30</sup> potentially at the expense of patient care. Indeed, Senator Rockefeller pointed to the legislative intent behind the drafting of the law on dual eligible coordination, demonstrating that fiscal savings were not the only goal. He noted that while several states are already planning to enroll dual eligible beneficiaries into the financial alignment initiative, CMS would fall short were it to assume "success" without evaluating these programs in terms of access to and quality of care.

### *Medical Loss Ratio Rebates*

The ACA requires health insurers to spend a certain percentage of premium dollars on medical claims, clinical services, and healthcare quality improvement initiatives, as opposed to administrative activities and profits.<sup>32</sup> The percentage spent on these clinical services and quality improvement is referred to as the medical loss ratio (MLR). Insurers in small group and individual markets must maintain an MLR of at least 80%; insurers in large group markets must maintain an MLR of at least 85%. In other words, insurers must spend 80 or 85% of the premiums they collect on clinical services or quality improvement. An insurer that falls below these thresholds must refund consumers to meet the appropriate ratio.

This provision of the law went into effect in January 2011,<sup>33</sup> and the first rebates were sent to beneficiaries (or employers) in August 2012.

### **Bridge to 2014**

#### *ACA Implementation Education Sessions*

In August 2012, HHS hosted ACA “Implementation Forums” in four cities (Atlanta, Chicago, Denver, and the District of Columbia). The sessions were open to the public and provided a forum for advocates and stakeholders to ask questions about implementation of the law.

- Community response: HHS officials did not comment on whether there would be a “partial expansion” option for the Medicaid expansion (i.e., extending eligibility to a lower threshold than 133% FPL) but did note that there is no deadline for states to expand, and that a state may “opt out” of the expansion after implementation, without penalty. It is important for advocates to highlight these flexibilities as they encourage state legislators to opt for the expansion.

### **Congress**

As the fiscal year comes to a close (September 30, 2012), Congress is once again narrowly focused on the budget. In response, President Obama signed into law the Sequestration Transparency Act of 2012 on August 7, 2012.<sup>34</sup> The law requires the Administration to demonstrate detailed plans to implement budget sequestration cuts scheduled to commence on January 2, 2013. If this occurs, HIV prevention, treatment, and research could suffer over \$500 million in cuts. In other words, reducing discretionary funding by 7.8% (as HHS has estimated may occur) would result in \$61 million loss to the CDC prevention program, \$189 million to Ryan White, \$240 million to the National Institutes of Health AIDS research program and \$26 million to housing assistance for HIV positive individuals.

Other proposals for cuts are also disturbing. For example, Republican congressmen have urged state governors to resist implementation of the ACA, including by failing to establish Exchanges,<sup>35</sup> and the Senate has proposed \$16 million reduction in the U.S. Military HIV Research Program (MHRP), which funds critical HIV treatment trials.<sup>36</sup>

## ACA Funding Opportunities

With sequestration deliberations consuming Congress, new appropriations for ACA implementation are on hold. However, HHS has been actively distributing already appropriated money for implementation activities. For example, to spur community health efforts, the Department recently awarded \$128.6 million to 219 community health centers, allowing the clinics to expand services to an additional 1.25 million patients.<sup>37</sup> To counter infectious disease, it recently allocated \$48.8 million across all 50 states, aimed at strengthening epidemiology and laboratory systems.<sup>38</sup> The Health Resources and Services Administration (HRSA) awarded an additional \$68 million – via the Ryan White Program – to increase HIV/AIDS services available to women, infants, and children.<sup>39</sup> Finally, to strengthen the public health workforce, HRSA awarded \$23 million to 37 public health training centers, readying the next generation’s workforce for the field, and CDC allotted \$25 million to fellowship programs, placing providers and public health professionals in rural areas and providing continuing education services to existing workers.<sup>40</sup>

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<sup>1</sup> National Federation of Independent Business v. Sebelius, No. 11-393, slip op. (U.S., June 28, 2012).

<sup>2</sup> Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 1557 (2010).

<sup>3</sup> The Public Health and Welfare, 42 USC § 2000d (2010).

<sup>4</sup> The Rehabilitation Act of 1973, 29 USC § 504 (2010).

<sup>5</sup> *Lau v Nichols*, 414 U.S. 563 (1974).

<sup>6</sup> The Public Health and Welfare, 42 USC § 2000d-4a (2010).

<sup>7</sup> 45 C.F.R. §§ 155, 156, and 157 (2012).

<sup>8</sup> ACA § 1001.

<sup>9</sup> 45 C.F.R. 156 (2012).

<sup>10</sup> Letter from AIDS Foundation of Chicago et al, to Kathleen Sebelius, Secretary, Department of Health and Human Services (Aug. 9, 2012).

<sup>11</sup> Letter from Doris Matsui et al, Congresspersons, to Kathleen Sebelius, Secretary, Department of Health and Human Services (July 12, 2012).

<sup>12</sup> Social Security Act, 42 U.S.C. § 1937 (2010).

<sup>13</sup> CENTER FOR CONSUMER INFORMATION AND INSURANCE OVERSIGHT, GENERAL GUIDANCE ON FEDERALLY-FACILITATED EXCHANGES (2012).

<sup>14</sup> ACA § 1311.

<sup>15</sup> ACA § 1002(a)(1)(C).

<sup>16</sup> Medicaid Program; Payments for Services Furnished by Certain Primary Care Physicians and Charges for Vaccine Administration under the Vaccines for Children Program, 77 Fed. Reg. 27671 (May 11, 2012).

<sup>17</sup> Request for Information Regarding State Flexibility to Establish a Basic Health Program Under the Affordable Care Act, 76 Fed. Reg. at 178 (Sept. 14, 2011).

<sup>18</sup> ACA § 1331(a)(1).

<sup>19</sup> Letter from Harvard Law School Center for Health Law & Policy Innovation, to Dr. Julian Harris, Medicaid Director, MassHealth (July 5, 2012) (on file with author).

<sup>20</sup> Letter from Kathleen Sebelius, Secretary, Dept. of Health & Human Services, to State Governors (July 10, 2012).

<sup>21</sup> Letter from Marilyn Tavenner, Acting Administrator, Dept. of Health & Human Services, to Robert McDonnell, Chairman, Republican Governors Association (July 13, 2012).

<sup>22</sup> CONGRESSIONAL BUDGET OFFICE, ESTIMATES FOR THE INSURANCE COVERAGE PROVISIONS OF THE AFFORDABLE CARE ACT UPDATED FOR THE RECENT SUPREME COURT DECISION (July, 2012).

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- <sup>23</sup> UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, REPORT TO THE COMMITTEE ON THE JUDICIARY, U.S. SENATE: MEDICAID EXPANSION, STATES' IMPLEMENTATION OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (2012).
- <sup>24</sup> Matthew Buettgens, Stan Dorn, & Caitlin Carroll. *Consider Savings as Well as Costs: State Governments Would Spend at Least \$90 Billion Less with the ACA than without it from 2019-2019*, URBAN INSTITUTE & ROBERT WOOD JOHNSON FOUNDATION (2011).
- <sup>25</sup> ACA § 2001(b)(2).
- <sup>26</sup> The ACA creates the Federal Coordinated Health Care Office to integrate these benefits. ACA § 2002(a)(2).
- <sup>27</sup> Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Setting Requirements for Community First Choice; Proposed Rule, 77 Fed. Reg. 26362 (May 3, 2012).
- <sup>28</sup> ACA § 2601.
- <sup>29</sup> Letter from Cindy Mann, Director, Center for Medicaid, CHIP and Survey & Certification, and Melanie Bella, Director, Medicare-Medicaid Coordination Office, to State Medicaid Directors (July 8, 2011).
- <sup>30</sup> Letter from John D. Rockefeller, Senator, U.S. Congress, to Secretary Sebelius, Dept. of Health and Human Services (July 10, 2012).
- <sup>31</sup> Letter from HIV Health Care Access Working Group et al, to Melanie Bella, Director, Medicare-Medicaid Coordination Office (July 13, 2012).
- <sup>32</sup> ACA § 9016(a).
- <sup>33</sup> Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 230 (Dec. 1, 2010).
- <sup>34</sup> Sequestration Transparency Act of 2012, Pub. L. No. 112-155 (2012).
- <sup>35</sup> Letter from Jim DeMint, Senator, U.S. Congress, et al, to National Governors Association (June 29, 2012).
- <sup>36</sup> Letter from Judith A. Aberg, Chair, HIV Medicine Association, to Tom Harkin & Richard Shelby, Senators, U.S. Congress (June 7, 2012).
- <sup>37</sup> Press Release, Dept. of Health & Human Services, Health Care Law Expands Community Health Centers, Serves More Patients (June 20, 2012).
- <sup>38</sup> Press Release, Dept. of Health & Human Services, The Affordable Care Act Helps States Prevent, Fight Infectious Diseases (August 16, 2012).
- <sup>39</sup> Press Release, Dept. of Health & Human Services, HHS Awards \$68 Million in Grants for HIV/AIDS Care for Women, Infants, Children, and Youth (Aug. 14, 2012).
- <sup>40</sup> Press Release, Dept. of Health & Human Services, Obama Administration Takes New Action to Improve Public Health (August 29, 2012).