Earlier Access to Care for Uninsured Women Living with HIV: The Affordable Care Act's Medicaid Expansion and 1115 Demonstration Projects

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Date: February 6, 2015

Introduction

Women account for a quarter of the people in the United States living with HIV.[1] Sixty-four percent of women living with HIV ("WLWH") receiving medical care report annual incomes of less than $10,000.[2] The Medicaid program has traditionally served as an important safety-net program for low-income and underserved communities, with communities of color representing 58% of non-elderly Medicaid enrollees.[3] Similarly, Medicaid enrollees living with HIV are disproportionately people of color.

However, many individuals living with HIV only become eligible for the traditional Medicaid program when their illnesses progress to AIDS. As a result, numerous women living with HIV are not covered under Medicaid. Although access to early treatment for persons living with HIV can result in extended and improved quality of life, a significant number of women living with HIV are not able to obtain early antiretroviral therapy ("ART") and subsequently, experience poorer health outcomes.[4]

In 1999, Congress proposed the Early Treatment for HIV Act ("ETHA") to amend the Social Security Act ("SSA") to permit state Medicaid programs to cover persons living with HIV *before* they develop AIDS.[5] Under ETHA, states would have had the option to receive greater federal reimbursement for providing HIV/AIDS related care. After ETHA repeatedly failed to proceed out of Congressional committee, Maine, the District of Columbia, and Massachusetts obtained approval for Medicaid § 1115 demonstration

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[1] U.S. DEP'T OF HEALTH AND HUMAN SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, HIV AMONG WOMEN 1 (March 2014), *available at* http://www.cdc.gov/hiv/pdf/risk_women.pdf.
[2] HIV L. Project, *Investing in Health: Supportive Services for Women Living with HIV/AIDS* 5 (July 2012), *available at* http://www.womenhiv.org/wp-content/uploads/2013/06/Social-Services-Report-FINAL.pdf.
[3] Kaiser Fam. Found., *Health Coverage by Race and Ethnicity: The Potential Impact of the Affordable Care Act* 6 (March 2013), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/04/8423.pdf.
[4] Standard ART consists of the combination of at least three antiretroviral ("ARV") drugs to provide maximum suppression of the HIV virus and stop the progression of HIV disease. WORLD HEALTH ORGANIZATION, HIV/AIDS – USE OF ANTIRETROVIRALS FOR TREATMENT AND PREVENTION OF HIV INFECTION (2014), http://www.who.int/hiv/topics/treatment/en/.
[5] *See e.g.* H.R. 1591, 106th Cong. (1999). *See also* S.902, 106th Cong. (1999).

projects (commonly known as "waivers") to provide early treatment for uninsured persons living with HIV/AIDS.

With the enactment of the Affordable Care Act ("ACA"), if a state participates in the Medicaid Expansion, previously ineligible low-income WLWH would become eligible for Medicaid. Unfortunately, political leadership in several states has rejected this opportunity, even in states with a high percentage of uninsured and low-income residents living with HIV.

Advocates and states are again considering § 1115 waivers to provide early treatment to persons with HIV until their states expand Medicaid eligibility. Demonstration projects created pursuant to § 1115 waivers must test innovative, pilot, or experimental health care delivery methods. This analysis reviews how § 1115 demonstrations can effectively be used to develop innovative models of reducing transmission, provide early treatment, and reduce long-term disabilities for WLWH.

Importance of Early Entry to Care for Women Living with HIV

ART and other interventions help individuals living with HIV/AIDS live healthier lives, if started early in the course of the illness. The Department of Health and Human Services ("HHS") Health Resources and Services Administration ("HRSA") guidelines on clinical care for women with HIV recommends ART initiation when the person initially receives an HIV diagnosis.[6] Studies indicate that very early ART treatment extends the life span of individuals living with HIV six to nine additional years, and results in reduced hospitalizations, decreased transmission rates, and increased employment and productivity.[7]

Women face several barriers to accessing early HIV testing, antiretrovirals ("ARV"), and related treatment. Even though guidelines recommend routine HIV testing for everyone from 13 to 64 years old, 15% of women who are HIV-positive are not aware of their HIV status.[8] Factors such as fear of stigma associated with an HIV diagnosis, family responsibilities, and poverty prevent women from obtaining early testing and treatment. In fact, many WLWH do not attempt to obtain health care until they become pregnant or experience other symptoms associated with HIV.[9] Among diagnosed WLWH, only 70%

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[6] U.S. DEP'T OF HEALTH & HUM. SERVICES, GUIDE TO THE CLINICAL CARE FOR WOMEN LIVING WITH HIV 98 (2013).
[7] *See e.g.,* John Romley, et al., *Early HIV Treatment Led to Life Expectancy Gains Valued at $80 Billion for People Infected in 1996 – 2009*, 330 HEALTH AFF. 370 (March 2014).
[8] U.S. Dep't. of Health & Hum. Services, *HIV and Women,* AIDSINFO (April 15, 2014), http://aidsinfo.nih.gov/education-materials/fact-sheets/24/69/hiv-and-women#.
[9] Mariam Aziz & Kimberly Y. Smith, *Challenges and Successes in Linking HIV-Infected Women to Care in the United States*, 52 CLINICAL INFECTIOUS DISEASE S231-33 (2011), *available at* http://cid.oxfordjournals.org/content/52/suppl_2/S231.full.pdf+html.

are linked to HIV care.[10] As a result, WLWH are more likely to obtain only emergency care and inpatient hospitalization.

Lack of health insurance also contributes to delayed access to treatment and care for WLWH. One study indicated nearly one in four WLWH is uninsured.[11] Because WLWH are disproportionately women of color, their communities are more likely to be adversely impacted by delays in treatment and care.[12]

Opportunities for Early Testing and Treatment of Uninsured WLWH: Medicaid Expansion and 1115 Demonstration Projects

Medicaid Expansion

Public programs like Medicaid and the Ryan White HIV/AIDS Program and its AIDS Drug Assistance Program ("ADAP") provide essential services to communities that are able to enroll in them.[13] The passage and implementation of the ACA provides an opportunity for more uninsured WLWH to obtain Medicaid coverage and subsequently receive HIV testing and services.[14] Medicaid is a jointly funded and administered federal and state program for individuals with low-incomes who meet one or more categorically needy eligibility requirements, such as having a disability, being pregnant, or being a caretaker for a dependent child.

Under traditional Medicaid rules, childless, non-pregnant, non-elderly adults living with HIV must wait until their disease progresses to an AIDS diagnosis before they can be

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[10] Kaiser Fam. Found., *Fact Sheet: Women and HIV/AIDS in the United States* 4 (March 2014), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2014/03/6092-women-and-hivaids-in-the-united-states.pdf. In addition, just 41% of WLWH are in regular care, 36% are prescribed ART, and 26% are virally suppressed. *Id.*

[11] Kaiser Fam. Found., *A Report on Women and HIV/AIDS in the United States* 11 (April 2013), *available at* http://www.womenhiv.org/wp-content/uploads/2013/06/KFF-2013-report-on-women-and-HIV.pdf.

[12] *See* Kaiser. Fam. Found., *Medicaid and HIV: A National Analysis* 7 (Oct. 2011), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8218.pdf. In FY 2007, an estimated half of Medicaid enrollees, male and female, living with HIV were African American (50%), a quarter were white (25 %), and 17% were Latino. *Id* at 6.

[13] *See id.* at 1. Part B of the Ryan White Program offers grants to states and U.S. territories to improve the quality, availability, and organization of HIV/AIDS health care and support services. Part B grants include funding for the ADAP that provides medications for the treatment of HIV disease. ADAP funds can be used to purchase health insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of drug treatments. U.S. Dep't of Health & Human Servs., Health Resources Services Admin., *Part B – AIDS Drug Assistance Progra*m, http://hab.hrsa.gov/abouthab/partbdrug.html. *See generally,* U.S. Dep't of Health & Human Servs., Health Resources Services Admin., *About the Ryan White HIV/AIDS Program-Legislation*, http://hab.hrsa.gov/abouthab/legislation.html.

[14] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (March 23, 2010). Amendments to the ACA were included in the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 (March 30, 2010); 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII).

considered disabled and categorically eligible to receive Medicaid coverage, even if they are impoverished.[15]

The ACA added a new mandatory coverage group to the Medicaid program to provide coverage for uninsured individuals who were previously ineligible for traditional Medicaid. Beginning in 2014, states were required to enroll low-income adults who are under 138% of the federal poverty level ("FPL"), which is $32,913 a year for a family of four in 2014.[16] To qualify for the Medicaid Expansion, individuals must be under age 65; not pregnant; not entitled to or enrolled in Medicare Part A; not enrolled in Medicare Part B; or excluded from any of the previously existing mandatory categorically needy groups set forth in the Medicaid statute.

The coverage expansion is significant for WLWH because, for the first time, Medicaid will be extended to all individuals below the income threshold without requiring a categorical link. This expansion eliminates the predicament that existed under traditional Medicaid requirements, where an AIDS diagnosis was needed before receiving Medicaid coverage. Unfortunately, the Supreme Court held in *National Federation of Independent Business v. Sebelius* that states could refuse to implement the Medicaid expansion without consequences from HHS.[17]

The Supreme Court's decision essentially created a state option, where states may now decide whether to cover these newly eligible individuals. As of January 2015, 28 states and the District of Columbia have indicated they will expand Medicaid eligibility. Sixteen states have declined to expand coverage. Approximately, 43% of persons living with HIV live in states that have not expanded Medicaid.[18]

In states not expanding Medicaid eligibility, almost five million low-income and uninsured adults have incomes above Medicaid eligibility levels, and yet below the eligibility for the ACA-created tax credits provided to those between 133-400% FPL.[19]

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[15] 42 U.S.C. § 1396a(a)(10)(A)(i)(II); 42 C.F.R. § 435.120. States must provide Medicaid to all persons with disabilities who receive SSI benefits. *But see* 42 U.S.C. § 1396a(f); 42 C.F.R.§ 435.121. Some states have elected to use the "209(b) option" for Medicaid services that requires a more restrictive definition of blindness, disability, or financial eligibility that are used in the SSI program.

[16] ACA § 2001(a)(1)(codified at 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII)); *see also* U.S. Dep't of Health & Hum. Services, Off. of the Assistant Secretary for Plann. & Evaluation, *2014 Poverty Guidelines*, http://aspe.hhs.gov/poverty/14poverty.cfm.

[17] *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012) (finding states cannot lose all federal Medicaid funding if they choose not to expand Medicaid to 133% FPL).

[18] Seven states are reportedly considering the Expansion. Kaiser Fam. Found., *Current Status of State Medicaid Expansion Decisions* (Jan. 27, 2015), http://kff.org/health-reform/slide/current-status-of-the-medicaid-expansion-decision/; Kaiser Fam. Found., *Assessing the Impact of the Affordable Care Act on Health Insurance Coverage for People with HIV* 3 (January 2014), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/12/8535-assessing-the-impact-of-the-affordable-care-act-on-health-insurance-coverage.pdf.

[19] Kaiser Comm. on Medicaid & the Uninsured, *The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid* 1 (March 2014), *available at*

As a result, uninsured WLWH in non-Expansion states are likely to remain uninsured and must rely on safety net programs, like the Ryan White Program, to obtain care.

Services

State Medicaid programs have the option of providing particular groups of Medicaid enrollees with alternative benefit plans ("ABPs"), formerly known as benchmark or benchmark equivalent plans.[20] Section 1937 of the SSA requires that ABPs are based on one of the three commercial insurance products in the state, or an alternative HHS Secretary-approved coverage.[21]

States must provide Medicaid coverage for the newly eligible adult eligibility group through an ABP.[22] States also have the option to provide Medicaid coverage through an ABP for those traditionally Medicaid eligible.[23] Medicaid enrollees in ABPs are entitled to coverage of ten categories of essential health benefits ("EHBs"). These include services that are critical to providing quality care to WLWH, such as ARVs or other HIV treatment, maternity care, gynecological visits, abortion services (the scope of which varies across states), and mental health and substance use treatment and counseling.[24]

The Medicaid Expansion population also receives coverage for preventive services for women, such as breast cancer screenings, contraception, STI screenings and counseling, well women visits, and domestic and interpersonal screenings and counseling.[25] Family planning services are mandatory in all categories of Medicaid.[26]

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http://kaiserfamilyfoundation.files.wordpress.com/2014/04/8505-the-coverage-gap_uninsured-poor-adults-in-states-that-do-not-expand-medicaid.pdf; 42 U.S.C. § 36B (describing eligibility for ACA tax credits).

[20] 42 U.S.C. § 1396u-7.

[21] SSA § 1937(b)(1), 42 U.S.C. § 1396u-7(b)(1). Benchmark coverage is the standard Blue Cross/Blue Shield preferred provider option for federal employees in the state; coverage offered by the largest commercial, non-Medicaid HMO in the state; or Secretary-approved coverage. *But see* 42 U.S.C. § 1396u-7(a)(2)(B) (stating exempted populations from mandatory enrollment in benchmark equivalent plans include, SSI beneficiaries, individuals with certain disabilities, and institutionalized persons).

[22] 42 C.F.R. § 440.305(b).

[23] §§ 440.305(c), 440.315.

[24] ACA § 1302 (codified at 42 U.S.C. § 18082). These 10 categories include ambulatory care services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services (including behavior health treatment), prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive and wellness services and chronic disease management, and pediatric services (including oral and vision care). *Id.*

[25] 42 U.S.C. § 300gg-13(a)(3)(2012) (ACA § 1001, amending Public Health Service Act ("PHSA") 2713); *see generally* U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., *Women's Preventive Services: Required Health Plan Coverage Guidelines*, http://www.hrsa.gov/womensguidelines.

[26] *See* 42 U.S.C. §1396a(a)(4)(C).

Certain uninsured adults, who would ordinarily be eligible for the Expansion, can qualify for traditional Medicaid. For example, medically frail individuals or those with special medical needs are not required to enroll in ABPs.[27] This exception may particularly apply to certain critically ill individuals living with AIDS. States can offer the same benefits of their traditional state Medicaid plan in their ABPs for the newly eligible Expansion population.[28]

In states implementing the Expansion, women will significantly benefit from expanded Medicaid eligibility because up to 10 million uninsured women will become newly eligible for Medicaid (based on their current income levels).[29] Moreover, people of color currently comprise 65% of the uninsured individuals who are newly eligible and residing in states moving forward with the Expansion.[30]

About half of all individuals living with HIV in the U.S. reside in the South, where conservative political leadership generally opposes the ACA, including the Medicaid Expansion. Some of these states, such as Louisiana, Texas, Florida, Georgia, and Mississippi happen to be among the top 10 states with the highest concentration of HIV diagnoses.[31] Southern states also rank prominently among the top 10 states with the majority of women and girls living with HIV/AIDS in the U.S. (e.g., Florida, Texas, Georgia, and North Carolina).[32]

Overview of 1115 Waivers for WLWH

Section 1115 of the SSA grants the Secretary of HHS the authority to allow states to implement "experimental, pilot, or demonstration projects" that are "likely to assist in promoting the objectives" of the Medicaid Act. Unless Congress objects, the Secretary may waive certain – but not all - provisions of the Medicaid Act to the extent they are necessary to facilitate the state carrying out the demonstration project.[33] However, the

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[27] § 1396u-7(a)(2)(B)(vi).
[28] 42 C.F.R. § 440.325; Michelle Lilienfeld, National Health Law Program, *Alternative Benefit Plans for the Medicaid Expansion Population: Trends in Approved Benefit Plans and Tools for Advocates* (July 28, 2014), http://www.healthlaw.org/issues/medicaid/medicaid-expansion-toolbox/alternative-benefit-plans-for-the-medicaid-expansion-population#.VNEnQC6de84 (describing process for offering traditional Medicaid benefits in their ABP).
[29] *See* Kaiser Fam. Found., *Medicaid's Role for Women Throughout the Lifespan: Current Issues & the Impact of the Affordable Care Act, Women's Issue Brief – An Update on Women's Health Policy* (Jan. 2012), *available at* http://www.kff.org/womenshealth/upload/7213-03.pdf.
[30] Kaiser Comm'n on Medicaid & the Uninsured, *The Impact of Current State Medicaid Expansion Decisions on Coverage by Race and Ethnicity* 2 (July 2013), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/06/8450-the-impact-of-current-state-medicaid-expansion-decisions.pdf.
[31] Christine Vestal, *How the ACA will Affect People with HIV and AIDS,* STATELINE, (Oct. 28, 2013), http://www.pewstates.org/projects/stateline/headlines/how-the-aca-will-affect-people-with-hiv-and-aids-85899515398.
[32] Kaiser Fam. Found., *supra* note 10, at 3.
[33] 42 U.S.C. § 1315(a) (referring to SSA § 1115(a)).

Secretary is prohibited from waiving constitutional requirements and other federal laws.[34]

Medicaid waivers created for people living with HIV may satisfy the requirement of an "experimental, pilot, or demonstration project" if they test unique services, new delivery mechanisms, or new ways to provide earlier treatment to delay or prevent the onset of AIDS. For example, in 2011, the Centers for Medicare and Medicaid Services ("CMS") emphasized, "early treatment and case management services provided to individuals with HIV create efficiencies in the Medicaid program enabling the extension of coverage to individuals who would otherwise be without health insurance."[35] Section 1115 demonstrations can be used to build upon these recognized efficiencies to pilot new services or uses of these services.

Among other requirements, the § 1115 waiver application must describe goals and objectives; the research hypothesis, a plan for testing the hypotheses, and the identification of feasible appropriate evaluation indicators; and if the proposed demonstration deviates from the provisions of the Children's Health Insurance Program ("CHIP") and Medicaid.[36]

Section 1115 waivers are time limited and last only to "the extent and for the period necessary" to enable the state to fulfill the objectives of the project.[37] These waivers must be budget neutral, as determined by CMS. The federal cost of the waivers cannot exceed the federal expenditures incurred if the demonstration projects were not in place.[38]

Submission and Evaluation Process for § 1115 Waivers

A state seeking a § 1115 waiver will go through the federal application process and a state approval process. The ACA requires states seeking new or extensions of existing § 1115 waivers to provide a 30-day notice and public comment period.[39] The ACA also requires an additional 30-day federal comment period on the final submitted

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[34] *See Burns-Vidlak v. Chandler*, 939 F. Supp. 765 (D. Haw. 1996) (waiver does not exempt program from Rehabilitation Act and the Americans with Disabilities Act); *See also* Kaiser Fam. Found., *An Overview of Recent Section 1115 Medicaid Demonstration Waiver Activity* (May 2012), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8318.pdf. Among other purposes, § 1115 waivers give states some flexibility to expand coverage to particular populations that might not otherwise be eligible for traditional Medicaid, provide various levels of cost-sharing, support safety-net delivery systems, and enroll high-need populations into managed care plans. *Id.*

[35] CMS, Dear State Medicaid Director Letter 6 (June 6, 2011).

[36] *Id*.

[37] 42 U.S.C. § 1315(a)(1).

[38] § 1315(e)(7).

[39] 42 C.F.R. § 431.408(a). Interested parties must also be permitted to submit comments electronically or via the postal service. The state must submit the application to CMS both electronically and printed. 42 C.F.R. § 431.408. The state must report the public's comments and the process the state used to incorporate the issues the public raised. § 431.412(a)(1)(vii).

application.[40] CMS must publish the waiver, receipt of the waiver, and other relevant materials on its website. In addition, CMS must create an electronic mailing list to allow interested parties to receive communications related to pending waivers.[41] CMS must allow 45 days for the public to submit comments, and CMS must publish these comments on their website and consider all comments received prior to the deadline.[42] The length of time it takes CMS to approve an application varies. CMS may waive portions or the entire federal or state public notice process to expedite a demonstration to address a public health emergency.[43]

States' Use of § 1115 Waivers for People Living with HIV/AIDS

In general, applications for § 1115 waivers have increased in recent years with 39 states operating at least one § 1115 waiver as of January 2015.[44] However, only three states have operated § 1115 demonstration projects for persons living with HIV/AIDS. Maine and Washington, D.C. have used innovative strategies to provide access to early treatment for persons living with HIV. Massachusetts used its § 1115 waiver as part of its efforts for comprehensive health reform in the state. Each state provides a different example for how a § 1115 waiver might test new approaches to provide care for persons with HIV/AIDS.

Maine

Since 2002, Maine has implemented a §1115 demonstration to extend coverage to persons living with HIV/AIDS. Care management services are the identified experimental feature of the demonstration that is designed to improve access to continuous care and assist in compliance with medication and treatment regimens. Maine's demonstration assigns a nurse coordinator to each enrollee to integrate their social, pharmacy, and other medical needs. According to Maine, the purpose of the waiver is to provide early treatment to prevent, delay, or reverse the onset of HIV/AIDS.[45]

Maine sought approval from CMS to waive SSA § 1902(a)(10)(B), the requirement that services be sufficient in amount, duration, and scope to reasonably achieve their purpose. According to the state, Maine sought this waiver to offer additional benefits to MaineCare [the state's traditional Medicaid program] members living with HIV/AIDS.[46] Maine sought to test the hypothesis that "early treatment and case management services provided to individuals with HIV/AIDS create efficiencies in the Medicaid

[40] 42 C.F.R. § 431.416(b).
[41] § 431.416(b)(2).
[42] §§ 431.416(e)(1), 431.416(d).
[43] § 431.416(g)(1).
[44] *See* MEDICAID.GOV, Demonstrations & Waivers, http://www.medicaid.gov/medicaid-chip-program-information/by-topics/waivers/waivers_faceted.html.
[45] CTRS. FOR MEDICARE & MEDICAID SERVS., MAINE MEDICAID SECTION 1115 HEALTH CARE REFORM DEMONSTRATION FOR INDIVIDUALS WITH HIV/AIDS, 11-W-00128/1 7 (2013).
[46] *Id.* at 90.

program that enable the extension of coverage to certain individuals who would otherwise be without health insurance."[47]

Under Maine's demonstration, participants can receive two different enrollment packages. Demonstration participants can be enrollees in both Maine's traditional Medicaid program and the demonstration, or enrolled solely in the demonstration. Traditional Medicaid enrollees in the demonstration receive the full package of available state Medicaid services, as well as the additional benefit of care management, which they otherwise would not receive under traditional Medicaid.[48] Those enrolled only in the demonstration receive selected benefits, including care management.[49]

The state estimates the demonstration covers about half of the known 1,616 Maine residents living with HIV/AIDS. The demonstration provides coverage to two populations -- those diagnosed with HIV/AIDS with incomes at or below 250% FPL and Maine's traditional Medicaid members diagnosed with HIV/AIDS with incomes at or below 100% FPL. The traditional Medicaid enrollees must have costs associated with their care for HIV that comprise at least 25% of their total cost of care.[50] Consistent with traditional Medicaid eligibility requirements, an individual must have a disability as defined in the Social Security Act. Having other insurance coverage does not preclude someone from enrolling in the demonstration. The demonstration can cover premiums and cost-sharing related to that insurance for eligible individuals through the state's traditional Medicaid Private Health Insurance Premium Benefit Program ("PHIP").[51]

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[47] CTRS. FOR MEDICARE & MEDICAID SERVS., SPECIAL TERMS AND CONDITIONS: MAINE MEDICAID SECTION 1115 HEALTH CARE REFORM DEMONSTRATION FOR INDIVIDUALS WITH HIV/AIDS, 11-W-00128/1 1-2 (2010). The state specified three goals of the demonstration: 1) improve access to continuous care, 2) provide early, high quality care that would delay the onset of AIDS and prove cost efficient for the state, and 3) use the cost savings to expand coverage to additional low-income individuals. *Id.*

[48] *See* MAINE DEP'T OF HEALTH AND HUMAN SERVICES, MAINECARE MEMBER HANDBOOK.

[49] These selected benefits include services, such as inpatient and outpatient care, physician, laboratory and x-rays, mental health and substance abuse, and all Medicaid-covered prescription medications. CTRS FOR MEDICARE & MEDICAID SERVS., SPECIAL TERMS AND CONDITIONS: MAINE MEDICAID SECTION 1115 HEALTH CARE REFORM DEMONSTRATION FOR INDIVIDUALS WITH HIV/AIDS, 11-W-00128/1 10 (2014). Transportation services are currently provided under a previously granted Medicaid §1915(b) waiver. Letter from Stefanie Nadeau, Director, MaineCare, Services to Interested Parties (March 1, 2013).

[50] CMS, *supra* note 45, at 10. Two-hundred fifty percent of the FPL is $17,235 for an individual and 100% of the FPL is $11,490 for an individual. MEDICAID.GOV, 2013 Federal Poverty Guidelines, *available at* http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Eligibility/Downloads/2013-Federal-Poverty-level-charts.pdf.

[51] Ctrs. for Medicaid & Medicare Servs., MAINE SECTION 1115 HEALTH CARE REFORM DEMONSTRATION FOR INDIVIDUALS WITH HIV/AIDS FACT SHEET 2 (December 2013), *available at* http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/me/me-hiv-fs.pdf; *see generally* MAINE DEP'T OF HEALTH & HUMAN. SERVS., MAINECARE SERVS., MAINECARE PRIVATE HEALTH INSURANCE PREMIUM BENEFIT (PHIP), *available at* http://www.maine.gov/dhhs/ofi/public-assistance/pdf/PHIP-Brochure.pdf. PHIP participants must be enrolled in the traditional Medicaid program and work-based private insurance that the state considers as cost effective. *Id.*

Maine's successful retention rate might be attributed to its rigorous care management and coordination departments that interact with persons living with HIV/AIDS. MaineCare services referred enrollees and case managers to ADAP staff in order for eligible beneficiaries to have copayments and premiums covered. They also referred enrollees to Private Health Insurance Premium Benefit Specialists and Medicare B buy-in programs (a program that allows Medicare-recipients to receive Medicaid benefits).[52] In addition, Maine has seemingly been successful at enrollment because of their active outreach.[53]

Even though Maine has the 42nd highest AIDS rate in the U.S., the state found added value in the demonstration and repeatedly renewed the waiver – once in 2007 and again in 2010.[54] The waiver was set to expire on Dec. 31, 2013, but the state received a temporary extension for the demonstration until Dec. 31, 2015.[55] Maine originally sought to extend the waiver until 2016, but the state and CMS disagreed on the permissible amount of cost-sharing.[56] Maine's § 1115 waiver approval letter requires the state to report to CMS the final results of the demonstration before April 2016.[57]

Without care management, Maine estimates that enrollees' disease progression would have been about 20% faster.[58] In an annual survey, the Centers for Disease Control and Prevention ("CDC") and MaineCare Services determined that 75% of beneficiaries responding reported they spoke with a nurse coordinator regarding their health and

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[52] CMS, *supra* note 45.
[53] Maine's traditional Medicaid staff attended relevant meetings and sent letters to encourage potential enrollees to apply to the demonstration project. Staff also distributed posters and brochures advertised the demonstration around the state, and enrollment applications were distributed to the state's DHHS regional offices and to all primary care providers, pharmacies and hospitals in the state. CMS, *supra* note 45, at 13, 17, 36.
[54] CMS, *supra* note 45, at 7.
[55] Maine received two temporary extensions-first, extending the waiver until 2014 and then again extending until 2015. *See* Letter from Cindy Mann, CMS Director to Stephanie Nadeau, MaineCare Services Director (Dec. 9, 2013) (approving the request to extend the demonstration program to 2014); *See also* Letter from Cindy Mann, CMS Director to Stephanie Nadeau, MaineCare Services Director (Nov. 25, 2014) (extending the demonstration to 2015).
[56] CMS reportedly wanted demonstration enrollees to pay the same copayments as MaineCare members. Currently, the state requires demonstration enrollees with incomes up to 250% FPL to pay a $10 copayment for prescriptions and physician visits. MaineCare members do not have a copayment for physician services, and the copayments for all other services vary based on the service provided and how much the state pays for each service. CMS, *supra* note 45, at 13. *See also* MAINE DEP'T OF HEALTH AND HUM. SERVICES, MAINECARE MEMBERS COPAYMENT SCHEDULE, http://www.maine.gov/dhhs/oms/member/.
[57] CMS, *supra* note 47. Maine's draft evaluation design was included in its application for renewal. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 45 at 64, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/me/me-hiv-pa.pdf.
[58] CMS, *supra* note 45, at Appendix C 6-7.

benefits.[59] In 2012, the emergency room usage among demonstration enrollees decreased nine percent compared to the previous year.[60]

Currently, because Maine is not expanding Medicaid, the demonstration will provide continued coverage for individuals with incomes between 101-250% FPL through 2016.[61] If Maine expands Medicaid, about 60% of the current demonstration enrollees not currently eligible for Medicaid would become newly eligible.[62]

District of Columbia

The District of Columbia's ("the District") demonstration was approved in January 2001. The District's hypothesis was that increasing early access to ART for people living with HIV in accordance with the HHS treatment guidelines would remove clinical barriers to treatment that currently exist in programs that finance HIV/AIDS care.[63] The demonstration's innovative approach utilized discount drug pricing to provide early access to affordable ARV drugs that delay the onset of AIDS.[64]

The District, as a federal jurisdiction, was in the unique position to use the Department of Defense ("DOD") drug pricing and limited network to provide ARVs at a price lower than other insurance programs, resulting in an estimated 15 to 20% reduction in ARV prices.[65] The demonstration provided full Medicaid benefits to demonstration enrollees, including individuals not otherwise eligible for traditional Medicaid. The Medicaid program drug benefit included all FDA-approved medications and a range of other specialty drugs.[66] The DOD pricing applied only to ARVs and all required pharmaceutical drugs. Enrollees also received case management services through the District's Ryan White program.

HIV-positive adult D.C. residents with incomes at or below 100% FPL with resources worth less than $2,600 for individuals and $3,000 for couples were eligible for the

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[59] Maine Dep't of Health and Hum. Services, *MaineCare Services HIV/AIDS Waiver-Member Survey Analysis* (2012).
[60] CMS, *supra* note 45, at 23, 26.
[61] Kaiser Fam. Found., *Status of State Action on the Medicaid Expansion, as of Oct. 22, 2013*, http://kff.org/medicaid/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/.
[62] CMS, *supra* note 45, at 97.
[63] DISTRICT OF COLUMBIA MED. ASSISTANCE ADMIN., APPLICATION FOR AN 1115 WAIVER PROGRAM TO ENHANCE MEDICAID ACCESS FOR LOW-INCOME HIV-INFECTED INDIVIDUALS IN THE DISTRICT OF COLUMBIA 2 (Sept. 25, 2000). Specifically, the District stated it would answer questions, such as the level of drug utilization among this population while enrolled in the demonstration, the clinical characteristics among demonstration enrollees, and the proportion of demonstration enrollees who enrolled in Medicaid after the demonstration ended. *Id.* at 13-15.
[64] CMS, *supra* note 35, at 6; District of Columbia Dep't of Health, DC Medicaid 1115 HIV Waiver Program Fact Sheet.
[65] District of Columbia, *supra* note 63, at 16.
[66] Gov't of the District of Columbia, Medicaid Expansion in the District of Columbia Presentation (Nov. 27, 2012).

demonstration. These individuals met the traditional Medicaid eligibility criteria, except for the categorical requirements (such as disability, blindness, or age).[67] The demonstration was designed to extend treatment access to low-income individuals who were diagnosed with HIV but did not qualify for Medicaid because their disease had not advanced to an AIDS diagnosis.

Enrollment and retention efforts in the demonstration were seemingly unsuccessful. The demonstration never filled its allotted slots and reportedly suffered from a lack of outreach to potential enrollees.[68] Case managers administering HIV/AIDS programs in the District conducted the intake for the demonstration and connected individuals to other HIV programs available in the area.[69] However, separate applications for the demonstration and ADAP increased the chances that individuals not using a case manager to sign up for one of the programs would be unaware of their eligibility for other programs. In addition, HIV/AIDS advocates reported a lack of coordination between offices within the District's Department of Health.

Despite the problems in the demonstration, those individuals who were able to obtain coverage had better access to health care and subsequently improved health outcomes. The District has the nation's highest HIV/AIDS rates with 2.7% of its population diagnosed with HIV.[70]

Between 2000 and 2010 (the demonstration period), the District experienced positive public health advancements related to HIV and AIDS. From 2006 to 2010, there was a 32% decrease in those progressing from HIV to an AIDS diagnosis. The number of deaths among people with HIV in 2010 was about half the number in 2006.[71] These benefits cannot be attributed solely to the waiver given several other efforts to reduce the HIV/AIDS epidemic in the District of Columbia took place simultaneously.[72]

The demonstration expired in 2010 after the District implemented early adult expansion of Medicaid eligibility to childless adults with incomes below 133% FPL in anticipation of the ACA-mandated expansion in 2014.[73] The District, however, used a § 1915(b) waiver

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[67] District of Columbia, Medicaid 1115 HIV Waiver Program Fact Sheet (2000).
[68] *See* Monte Reel, *Old 'Deficiencies' Continue to Haunt Medicaid Agency; Staffing, Paperwork Problems,* WASH POST (June 22, 2003) (covering a city Committee on Human Services meeting where testimony was heard that the city had not taken measures to enrollee those infected with HIV in the Medicaid demonstration).
[69] CMS, *supra* note 35, at 6 (regarding coverage opportunities for persons living with HIV/AIDS).
[70] Kaiser Family Found., *Fact Sheet: The HIV/AIDS Epidemic in Washington D.C.* 1 (July 2012).
[71] *Id*.
[72] For instance, in 2006, the District implemented a large condom distribution program; in 2007, 30 public and private organizations produced a three year Youth and HIV Prevention Plan; and from 2007 to 2008, the District provided 70 % more HIV screenings. Alan Greenberg *et al.*, *Fighting HIV/AIDS in Washington, D.C.*, HEALTH AFF. 1677-87 (2009).
[73] Kaiser Family Found., *Research Roundup: Impact of Early Adult Expansion* (Jan. 10, 2014), http://www.kaiserhealthnews.org/Daily-Reports/2014/January/10/research-roundup.aspx.

to continue using the DOD reduced-drug pricing to provide less costly ARVs and HIV-related medications to Medicaid recipients.[74]

The Massachusetts Experience: Use of § 1115 Waivers in State Health Reform

Massachusetts took a different approach from Washington, D.C. and Maine. The Massachusetts demonstration was the precursor to the state's 2006 comprehensive health reform.[75] In 1997, Massachusetts implemented a § 1115 demonstration program to expand Medicaid income eligibility to certain categorically eligible populations, including pregnant women, parents or adult caretakers, infants, children, and disabled individuals. In April 2001, an amendment to the §1115 waiver also expanded coverage to certain non-categorically eligible populations, including unemployed adults and non-disabled persons living with HIV.[76]

The purpose of the demonstration was to determine whether Massachusetts could provide all residents with access to affordable, high quality health coverage. Specifically, the state seeks to answer the following questions (among others):

- What is the impact of health care delivery system and access reform measures on the quality of care delivered by participating providers?
- What is the impact of the payment redesign and infrastructure investments to improve cost efficiency?
- How did the amount paid in incentives compare with the amount of improvement achieved?[77]

The demonstration amended the waiver to include non-disabled persons living with HIV to increase early access to treatment after an individual tested positive for HIV. The available benefits package included family planning services and supplies, primary care,

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[74] Dist. of Columbia, Section 1915(b) waiver application (Oct. 25, 2012). This waiver allows the District of Columbia to waive SSA § 1902(a)(23), which requires the state plan to permit all Medicaid-eligible individuals to obtain medical assistance from any qualified provider in the State, and instead, permits the state to use a selected network of pharmacies to dispense HIV/AIDS related medications. This demonstration became effective in 2012 and is set to expire April 30, 2015. *Id.*

[75] Massachusetts Dep't of Health and Human Servs., *MassHealth,* http://www.mass.gov/eohhs/gov/departments/masshealth/. MassHealth is the state's traditional Medicaid program. *See* Act Providing Access to Affordable, Quality, Accountable Health Care, Chapter 58 of the Acts of 2006 (legislation creating comprehensive health reform in Massachusetts).

[76] CTRS. MEDICARE & MEDICAID SERVS., MASSACHUSETTS SEC. 1115 DEMONSTRATION FACT SHEET 1 (Sept. 11, 2013). Currently, the waiver expands income eligibility for categorically eligible populations to the following FPLs: pregnant women over 21 years old (201-300%), parent or child caretaker (133-300%), and children (201-300%). For individuals with disabilities, income eligibility is below 133% under the standard Medicaid expansion. CTRS. MEDICARE & MEDICAID SERVS., CMS APPROVAL DOCUMENTS, MASSHEALTH MEDICAID SECTION 1115 DEMONSTRATION, 11-W-00030/1 14-27(October 1, 2013).

[77] CTRS. OF MEDICAID & MEDICARE SERVS., MASSHEALTH MEDICAID SECTION 1115 DEMONSTRATION 11-W-00030/1 86 (Oct. 30, 2014).

diagnostic care, inpatient services, prescription drug coverage, and substance abuse and mental health treatment. The waiver also covered medical expenses eligible individuals incurred while their application was being processed. Once an individual was determined eligible for the demonstration, the program covered any expenses incurred within 10 days prior to the application's submission.[78]

CMS waived several state plan requirements to create the § 1115 demonstration, such as the following:

- CMS waived the requirement for all services to be provided sufficient in amount, duration, and scope and comparable across all eligibility groups. The state sought to provide demonstration enrollees with a set of benefits different from Medicaid beneficiaries.[79]
- Eligibility procedures and standard requirements, including those governing mandatory and optionally covered populations, were also waived. Massachusetts sought to exclude these requirements to streamline eligibility procedures in determining and re-determining Medicaid eligibility based on gross income levels. The state also requested use of Express Lane eligibility determinations for children, parents, and caretaker relatives.[80]
- Medicaid law requires beneficiaries to have freedom of choice to determine their provider of choice. The state sought to restrict this freedom of choice to enable Massachusetts to mandatorily enroll demonstration enrollees into managed care organizations.[81]
- When determining Medicaid eligibility, Medicaid law, generally, prohibits a state from considering income and resources not available to an applicant for Medicaid. The state requested the authority to attribute family income and resources to the applicants in determining income eligibility, even if the family income and resources are not actually available to the applicants.[82]

Before December 31, 2013, individuals younger than 65 years old with an HIV diagnosis and with incomes at or below 200% FPL were eligible for the demonstration. Because Massachusetts adopted the Medicaid Expansion, individuals below 133% FPL became Medicaid-eligible on January 1, 2014, but the demonstration was continued until June 30, 2019.[83] The state will be required to submit a report documenting the

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[78] CMS APPROVAL DOCS., *supra* note 76, at 1, 31, 51.
[79] *Id.* at 4; *see also* SSA § 1902(a)(10)(B), 42 U.S.C. § 1396a(a)(17), 42 C.F.R. § 440.230(b)(requirements for sufficient amount, duration and scope of services comparable across eligibility groups).
[80] CMS APPROVAL DOCS., *supra* note 76, at 4; *see also* SSA §§§ 1902(a)(10)(A), 1902(a)(10)(C)(i)-(iii), 1902(a)(17); 42 U.S.C. §§§ 1396a(10)(A),1396a(10)(C)(i)-(iii), 1396a(17) (eligibility procedures and standards).
[81] CMS APPROVAL DOCS., *supra* note 76, at 5; *see also* SSA § 1902(a)(23)(A), 42 U.S.C. § 1396a(a)(23).
[82] CMS APPROVAL DOCS., *supra* note 76, at 5; *see also* SSA § 1902(a)(17); 42 U.S.C. § 1396a(a)(17).
[83] Letter from Cindy Mann, Director at Ctrs. for Medicaid & Medicaid Servs. to John Polanowicz, Secretary, Executive Office of Health & Hum. Servs. (Oct. 30, 2014).

demonstration's findings in October 2019, which is 120 days after the demonstration ends.[84]

The demonstration currently provides coverage for those with incomes between 133 - 200% FPL. There is no asset limit. The program precludes individuals from enrollment if they are eligible for the state's traditional Medicaid program ("MassHealth") or institutionalized. When it is determined cost-effective for an individual to enroll in private health insurance, the individual is required to obtain and maintain the insurance. Individuals may enroll in the demonstration, even if they have access to employer-sponsored insurance or other private insurance. These persons may be eligible to receive, through the demonstration, premium assistance to assist with their premium costs.[85]

Massachusetts' use of a § 1115 waiver for persons with HIV/AIDS is an example of how a waiver might be implemented in a state that is expanding Medicaid eligibility as part of health reform. The benefits of the Massachusetts waiver for persons with HIV/AIDS are intertwined with the benefits of the state's broader comprehensive health reform efforts. Because of the state's waivers and reforms, 439,000 more individuals have health care coverage, resulting in 98% of all Massachusetts residents having insurance coverage.[86] In total, the § 1115 waiver combined with the health reform efforts cover about 1.5 million people.[87]

There have also been positive public health benefits for persons with HIV/AIDS in the state. The death rates for persons with HIV decreased 41% from 2000 to 2013.[88] Further, since the mid-1990s, mother-to-child transmission of HIV has dramatically decreased, and this success is partially attributed to more HIV-infected pregnant women being placed into ART.[89]

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[84] CTRS. OF MEDICARE & MEDICAID SERVS., MASSHEALTH MEDICAID SECTION 1115 DEMONSTRATION 11-W-00030/1 68-69 (Oct. 30, 2014). MassHealth Interim Evaluation report is publicly available. Ctr. for Health Policy & Research, MassHealth Section 1115(a) Demonstration Waiver 2011-2014 Interim Evaluation Report (2013), *available at* http://www.mass.gov/eohhs/docs/eohhs/cms-waiver/appendix-b-interim-evaluation-of-the-demonstration-09-2013.pdf.

[85] CMS APPROVAL DOCS., *supra* note 76, at 46.

[86] Jane Perkins, National Health Law Program, *50 Reasons the Medicaid Expansion is Good for the State* 7 (August 5, 2012), http://www.healthlaw.org/publications/50-reasons-medicaid-expansion-is-good-for-your-state#.U1Gcv1fvKW8.

[87] CMS APPROVAL DOCS., *supra* note 76, at 3.

[88] Mass. Dep't of Public Health, Off. of HIV/AIDS, *Massachusetts HIV/AIDS Fact Sheet: The Massachusetts HIV/AIDS Epidemic at a Glance* 1, *available at* http://www.mass.gov/eohhs/docs/dph/aids/2014-profiles/epidemic-glance.pdf.

[89] MASS. DEP'T OF PUBLIC HEALTH, BUREAU OF INFECTIOUS DISEASES, MASSACHUSETTS STD, HIV/AIDS AND VIRAL HEPATITIS SURVEILLANCE REPORT: 2012 11 (Dec. 2013). Specifically, the level of mother-to-child HIV infection transmission decreased from four infants born with HIV in 2002 to zero in 2006 and 2008.

Conclusion and Recommendations

The ACA sought to extend Medicaid coverage and benefits to many low-income individuals denied insurance coverage because they could not fit any of the traditional eligibility categories. In an Expansion state, low-income WLWH could quickly realize these benefits. New enrollees in Expansion states are entitled to a core benefit package, including the essential health benefits and preventive services for women. The Medicaid Expansion is also cost-efficient for states given its generous federal reimbursement.

By contrast, benefits offered in § 1115 waivers may vary among states depending on how the demonstration is designed and what is being tested. The innovative or experimental nature of a § 1115 waiver can affect offered benefits and the overall program design. The FMAP available to each state for §1115 waivers will depend on the current reimbursement rate the state receives for its traditional Medicaid program.

When designed as an innovative method of health care delivery, § 1115 demonstrations still can be effective tools to extend coverage and services for WLWH. Section 1115 demonstrations in Maine and the District of Columbia proved to be examples of innovative approaches in care management and reduced HIV drug pricing for people living with HIV/AIDS. The Massachusetts' demonstration is an example of how to maximize public health benefits by pairing a targeted HIV/AIDS § 1115 demonstration with the Medicaid Expansion and other health care reforms.

Depending on the state's implementation of the demonstration, a § 1115 waiver can produce varied results for demonstration enrollees, as evidenced by experiences in Maine, Massachusetts, and the District of Columbia. Maine's demonstration illustrates how outreach to increase enrollment and case management ensures retention. However, the District of Columbia demonstrates how limited enrollment, outreach, and retention activities and a lack of coordination between state departments administering the waiver and other care programs can diminish the purpose of the waiver program.

Advocates should continue to support efforts to expand Medicaid eligibility in their states. However, recognizing the current political landscape in some states, § 1115 waivers might be an effective tool to provide innovative approaches of health care delivery to WLWH for the present time. If a § 1115 waiver is a state's only option for the immediate future, advocates should provide input for its design and available services during the waiver application's comment period. Moreover, advocates should also carefully monitor and provide feedback during the implementation of the demonstration to ensure that low-income WLWH in their states obtain benefits to improve their health status.