



A Fair Pricing Coalition (FPC) Policy Guide February 2014

Health Insurance Marketplace Plans and People Living with HIV and/or Viral Hepatitis: The Affordable Care Act Requires Fair Drug Pricing and Access

The Affordable Care Act (ACA) has the potential to vastly improve health care coverage in the United States. This is a welcome development for the Fair Pricing Coalition (FPC), which has consistently advocated for improved access to affordable medications for the estimated 1.2 million people living with HIV/AIDS and the more than 3.2 million people living with chronic hepatitis C virus (HCV) infection in this country.

As people begin accessing care via Qualified Health Plans (QHPs) in the health insurance marketplaces, or exchanges, the FPC has identified issues and challenges that must be addressed, through sound government policies and cooperation of the pharmaceutical and health insurance industries, to ensure affordable access to essential medicines. These issues and challenges include:

- **Some health insurance companies are engaging in discriminatory practices.** A clear mandate of ACA is to prevent companies from denying coverage to people with pre-existing and/or chronic health conditions. FPC and others have documented that some QHPs are not including certain standard-of-care HIV medications, including single-tablet regimens, in their formularies, and many are placing HIV and HCV drugs in tiers associated with exorbitant out-of-pocket (OOP) costs (see next paragraph). In effect, insurance companies participating in federal and state marketplaces are placing the burden of paying for life-saving drugs on people who have chronic conditions, essentially circumventing the non-discrimination backbone of ACA.
- **High out-of-pocket (OOP) expenditures.** Many marketplace QHPs are placing prescription medications for HIV and HCV in high "specialty drug" tiers (Tier 4 or 5), which impose exorbitant OOP costs in the form of co-insurance (i.e., patients pay a percentage of prescription drug costs, rather than a flat co-payment). According to [a survey of 600 QHPs conducted by Avalere Health](#), a data analysis firm, roughly 91 percent had specialty drug tiers, compared with only 23 percent of employer-based plans.

Under some QHPs—depending on the state, level of the plan (bronze, silver, gold, or platinum), and a drug's tier placement—people are paying as much as 40 to 50 percent of their prescription costs. Though ACA requires QHPs to cap their OOP costs—individuals may be required to pay up to \$6,350 in annual co-payments, co-insurance, or deductibles (\$2,250 if their incomes are less than 200 percent of the [federal poverty](#)

[level](#) (FPL), or \$5,200 for those with incomes between 200 and 250 percent of FPL¹—many people with HIV and/or HCV would incur the maximum OOP for their medications, likely in the first few months of each annual cycle.

- **High drug prices.** In addition to discriminatory health insurance industry practices, high wholesale prices of drugs used to treat HIV and HCV are a key driver of QHPs placing standard-of-care medications on the highest co-payment and co-insurance tiers, resulting in prohibitive OOP costs. Not only do newly approved drugs for these diseases typically enter the market at price points higher than their immediate predecessors—often despite comparable efficacy, safety, and dosing—but also, annual and semi-annual drug price increases far exceed, and contribute to, growth in inflation.

For example, the single-tablet regimen Atripla (efavirenz/emtricitabine/tenofovir DF) is among the least expensive [U.S. Department of Health and Human Services \(HHS\)-preferred drug combinations](#) for HIV. The current estimated wholesale acquisition cost (WAC), the publicly available price for medications, is \$24,026 per year. This reflects a 6.6% increase over the 2013 WAC price and a 12.3% increase over the 2012 WAC price. For comparison, the Consumer Price Index (CPI), a measure of U.S. inflation, rose only 1.4% in 2013. The medical CPI for 2013 was 2.5%.

Stribild (cobicistat/elvitegravir/emtricitabine/tenofovir DF), Gilead Sciences' single-tablet regimen approved by the U.S. Food and Drug Administration (FDA) in August 2012, entered the market with an annual WAC price of \$28,500. The WAC price increased 4.9% in January 2014.

Tivicay (dolutegravir), ViiV Healthcare's once-daily integrase inhibitor, approved in August 2013, entered the market with an annual WAC price of \$14,105 (\$28,210 for those requiring twice-daily dosing, which includes people living with HIV resistant to other integrase inhibitors and those taking certain non-HIV medications). The WAC price increased 4.9% in January 2014. Additionally, Tivicay must be combined with other HIV medications, usually Truvada (emtricitabine/tenofovir DF) or Epzicom (abacavir/lamivudine), with annual WAC prices of approximately \$15,000 and \$14,000, respectively.

Gilead Sciences' Sovaldi (sofosbuvir), approved in December 2013 for the treatment of HCV, has gained notoriety for its pricing debut: \$84,000 for twelve weeks of treatment. Combined with other drugs required to treat HCV, notably pegylated interferon and/or ribavirin, a single course of therapy containing Sovaldi is associated with a WAC price between \$93,000 and \$168,000.

For people living with HIV and/or HCV, there are no generic equivalents to standard-of-care drugs.

- **Lack of transparency regarding drug formularies and the associated cost sharing.** People living with HIV and/or HCV must have access to comprehensive information

¹ Families may be required to pay up to \$12,700 in OOP costs. The cap on OOP costs will be lower for families with incomes up to 250 percent FPL (\$49,475 for a family of three).

detailing QHP formularies and their associated OOP expenses in order to make an educated plan choice. Currently, it is extremely difficult to access the correct plan formulary and virtually impossible to fully understand the cost-sharing obligations associated with individual drugs. The federally facilitated marketplace does have a link to plan formularies, but the information is not always correct. Some state marketplaces, including Covered California, don't provide links to plan formularies.

- **Soaring drug prices limit access and are bad business practices.** Because a large percentage of Medicaid, private insurance, and Ryan White expenditures are directly related to prescription drug costs, compounded by growing political intolerance for disease-specific funding and nationwide efforts to reduce health care spending in the U.S., prescription drug cost containment is not so much a desire as it is a necessity.

Restricted budgets among public programs (which cover a substantial number of people living with HIV and/or HCV), as well as strategies intended to control costs among QHPs, would indicate that new drugs should match or undercut existing products on price to earn their place as better treatments. Even if a new product's efficacy, safety, and dosing convenience are incrementally better than those of currently used HIV or HCV medications, the price will increasingly determine formulary inclusion and accessibility. Higher pricing in an increasingly competitive market will ultimately translate into a missed opportunity to recoup development costs, and potentially better drugs will be underutilized.

Mechanisms also need to be put in place to ensure that savings—as a result of voluntary wholesale price containment by manufacturers, pricing approaches available to payers (e.g. use of purchasing pools, higher rebates through market leverage, use of restricted pharmacy networks), or regulatory efforts (e.g., expanded access to Medicaid rebates, direct price regulation, or regulation of direct-to-consumer advertising practices)—are reinvested in programs, such as supportive/ancillary care services needed for prevention, improvement of universal HIV and HCV testing, implementation of engagement-in-care best practices, and maximization of treatment utilization (i.e., only 25% of people living with HIV have maximally suppressed virus as a result of antiretroviral therapy use). Ensuring that HIV and HCV treatment cost savings are reabsorbed by other HIV and viral hepatitis programs is critical, considering that the objectives of the 2010 National HIV/AIDS Strategy and the 2011 Viral Hepatitis Action Plan, absent new funds, are to be financed by redirected fiscal resources.

- **Co-payment assistance programs are in a state of flux.** Some manufacturers have indicated that they are unwilling to extend their co-payment assistance programs to QHP beneficiaries because of conflicting government guidance.

In an [October 2013 letter to Representative Jim McDermott](#) (D-WA), U.S. Health and Human Services (HHS) Secretary Kathleen Sebelius indicated that the agency would permit drug manufacturers to defray patient co-payments, stressing that QHPs offered through ACA's health insurance marketplaces do not constitute federal health care programs and, as a result, are not affected by the federal anti-kickback statute (42 USC § 1320a-7b). The HHS Center for Consumer Information and Insurance Oversight (CCIIO), however, then issued a contradictory statement in a [Q&A document](#): "HHS

discourages this practice and encourages issuers to reject such third party payments.” Legislative mandates to explicitly ban co-payments under ACA are being sought by Senators Chuck Grassley (R-IA) and David Vitter (R-LA).

This provision is already a barrier for people living with HIV and/or HCV who receive treatment under Medicare Part D and face unaffordable OOP costs, particularly in the case of most HIV and HCV medications that do not have suitable generic equivalents.

Following are immediate measures and long-term solutions that would ease the burdens of these current and anticipated barriers to affordable HIV and/or HCV treatment:

1. **Require access to all HHS–preferred and HHS–alternative antiretrovirals for HIV and FDA-approved treatments for HCV.** The FPC and its partners have confirmed that some QHPs are not covering some standard-of-care HIV medications, including single tablet regimens that may promote adherence and decrease OOP cost barriers.
2. **Monitor tiering of HIV and HCV drugs for discriminatory practices, such as placing all recommended treatment options on the highest cost-sharing or specialty tiers.** QHPs should be required to make standard-of-care drugs for HIV and HCV available at lower cost-sharing tiers if there are no generic equivalents available.
3. **Mandate QHP benefits and drug formulary transparency.** People living with HIV and/or HCV require access to comprehensive and clear information regarding the specific benefits—including health care provider participation, specialty care, social/ancillary services, laboratory tests and imaging, drug formularies, and cost-sharing obligations, as well as co-payment or co-insurance tiers (including precise OOP cost details)—of QHPs participating in state or federal health insurance marketplaces to determine which plans best meet their needs. This information is also required by Ryan White Part B and other programs, as well as AIDS Drug Assistance Programs (ADAPs) providing QHP premium and OOP assistance.
4. **Confirm Secretary Sebelius’ indication that manufacturers and non-profit payers may help defray OOP costs for medications under ACA.** This is especially important where there is no generic equivalent. A model for this exists in Massachusetts, which passed analogous provisions last year (Mass. Gen. Laws ch. 175H, sec. 3). This principle should also extend to Medicare Part D beneficiaries.
5. **Lower the OOP spending caps.** As [defined by the Commonwealth Fund](#), a foundation focusing on health care access and reform, individuals within 200 and 250 percent of the federal poverty level facing OOP expenditures greater than 5 or 10 percent of their annual incomes, respectively, are underinsured. A single man living with HIV earning \$24,000 a year—slightly more than 200 percent of the federal poverty level—may ultimately be billed \$5,200 in expenses, or roughly 22 percent of his income, with much of that coming at the front end of his coverage period. Should the QHP practice of placing critical HIV and HCV drugs on high co-payment or co-insurance tiers continue, substantially reduced caps will be essential. Also, as is being explored in California, monthly OOP expense associated with prescription drugs should be limited to one-twelfth of the full OOP cap.
6. **Include HIV and HCV diagnoses as qualifying life events for new enrollment in, or a switch to, a QHP offering comprehensive and affordable care and treatment.** To achieve National HIV/AIDS Strategy and Viral Hepatitis Action Plan goals to maximize linkage to care, retention in care and access to treatment, prompt enrollment in a QHP

- that adequately and affordably covers comprehensive care and prescription drugs is essential.
7. **Disclose pricing practices.** Manufacturers should disclose the costs of research and development, manufacturing, marketing, and offsetting contributions, such as outside research. This information is essential to efforts promoting fair pricing, rebates and discounts, and public knowledge of the returns on investments required to promote innovation and competition.
 8. **Insurance companies must ensure there is HIV and HCV expertise on their pharmacy and therapeutics committees or that they consult disease experts regarding formulary and tiering decisions.** It is currently unclear how formulary decisions are made by plans and/or whether there is sufficient consultation of experts in particular diseases such as HIV and HCV. Given the extreme range of QHP formulary coverage and pricing decisions, more scrutiny—and transparency—of this process is warranted.

These problems are not insurmountable. The FPC believes that the Affordable Care Act, while not perfect, has tremendous potential to redress disparities for U.S. residents whose access to healthcare has previously been at the whim of conflicting political and economic forces. This applies not only to HIV/AIDS and viral hepatitis, but also to many other chronic, debilitating, and costly health challenges beyond the capacity of individuals to manage on their own. The FPC supports urgent attention to these matters for all Americans at this moment of new hope for achieving universal, affordable, quality health care.

The [Fair Pricing Coalition \(FPC\)](#), founded by the late Martin Delaney of Project Inform, is a national coalition of activists who work on HIV and viral hepatitis drug pricing issues and to help control drug costs for patients who are privately insured, underinsured and uninsured. The FPC also works to ensure access for recipients of state ADAPs, Medicare, and Medicaid as well as for other underinsured and uninsured individuals.