Chapter 2 HIV AND PUBLIC HEALTH LAW

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Because HIV is an infectious disease, many of the legal issues related to HIV involve questions of public health. In the context of infectious disease, public health law is understood as the set of legal rules concerned with infection control and prevention. The government sometimes has authority to take measures—that can infringe on individual liberties—in order to protect the public’s health. However, often the best public health approach is also the approach that preserves individual liberties.

Public health law constantly seeks to identify a balance between protecting the common good of a healthy society and the individual liberties that can come into tension with prevention of disease. This is particularly salient when discrimination is a concern—because HIV has disproportionately affected populations that have been subject to discrimination (e.g., men who have sex with men and Black people), the balance between coercive measures (e.g., mandatory testing), and individual liberties (e.g., the right to refuse testing and the right to keep one's HIV status confidential) has been especially important. Particularly in the early stages of the HIV epidemic, HIV-rights advocates were in conflict with public health professionals, especially the Centers for Disease Control and Prevention (the federal public health agency), over the best approach to combating
HIV. However, by the late 1980s, a consensus was reached that public health goals of controlling the spread of HIV, and ensuring that everyone infected knows their status and has access to treatment, were consistent with civil rights and civil liberties—including consensual rather than mandatory testing in most circumstances, privacy rights, and the rights to be free of discrimination. Because HIV is largely spread by sex and, to a lesser extent, drug use—activities that are particularly difficult to control through coercive means—the cooperation and commitment of affected communities is critical to effective public health measures. And because coercive and punitive measures increase stigma associated with the disease, which in turn deters people from learning their status and seeking care, such measures are not in the interest of public health.

Public health efforts to address the HIV epidemic in the United States, of course, depend on the health care system—which is complex, cumbersome, and flawed in many respects. Therefore, public health law as it relates to HIV/AIDS is intertwined with health care law generally, and with efforts to reform the U.S. health care system. Moreover, racial, ethnic, and other inequities in our health care system are highlighted by the disparities in HIV incidence, prevalence, treatment, and prevention. The burdens of the disease continue to disproportionately affect Black and Latinx persons; gay and bisexual men, especially gay and bisexual men of color; and transgender women, especially those of color.

Health care and public health law are largely a matter of state law in the United States. However, since the beginning of the HIV/AIDS epidemic, the federal government has been key to the public health response (and initially, the failure to respond) to the epidemic. This chapter largely focuses on federal law.

In the wake of substantial medical breakthroughs in HIV treatment and prevention, the legal issues related to HIV have changed considerably—although the struggle against stigma and discrimination, and related concerns over medical privacy, remain critical. The most important HIV-related issues in public health law today include:

- Changing and contradictory federal policies and actions by the Trump Administration—which, on the one hand, announced an “End the HIV Epidemic” initiative in 2019 consisting of new funding for HIV prevention and treatment in specifically targeted jurisdictions with particularly high infection rates—and, on the other hand, has sought to undermine laws and regulations which most experts believe are essential to the fight, including the Affordable Care Act, Medicaid, Medicare, federal housing and nutrition assistance programs, and federal laws prohibiting discrimination in health care and health insurance.
- The fate of the Affordable Care Act, which has substantially improved access to affordable health care for many people living with HIV, and for communities at heightened risk of HIV (persons of color, and sexual and gender minorities).
- Continuing substantial disparities in new HIV infections, and in access to affordable and adequate treatment, affecting racial and ethnic minorities—especially Black and Latinx people.
- Continuing tensions between scientific evidence-based public health measures and moralism, which exist in the criminal law—HIV criminal exposure statutes, criminalization of consensual sex work, syringe exchange for users of illegal injection drugs—and in the educational system—sex education and access to condoms and HIV testing, treatment and prevention by minors.
- The continuing need to balance individual concerns about privacy—often based on realistic fears of stigma and discrimination—against the public health and health care systems’ needs for robust information-sharing.

Some of the discussions in this chapter overlap with portions of Chapter 5 (Schools and Educational Programs), Chapter 7 (Criminal Law), Chapter 9 (Public Benefits), Chapter 11 (Immigration), Chapter 12 (Insurance Law), and Chapter 13 (Family Law). The reader interested in those issues should consult those sections as well as this chapter.

Footnotes
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In 2008, the Office of National AIDS Policy (ONAP) began developing a National HIV/AIDS Strategy to respond to the HIV epidemic in the United States. The National HIV/AIDS Strategy (NHAS), issued by executive order first in 2010 and again in 2015, seeks to coordinate existing federal resources across several agencies to allow providers and public health practitioners to address HIV more effectively. To accompany the release of the NHAS in 2010, President Obama sent a memorandum to executive agencies, noting successful implementation of the Strategy would “require the Federal Government to work in new ways across agency lines.” Federal agencies involved in implementing the NHAS include the Health Resources and Services Administration (HRSA), Indian Health Service (IHS), the National Institutes of Health (NIH), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and more.

With oversight and involvement by the ONAP and these federal agencies, the NHAS sets forth both goals and agency-specific strategies for reaching those goals, specified in the NHAS Federal Implementation Plan. In December 2015, the government released a Federal Action Plan, to discuss immediate actions to be taken by federal agencies to achieve the program's goals by 2020. The vision and goals laid out in the NHAS did not change between 2010 and 2015, but strategies for obtaining certain goals evolved. The 2010 and 2015 strategies highlight the following three main goals, and the 2015 version set a target of reaching these goals by 2020:

1. **Reduce new HIV infections.** The 2010 and 2015 strategies to reduce the incidence of HIV infections both emphasize concentrating prevention resources where transmission rates are highest (e.g., southern states) and promoting research and development of *pre-exposure prophylaxis* (PrEP). The 2015 strategy goes further, emphasizing the importance of using PrEP as a “treatment as prevention” model (see §2.03[B]) and making condoms, testing, and clean needles easily accessible. The 2015 strategy also notes policy changes and scientific advances that occurred between 2010 and 2015, such as the implementation of the Affordable Care Act and evidence of the positive impact of early treatment on health outcomes. It also discusses challenges to be addressed in reaching the goal of reducing new infections by 25 percent by 2020, such as increases in substance abuse disorders and increased diagnoses of HIV in young gay and bisexual men.

2. **Increase access to care and improve outcomes.** While both the 2010 and 2015 strategies emphasize the importance of social determinants of health (e.g., housing and support services), the 2015 strategy further calls for increased attention to substance abuse disorders and improved attempts to reconnect with patients who have fallen out of care. The 2015 strategy also emphasizes researching and
3. **Reduce HIV-related disparities and health inequities.** To reduce health disparities, the 2010 strategy emphasizes the importance of promoting community health centers and collecting more data in areas with highest prevalence rates, while the 2015 strategy shifts emphasis toward focusing on contributing factors to disparities (e.g., domestic violence). The strategies both discuss reducing stigma and eliminating discrimination associated with HIV status. Reducing social stigma of an HIV diagnosis can lead to more individuals getting tested, seeking care, and adopting prevention measures, such as disclosing their HIV status.

In addition to setting forth these goals, both the 2010 and 2015 strategies call for improvement in coordinating efforts across federal agencies, across all levels of government, and throughout the healthcare system. They also emphasize improved mechanisms to monitor and report on progress toward reaching these goals. For example, the NHAS has established indicators to benchmark progress in the HIV epidemic. The 2015 strategy notes 10 indicators of progress “to monitor annual progress toward achieving the goals of the Strategy.” Examples of indicators include reducing the number of new diagnoses by at least 25 percent, reducing the percentage of young gay and bisexual males who have engaged in HIV-risk behaviors by at least 10 percent, and reducing the death rate among persons with diagnosed HIV infection by at least 33 percent. The nation has made progress on several indicators under the NHAS; for example, there have been declines in the number of new HIV diagnoses despite an increase in testing, and the death rate among persons diagnosed with HIV declined more than expected. However, the percentage of young gay and bisexual males who have engaged in HIV-risk behaviors has increased from the baseline, illustrating the reality that additional efforts are needed to reach the NHAS's goals.

As of 2017, the United States was on track to reach many of the NHAS's 2020 goals: fewer people are being diagnosed with HIV; more people with HIV are getting the treatment and care they need to live healthy lives; more people are taking pre-exposure prophylaxis (PrEP) to reduce the danger of HIV infection; and the unequal impact of HIV for some populations, including Black women and girls, has been reduced. However, significant challenges remain in reaching the NHAS's 2020 goals. For example, homelessness among persons diagnosed with HIV has continued to grow, as well as the disparities in new diagnoses and HIV-risk behaviors among gay and bisexual men and new HIV diagnoses in the South. As the 2016 NHAS Indicator Supplement Progress Report stresses, achieving the goals of the NHAS requires consistently monitoring progress and improving prevention and care efforts in order to resolve the nation's HIV epidemic.

**[B] Developments in the Trump Administration**

The uncertain fate of the NHAS in the Trump Administration. While creating the NHAS via executive order (instead of by legislation) provides agencies with increased flexibility in how they allocate funds based on local and regional need, it has led to uncertainties with respect to the future of the strategy in a new Administration. Following the inauguration of President Trump in January 2017, the content of certain White House websites, including that of the ONAP, was removed. As of the time this chapter was being finalized for publication (June 2020), there was still no content for ONAP or the NHAS on the White House website, although information on the NHAS is posted on HHS’ website, www.HIV.gov. As of the time this chapter was being finalized, the federal government had announced that plans were underway to update both the NHAS and the National Viral Hepatitis Action Plan and had held 18 “listening sessions” in various locations and at HIV-related conferences to solicit community input.

**Developments regarding the Presidential Advisory Council on HIV/AIDS.** The Presidential Advisory Council on HIV/AIDS (PACHA) was created by Executive Order of President Clinton in 1995. In mid-2017, six members resigned in protest over President Trump's lack of action on HIV. In December 2017, the
President dismissed all of the remaining members. In March 2019, the Administration announced the appointment of new co-chairs and new members. As of June 2020, PACHA has held five meetings to discuss recommendations to the HHS Secretary regarding programs and policies intended to promote effective prevention and care of HIV infections and AIDS.

**The Administration’s “End the HIV Epidemic” initiative.** In his State of the Union address on February 5, 2019, President Trump announced an initiative with the goal of ending the HIV epidemic in the United States in 10 years. Although details are still developing, the basics appear to be the following:

- The overall goals are to reduce new HIV infections by 75 percent in five years and by at least 90 percent in 10 years.
- The four fundamental strategies are to:
  1. Diagnose persons living with HIV as soon as possible;
  2. Treat everyone diagnosed with HIV as soon as possible and keep them engaged in treatment to become and remain virally suppressed;
  3. Prevent uninfected persons from acquiring HIV through Pre-Exposure Prophylaxis (PrEP), Syringe Exchange Programs, and other proven interventions;
  4. Detect clusters of new transmissions and quickly respond with prevention and treatment services focused on those specific areas and populations.
- Phase I of the initiative will focus on specific geographical areas where new HIV infections are highly concentrated: 48 counties; Washington, DC; San Juan, Puerto Rico; and seven states with substantial HIV diagnoses in rural areas (Alabama, Arkansas, Kentucky, Mississippi, Missouri, Oklahoma, and South Carolina).
- “In Phase II, efforts will be even more widely disseminated across the nation to reduce new infections by 90 percent by 2030. In Phase III, intensive case management will be implemented to maintain the number of new infections at fewer than 3,000 per year.”

Specific tools relied on by the initiative, including the benefits of treatment that reduces viral load to undetectable levels, PrEP, and techniques to identify transmission clusters, are discussed below.

The initiative involves all federal agencies with a significant role in addressing the epidemic, including the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), the National Institutes of Health (NIH), the Office of the HHS Assistant Secretary for Health, and the Substance Abuse and Mental Health Services Administration (SAMHSA). As this chapter was being prepared for publication, the Administration’s FY 2021 budget request included an increase of $716 million for the second year of the multiyear initiative, a $450 million increase compared to that in FY 2020. However, the Administration proposed to cut $80 million from Housing Opportunities for People With AIDS (the HOPWA Program), to international HIV prevention and treatment, and to the budgets of NIH, SAMSHA, and other agencies important to HIV treatment and prevention. This raises the question of whether the “End the HIV Epidemic” initiative will be vitiated by other Administration policies and actions that undercut programs and laws that are critical to providing many persons with access to affordable health care and other services that are important to health, and that provide safeguards against discrimination for populations hard hit by the epidemic, including gay and bisexual men, transgender women, and Black and Latinx people. Furthermore, in the wake of the international COVID-19 crisis, the Administration requested additional funding to address pandemic preparedness and response efforts. How the proposed budget changes will impact the HIV initiative remains an open question.

**Administration actions that appear to be at cross-purposes with the “End the HIV Epidemic” initiative.** Many of these developments are discussed in more detail in other chapters, or later in this chapter, but they are also highlighted here.
Administration actions that undermine access to affordable health insurance. HIV testing, prevention, and treatment all depend on individuals living with HIV, and individuals at risk of HIV, having access to, and staying engaged with, the health care system. For many, if not most, people, this requires good, affordable health insurance. As discussed below, major advances have been achieved in reducing the percentage of Americans who are un- or under-insured, thanks to the Affordable Care Act and the Medicaid program. The Administration’s continuing efforts to undercut or abolish the Affordable Care Act are discussed in §2.03[A][2][G], and its efforts to reduce the Medicaid program by encouraging states to impose work requirements on recipients are discussed in §2.03[A][2][A]. In addition, the Centers for Medicare and Medicaid Services at HHS recently proposed modifying the Medicare Part D prescription drug program to cut back on existing rules that require Part D plans to include all FDA-approved antiretroviral drugs in their formularies. The proposal provoked substantial opposition from health care providers, patient advocates, and pharmaceutical companies, and HHS ultimately withdrew the proposal.

Administration effort to cut back on the Supplemental Nutrition Assistance Program (SNAP). Adequate nutrition is critical to the health of people living with HIV. The SNAP program, which plays a vital role in helping millions of individuals and families secure adequate food, has been a target of the Trump Administration since 2017. Having failed to persuade Congress to enact legislation cutting back on the program, the Administration has been attempting to accomplish its aim through regulations. Most recently, the Administration has proposed eliminating automatic SNAP eligibility for persons who qualify for other income-based public benefits. Estimates are that this new rule, if it becomes final, would eliminate more than 3 million people from the program.

Administration efforts to reduce safeguards against health care discrimination. HIV primarily affects populations that traditionally have been stigmatized and subjected to systemic discrimination, in health care as well as in other sectors: Black and Latinx people, gay and bisexual men, and transgender persons. In recent months, HHS has significantly weakened legal protections against discrimination by (1) issuing a final rule which substantially expands the rights of health care providers and staff, and health insurance plan sponsors and personnel, to opt out of providing care when they object to a particular type of care based on their personal religious or moral views, although the rule was recently struck down by three separate federal district courts; and (2) issuing a rule re-interpreting Section 1557 of the ACA to greatly curtail protections against discrimination by health care providers and institutions, and health plans, that receive federal funds, which had been challenged in several lawsuits at the time these updates were prepared. Both developments are discussed in §2.03[A][2][F].

Administration actions targeting immigrants. Developments in immigration law are beyond the scope of this chapter; see Chapter 11. However, it is important to note that the Administration's systemic efforts to target undocumented immigrants, and to erect barriers to legal immigration for lower-income persons dependent on public health care, housing, food assistance, and other programs, are discouraging many individuals and families from seeking health care and other health-supportive services. A particularly striking recent action is the new “public charge rule,” which penalizes many immigrants who access Medicaid and other public health and social service programs by limiting their ability to adjust their status to lawful permanent resident, and to eventually become citizens.

Thus, whether and to what extent the Administration’s “End the HIV Epidemic” will be effective is uncertain at this time.

Footnotes


Id.

Id. at 6–7.


Id.


The "End the HIV Epidemic Plan" was explained, more or less simultaneously with the President's announcement in Anthony S. Fauci et al., Ending the HIV Epidemic: A Plan for the United States, 321 JAMA 844 (2019), https://jamanetwork.com/journals/jama/fullarticle/2724455; and by issuances on HHS' web site; Alex Azar, Ending the HIV Epidemic: A Plan for America (Feb. 5, 2019), https://www.hhs.gov/blog/2019/02/05/
Access to Care: Federal Legislation

Ensuring access to affordable health care for individuals with HIV/AIDS is essential for controlling and treating the disease in individuals who are infected. Appropriate treatment is also one of the most essential mechanisms of prevention. As discussed in Chapter 1, individuals with a well-controlled and treated disease are much less likely to transmit the disease to others. A Consensus Statement joined by many HIV experts declares that with respect to the risk of transmission through sexual activity “U=U”—undetectable = untransmittable:

There is now evidence-based confirmation that the risk of HIV transmission from a person living with HIV..., who is on Antiretroviral Therapy...and has achieved an undetectable viral load in their blood for at least 6 months is negligible to nonexistent. [30]

This conclusion has been endorsed by the leading HIV authorities in the federal government: the Centers for Disease Control and the National Institutes for Health. The CDC specifically notes that with undetectable viral load, there is “effectively no risk” of sexual transmission (oral, anal, or vaginal), and that the risk from sharing drug injection equipment is “unknown, but likely reduced.” [32]

HIV/AIDS treatment adherence is essential to effectively managing the disease, and interruptions in care caused by access issues fundamentally threaten the ability to successfully treat and control the disease in the infected individual and reduce new infections in the community. Individuals with HIV/AIDS have faced significant barriers to accessing affordable and consistent care, including difficulty or inability in obtaining coverage, prohibitively expensive care and treatment if uninsured or underinsured, and potential discriminatory practices that can create barriers to accessing affordable and appropriate care.
Two key federal legislative initiatives have vastly improved access to care for individuals with HIV/AIDS: the Ryan White Compressive AIDS Resources Emergency Act of 1990 [33] (Ryan White CARE Act or CARE Act) and the Affordable Care Act of 2010 [34] (Affordable Care Act or ACA). This section discusses each of these laws, including the significant progress that each has achieved with respect to access to health care, as well as certain limitations and ongoing challenges.

[1] Ryan White CARE Act

[a] Overview

Federal legislative attention to the AIDS epidemic found its most focused and positive response in one piece of legislation: the Ryan White CARE Act of 1990. [35] The CARE Act created the Ryan White HIV/AIDS Program, which provides a comprehensive system of medical care and support services for people living with HIV. [36] The CARE Act is dedicated to the memory of the 70,000 persons, who lost their lives to AIDS as of the date of the law's enactment in 1990, and to the memory of Ryan White, who died at age 18 on April 8, 1990, after living with AIDS for nearly six years, from the age of 13. [37] The 1990 bill received significant bipartisan support, passing the Senate by a margin of 95 to 4. [38] The CARE Act was initially authorized for five years and was amended and extended in 1996, [39] and again in 2000, 2006, [41] and 2009. [42] Although the 2009 reauthorization expired in 2013, reauthorization legislation for the Ryan White CARE Act is not required to continue funding the program. Previous reauthorizations contained specified end dates; for example, the 2006 reauthorization specified an end date of September 30, 2009. Under the 2009 reauthorization legislation, however, Congress eliminated the sunset provision. This means that the program can continue to operate and the federal budget can continue to appropriate funds, so long as Congress provides for such appropriations and does not take legislative action to end the program or discontinue its funding. As of FY 2020, Congress has continued funding for the Ryan White HIV/AIDS Program each year via annual appropriations. [43]

Federal funding for the program began in 1991 and increased significantly in the mid-1990s, in order to help people purchase new therapy options, namely Highly Active Antiretroviral Therapy (HAART). [44] Funding continued to increase slowly, but has plateaued in recent years. [45] As of FY 2020, the program was funded at $2.38 billion. The Ryan White HIV/AIDS Program is the third largest source of federal funding for HIV care in the United States, following Medicare and Medicaid. [46] An important distinction between Ryan White funding and that of Medicaid and Medicare is that the Ryan White Program is not an entitlement that people are guaranteed if they meet the qualifications. [47] The Ryan White Program is a discretionary program to which the federal budget allocates appropriations each year. The Ryan White Program also does not provide health care insurance; rather, it provides grants and other assistance that can be used for treatment when no other resources are available.

More specifically, the CARE Act establishes an HIV Health Care Services Program “to provide emergency assistance to localities that are disproportionately affected” by the epidemic and to fund states and other public or private nonprofit entities “to provide for the development, organization, coordination and operation of more effective and cost efficient systems for the delivery of essential services to individuals and families with HIV disease.” [48]

The CARE Act, as amended, is composed of several funding streams, referred to as Parts A, B, C, and D (and, later, also Parts E and F). Part A provides emergency relief for eligible metropolitan areas (EMAs) and for transitional grant areas. [49] Part B provides grants to states for core medical services and support services, including the AIDS Drug Assistance Program. [50] Part C provides funding for early intervention services, including core medical and support services. [51] Part D funds services for women, infants, children, and youth and required the General Services Administration to report to Congress on how CARE Acts have been used.
[52] Part E gives the Secretary of HHS the authority to use up to 5 percent of supplemental funds appropriated under Parts A and B for addressing the needs of public health emergencies, such as aiding people requiring HIV/AIDS care and treatment in disaster areas. [53] Finally, Part F, first added to the Act in 1996, funds demonstration and training projects, AIDS Education and Training Centers, dental services, and Special Projects of National Significance and codifies the Minority AIDS Initiative. [54]

[b] Reauthorization History

The CARE Act’s reauthorization history in Congress has involved successive efforts to distribute funding equitably and to not unfairly favor some areas, regions, or municipal areas over others. [55] In its 2006 reauthorization, Congress overhauled the funding distribution formula. [56] Perhaps most significantly, Congress based the funding distribution formula for Parts A and B on living HIV and AIDS cases from name-based reporting states as reported to and confirmed by the CDC (as opposed to all cases, including deaths). Beginning with fiscal year 2007, the distribution of this funding is based only on HIV cases. Because some states had only recently implemented name-based reporting at the time of the 2006 reauthorization and, thus, would have lost significant funding under this formula because their name-based system did not have a complete count of HIV cases, [57] Congress allowed states a four-year grace period. Also, under Part A, cities that were no longer eligible under the new EMA formula were grandfathered in for at least three years, and a hold-harmless provision for most Parts A and B funding provided that EMAs receive 95 percent of their fiscal year 2006 award for up to three years in the future. In sum, the 2006 CARE reauthorization institutionalized HIV name-based reporting as well as provided CARE Act funding recipients with an incentive to identify persons with HIV through name-reported HIV testing.

In 2009, reauthorization of the CARE Act added a formula-based system for allocation of funding for Minority AIDS Initiative grants (based on population density of demographics with disproportionate infection rates). The 2009 reauthorization further requires EMA and transitional grant area grantees to demonstrate ability to track rates of individuals who are unaware of their HIV status and to implement plans to reduce these numbers; it also eliminates the requirement that funds earmarked for primary care services be used exclusively for primary care in cases where other reimbursement (e.g., health insurance) is available to cover primary care costs. [58]

As noted above in this section, although the 2009 reauthorization expired in 2013, Congress has continued to fund the CARE Act each year via annual appropriations. As of FY 2020, the CARE Act was funded at $2.38 billion and serving more than half a million people living with HIV each year. [59]

[c] Impact of the Affordable Care Act on Ryan White

Following the ACA’s enactment in 2010, a number of people speculated or expressed concerns that the new health care reform legislation would lead to reduced resources for the Ryan White CARE Act or would make the Ryan White HIV/AIDS Program obsolete in light of anticipated coverage expansions and market reforms. [60] Prior to the ACA, the Ryan White HIV/AIDS Program supported about half of Americans diagnosed with HIV. [61] The majority of the ACA’s coverage reforms—including the Medicaid expansion, the establishment of the health insurance exchanges (or Marketplaces) for the individual and small group markets, among others—took effect January 1, 2014. Rather than becoming unnecessary, however, the Ryan White CARE Act has continued to provide assistance to people living with HIV/AIDS. Indeed, even after the implementation of major ACA reforms, the number of individuals supported by the Ryan White HIV/AIDS Program has slightly increased, demonstrating the program’s continued (and growing) role in assisting people with HIV regardless of insurance status.

As discussed further in §2.03[A][2], the ACA provided states the option to expand Medicaid coverage for adults with incomes up to 138 percent of the federal poverty level. [62] Even in states that have expanded their Medicaid programs, the Ryan White Program continues to provide services to those diagnosed with HIV, including by
filling gaps in Medicaid coverage, such as dental care, support services (e.g., transportation and legal services), and coverage for undocumented immigrants with HIV/AIDS. [63]

The ACA also expanded private insurance coverage in several ways, including by prohibiting insurers from denying or cancelling coverage due to preexisting conditions and eliminating annual or lifetime caps on insurance benefits. [64] Because, pre-ACA, individuals with HIV/AIDS were at risk for denial of coverage because of a preexisting condition or reaching annual or lifetime caps, the ACA has benefited the HIV/AIDS population with respect to private insurance coverage. That being said, similar to trends seen in Medicaid, the Ryan White Program remains important even for enrollees in private health insurance plans, as it provides assistance in affording prescription drugs (which, even if covered, often involve high cost-sharing amounts) and in filling gaps in coverage under the private plans, such as case management and legal assistance (which play a significant role in retaining people in treatment), oral health care, and hospice services. [65] The Ryan White Program also provides health education and seeks to improve treatment compliance, positively impacting public health. Insurance programs under the ACA generally do not focus on these types of public health initiatives. [66] Importantly, however, the ACA exchange plans cover some services that the Ryan White Program cannot, such as inpatient hospital care. [67] Thus, the two statutory frameworks work in a complementary manner in providing access to care for individuals with HIV/AIDS.

Although the CARE Act legislation has not been reauthorized, the government to date has consistently recognized the Ryan White Program as a priority safety-net program. [68] Health policy experts have emphasized the possibility that, if budget cuts occur, the Ryan White Program may be unable to sustain current levels of support services. [69] Sustained funding is crucial to maintaining the level and quality of care required by clients of the program. [70] In addition, if the ACA were to be repealed, coverage gains that have occurred because of both Medicaid and private insurance expansion could be lost. Because Ryan White is not an insurance program and it covers only HIV-related care, those who have gained insurance could lose access to coverage for other health conditions and emergency services if the ACA is repealed. [71]

[2] Affordable Care Act

The ACA took important steps to improve access to care and enhance treatment options for all patients. The ACA expanded Medicaid, created protections for patients with preexisting conditions, established categories of essential health benefits that most insurance plans must cover, created new health insurance exchanges, and banned annual and lifetime coverage caps. [72] Health care reform through the ACA has led to significant progress in providing and facilitating affordable coverage for care and treatment of numerous chronic and communicable diseases, including HIV/AIDS. ACA implementation also has faced a number of challenges, however, which have created or continued certain barriers to access, have prevented full execution of certain provisions, and have raised certain threats and uncertainties with respect to the future law and its protections.

A. Medicaid Expansion

The expansion of Medicaid was a centerpiece of the ACA and its coverage expansion goals. Under the ACA’s original construction, about half of newly insured individuals would gain private health insurance through exchanges (or Marketplaces), and the other half would become eligible for government benefits under Medicaid, the federal health care program jointly administered by the federal government and the states. In expanding the Medicaid program, the ACA sought to consolidate and simplify certain existing eligibility rules, which varied widely from state to state, and replace them with a national standard. Under the national standard, any person with income up to 138 percent of the federal poverty level (FPL) could qualify for Medicaid.

In 2012, the ACA faced potential invalidation when the U.S. Supreme Court considered the law's constitutionality in National Federation of Independent Businesses v. Sebelius. [73] In that case, the Court upheld the ACA’s overall constitutionality, and the constitutionality of the “individual mandate”—the requirement that most people
obtain health insurance coverage or pay a tax penalty—deemed essential to the viability of insurance markets since insurers are required to cover persons with costly medical conditions. However, the Court struck down the requirement that all states participate in the Medicaid expansion. Instead, the Court held, states must be allowed to choose whether to participate in the Medicaid expansion or to continue at pre-ACA levels of Medicaid funding and eligibility. As of August 5, 2020, 39 states and the District of Columbia have adopted the ACA’s Medicaid expansion. [74] For the states adopting Medicaid expansion, the federal government paid 100 percent of the cost for newly eligible enrollees until 2016, after which federal support is set by statute to decrease over time until it levels off at 90 percent. [75]

The ACA’s Medicaid expansion represents the first expansion of the Medicaid program since its creation in 1965. In a review of more than 400 studies on the impact of the Medicaid expansion published between January 2014 (when the coverage provisions of the ACA went into effect) and January 2020, the Kaiser Family Foundation found that the expansion had a positive impact on three broad categories: (1) coverage; (2) access to care, utilization, affordability, and health outcomes; and (3) economic outcomes for states and providers. [76] These general positive outcomes extend to the treatment of persons with HIV, as Medicaid is the largest source of insurance coverage for people with HIV/AIDS, estimated to cover more than 40 percent of this population in 2009. [77]

According to data from the Medical Monitoring Project, a CDC surveillance system designed to produce nationally representative estimates of behavioral and clinical characteristics of HIV-infected adults (those aged 18 and older) in the United States, the ACA led to a significant overall increase of Medicaid coverage for individuals with HIV following the ACA’s enactment, driving a nationwide increase in coverage for people with AIDS. [78] The same analysis also found the “role of the Ryan White Program has increased since implementation of the major coverage reforms under the ACA,” with noticeable increases in the reliance on Ryan White services seen in those individuals with HIV/AIDS who had insurance. [79]

**Trump Administration support for state imposition of work requirements on Medicaid recipients.** In early 2018, the *Centers for Medicare and Medicaid Services* (CMS) issued guidance permitting states to seek Medicaid waivers that impose work requirements on recipients. [80] According to an April 2020 Kaiser Family Foundation report, as a result of litigation challenging work requirements, four states (Arkansas, Kentucky, Michigan, and New Hampshire) have had such waivers set aside by the courts. Indiana and Utah are the only states to have implemented a work requirement waiver. Four more states (Arizona, Ohio, South Carolina, and Wisconsin) have approved waivers that are not yet implemented, and another ten states (Alabama, Georgia, Idaho, Mississippi, Montana, Nebraska, Oklahoma, South Dakota, Tennessee, and Virginia) have waiver requests pending with CMS. [81] If implemented, work requirements, together with substantial reporting requirements imposed on beneficiaries, are likely to force large numbers of otherwise eligible individuals off Medicaid rolls.

**B. Preexisting Condition Protections**

Prior to the ACA, people with AIDS were often unable to obtain insurance coverage because the disease was considered a preexisting condition. [82] This effectively meant that in most cases people with HIV were barred from the individual market. The ACA prohibits health insurance companies from refusing to cover patients or charge them more for having a preexisting condition. [83] The ACA’s ban on preexisting conditions is essential to protecting insurance coverage for those living with HIV and other diseases.

**C. Essential Health Benefits**

The ACA also requires all non-grandfathered health plans in the individual and small group markets (both on and off the exchanges) to cover essential health benefits. By statute, essential health benefits include the following 10 categories: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive...
Services included in the essential health benefits—such as prescription drug services, hospital inpatient care, laboratory tests, outpatient services, and other benefits—are critical to help patients manage a chronic disease, including HIV/AIDS, and any associated mental health problems. Although the ACA requires coverage of these benefit categories for all non-grandfathered individual and small group plans, the statute also provides significant discretion to the HHS Secretary to define the contours of the benefit categories.

In 2013, HHS issued a final rule to implement the essential health benefits requirements. This rule, and other HHS rulemakings addressing essential health benefits requirements, has played an important role in defining the level and type of care provided to plan enrollees under these categories of care. Under this regulatory framework, states are permitted (within certain federally prescribed parameters) to choose an essential health benefits “benchmark plan” to guide plans’ benefit packages in the relevant categories. The regulations also provide for specific nondiscrimination protections in connection with the essential health benefits, which supplement the ACA’s other nondiscrimination provisions (discussed below in §2.03[A][2][F]).

D. Health Insurance Marketplaces

The ACA created health insurance exchanges, or Marketplaces, through which consumers can purchase health insurance. These Marketplaces, which can be either federally facilitated or state-run, are intended to generate a more competitive and user-friendly market for consumers buying health insurance. As of 2019, the federal government operates the Marketplace for just over half of the states, while fewer states manage their own Marketplaces. The Marketplaces are designed to help individuals, families, and small businesses purchase health insurance by offering a choice of health plans, certifying participating plans, and providing information to consumers to understand their options by making it easier compare benefits across plans. Often the Marketplace provides these services through websites, call centers, and in-person meetings. In addition to exchanges offered for individual and small market plans, the Small Business Health Options Program (SHOP) Marketplace helps small businesses with 50 or fewer full-time equivalent employees provide health insurance to their employees.

Marketplace plans are offered at different “metal levels”—bronze, silver, gold, and platinum; a “catastrophic” coverage option is also permitted in certain cases. The different metal levels are tied to Actuarial Value (AV), which refers to the percentage of plan benefits paid for by the plan (vs. by the enrollee). Premiums are typically higher for plans with higher AV, as a tradeoff for the more generous benefits. Under the ACA, bronze plans have 60% AV; silver plans have 70% AV; gold plans have 80% AV; and platinum plans have 90% AV. Catastrophic plans provide limited coverage and are allowed only in the individual market for individuals who meet narrow criteria.

The ACA also provides financial assistance for people with low to moderate incomes to purchase insurance in the Marketplace. The assistance takes the form of tax credits that lower the cost of monthly premiums and lower out-of-pocket costs and is available to those with a household income between 100 and 400 percent FPL. In addition, cost-sharing reduction (CSR) assistance is available for those with household income up to 250 percent FPL who enroll in a silver plan.

The ACA Marketplaces and Medicaid expansion have significantly expanded coverage for individuals with HIV/AIDS, and the ACA’s subsidies and CSRs have provided further assistance for individuals purchasing private coverage. However, individuals who live in certain nonexpansion states and have incomes below 100 percent FPL (but incomes above that necessary to qualify for Medicaid in their state) fall into a “coverage gap” where they do not qualify for Medicaid under the state’s rules and do not qualify for tax credits to purchase private insurance under the ACA. Reports estimate that more than two million individuals fall into this coverage gap.
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gap as of early 2019, including thousands with HIV/AIDS. This issue further highlights the continued importance of the Ryan White Program even post-ACA.

E. Ban on Annual and Lifetime Coverage Limits

The ACA prohibits health plans from establishing annual or lifetime dollar limits on services provided in the 10 categories of essential health benefits. “Dollar limits” under this provision refers to the amount an insurer will pay toward a patient’s treatment after the patient has reached their deductible. There are two types of dollar limits: annual and lifetime. These dollar limits are separate and differ among plans. The ACA’s prohibition on annual and lifetime dollar limits applies to individual and small group plans as well as large group plans.

The elimination of annual and lifetime coverage limits expanded access to care for people living with HIV and other chronic diseases. Reports suggest that the ban was a critical element to enhancing the ability of individuals with HIV/AIDS to treat their disease and ensure long-term management of the condition.

F. Nondiscrimination

Prior to the passage of the ACA, health plans in the individual and small group markets were not restricted from discriminating against enrollees or potential enrollees on the basis of their health status or other characteristics. This often meant that individuals with serious or chronic health conditions, including but not limited to HIV/AIDS, were charged significantly more for coverage than those without such conditions, or were denied coverage altogether. Pre-ACA, individuals could be denied coverage, could have certain treatments excluded from their coverage, or could face higher cost-sharing obligations based on their health status. The ACA and its implementing regulations established protections to address and prohibit health status discrimination by insurers on the basis of health status or condition, including discrimination against people with HIV/AIDS.

Under Section 1557 of the ACA, health plans offered on the Marketplaces, as well as any health program or activity that receives federal funding from HHS, are prohibited from excluding from participation in a plan, denying benefits, or otherwise discriminating against enrollees or potential enrollees in a plan's benefit offerings based on an individual's race, color, national origin, age, disability, or sex. Section 1557 references and incorporates the protections of several existing federal anti-discrimination and civil rights laws, including, among others, the Americans with Disabilities Act and the Rehabilitation Act of 1974, which prohibit federal discrimination in federal programs against people with disabilities.

The ACA also addressed discriminatory practices through the law’s requirements for essential health benefits. Specifically, the law instructs the HHS Secretary to define essential health benefits in a manner that does “not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life.” As a practical matter, this means that insurers cannot deny coverage to, charge higher premiums for, or design discriminatory benefit plans with respect to people with serious health conditions.

Implementing regulations further define the scope of the ACA’s nondiscrimination protections. In February 2013, HHS finalized a regulation covering the essential health benefits and other plan requirements. The final rule established that an insurer subject to the essential health benefits criteria does not provide essential health benefits, and thus does not meet the requirements of the law, if its benefit design or implementation thereof “discriminates based on an individual’s age, expected length of life, or present or predicted disability, degree of medical dependency, quality of life, or other health condition.” The final rule clarified that the discrimination protections extend not only to benefit standards but also to benefit implementation, including marketing practices, benefit design, coverage decisions, or reimbursement rates.

In May 2016, the HHS finalized implementing regulations for Section 1557 of the ACA. The final rule established numerous requirements that insurers must follow to ensure compliance with the nondiscrimination
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requirements. The rule specifically stated that plan designs that discriminate against persons with a disability or other protected characteristics are prohibited. [106] The rule stated, as an example of a plan design that "might be discriminatory," "placing most or all prescription medications that are used to treat a specific condition on the highest cost formulary tiers." [107] The final rule also addressed enforcement of the requirements and provided the enforcing agency, the HHS Office for Civil Rights (OCR), with direction about mechanisms that it should use in this regard, including initiating noncompliance proceedings. The final rule did not, however, offer more specific protections that some patient groups advocated for, including specific regulatory provisions focused on discriminatory cost sharing and limits on excessive medication management tools that could be used to discriminate against people with HIV and other costly medical conditions. [108] In June 2020, HHS issued a comprehensive revision to the 2016 rule that deleted the provision on discriminatory plan design. [109] Although the new rule has been challenged in several lawsuits, it remains to be seen how receptive HHS will be to complaints against plan designs that have the intent or effect of discriminating against HIV or other serious health conditions.

While the ACA and its implementing regulations have made significant progress in prohibiting discrimination in health care, some insurers have continued to engage in practices that may be discriminatory with respect to benefit design and offerings. Some of these continued discriminatory practices directly impact individuals with HIV/AIDS. In 2014, for example, two national nonprofit organizations, the AIDS Institute and the National Health Law Program, filed an administrative complaint with the HHS OCR, which enforces HHS nondiscrimination protections, alleging that four Florida insurers were violating the ACA and other federal civil rights laws in the way they structured their prescription drug policies. [110] Specifically, the complaint alleged that the identified plans, offered through the Florida Marketplace, discriminated against people with HIV/AIDS by discouraging them from enrolling in the plans through the plans’ formulary designs, which designated all medically necessary drugs for HIV/AIDS—including all generic options—as “specialty drugs” and placed them on the highest formulary tier with significant (as much as 40 to 50 percent) co-insurance obligations and, in many cases, strict utilization management criteria such as prior authorization, step therapy requirements, and/or quantity limits. The complaint challenged this benefit design as a violation of the ACA’s nondiscrimination requirement on the grounds that it discriminated against HIV/AIDS patients by making their treatments inaccessible due to the high cost-sharing obligations and by discouraging enrollment in these plans by individuals with HIV/AIDS, thus amounting to discrimination based on health status and/or disability.

The complaint asked HHS to investigate the conduct and take corrective action against the Florida plans, as well as other plans throughout the country that may be engaged in similar conduct. Rather than acting on the complaint directly, HHS referred the case to the state insurance agency. The Florida Office of Insurance Regulation (OIR) subsequently reached settlement agreements with the plans identified in the complaint. [111] The Florida OIR also issued a guidance memorandum directing insurers offering plans on the Florida Marketplaces to refer to a benchmark plan to assess plans’ formulary treatment of HIV/AIDS drugs. [112] Specifically, OIR indicated that it would consider a plan’s formulary compliant with state and federal laws prohibiting discrimination only “if the tiered formulary of HIV/AIDS medications is at least as favorable as the state's benchmark plan.”

The issues addressed in the complaint filed by The AIDS Institute and the National Health Law Program represents one example of how, notwithstanding the protections in the law, discriminatory practices by insurers may continue to negatively impact individuals with HIV/AIDS. This reality demonstrates the importance of consistent implementation of the ACA’s standards and robust enforcement of the law’s requirements. In addition, individuals with HIV/AIDS who have health insurance coverage often still face high out-of-pocket costs in the form of premiums, deductibles, and co-pays or co-insurance, which may limit their ability to access affordable care, including prescription drugs. As a result, programs such as the Ryan White AIDS Drug Assistance Program and other assistance have remained important to access even in the post-ACA period.
Recent Administration actions undercutting the ACA's nondiscrimination provisions. In June 2020, HHS issued a new rule that substantially modified the 2016 existing rule and dramatically reduced the protections against discrimination announced in that rule. [113] The new rule:

- Expressly withdrew provisions addressing discrimination based on gender identity, declare that gender identity and sexual orientation discrimination are not covered under the statute's prohibition of discrimination based on sex, and eliminate references to discrimination based on sexual stereotypes and based on association with someone of a specific sex, race, national origin, color, age, or disability.
- Exempted many forms of health insurance from any nondiscrimination obligation under Section 1557 (not only sex, but also disability, race, color, national origin, age).
- Deleted provisions that provided notice of individuals' rights under Section 1557.
- Inserted broad language about the rights of covered health care providers and insurers to opt out of nondiscrimination requirements based on their religious beliefs.
- Weakened safeguards for Limited English Proficiency patients.

The new rule also eliminated prohibitions on gender identity and sexual orientation discrimination in a number of other HHS regulations unrelated to Section 1557, including regulations addressing state Medicaid plans, health insurance exchanges and marketplaces, and ACA-regulated health plans. [114]

HHS cannot change Section 1557 by regulation. A number of federal courts have held that that statute, and other federal sex discrimination statutes, cover gender identity discrimination, and some courts have held that sexual orientation discrimination is also covered by sex discrimination laws. As noted below, on June 15, 2020 the Supreme Court adopted this interpretation of sex discrimination in Title VII. However, the new HHS rule threatens to confuse and mislead patients and providers alike, and would eliminate an important venue for redress (administrative agency action as distinct from recourse to the courts, which as a practical matter is unavailable to most people).

As this publication was being finalized, five separate lawsuits had been filed challenging the new rule as violating the Administrative Procedures Act, Section 1557 itself and other provisions of the ACA, Supreme Court precedent, and a number of constitutional safeguards. [115] Two Federal District Courts – in the Eastern District of New York and the District of Columbia have entered preliminary injunctions enjoining portions of the HHS rule, pertaining to the changed definition of sex discrimination and to the importation into Section 1557 of Title IX's broad religious exemption. [116]

Relevance of the Supreme Court's June 2020 ruling on sex discrimination under Title VII. On June 15, 2020, the Supreme Court ruled, in Bostock v. Clayton County, Georgia, [117] that Title VII's prohibition of sex discrimination in employment includes discrimination based on gender identity and discrimination based on sexual orientation. Courts have generally relied on Title VII case law in interpreting Title IX's prohibition of sex discrimination, which is incorporated into Section 1557. [118] However, HHS has not conceded that Bostock applies to title IX or Section 1557, and the courts have not yet addressed this question in the pending lawsuits challenging the new HHS rule.

Federal court ruling vacating the Obama era Section 1557 rule's provisions on sex discrimination. On October 15, 2019, Judge Reed O'Connor of the U.S. District Court for the Northern District of Texas vacated the portions of the 2016 rule that provided that Section 1557 covered discrimination based on gender identity and presentation, and discrimination based termination of pregnancy. The judge ruled that these provisions violated Title IX and the Religious Freedom Restoration Act. [119] The Trump Administration did not appeal this ruling, and in the new Section 1557 rule issued in June 2020, HHS relied heavily on Judge O'Connor's ruling.

Relevance of the Supreme Court's June 2020 ruling in Bostock. As noted above, the Supreme Court ruled on June 15, 2020 that the prohibition on sex discrimination in Title VII includes discrimination based on sexual orientation and gender identity. [120] The Supreme Court's ruling appears to completely undermine Judge O'Connor's legal analysis of sex discrimination and gender identity. As this update chapter was being prepared,
two Courts of Appeal have already ruled, relying on Bostock, that Title IX covers gender identity discrimination. [121] ACA Section 1557, of course, is based in relevant part on Title IX. However, how Bostock technically applies to Judge O’Connor’s final ruling vacating parts of the 2016 rule has not yet been determined. The two Federal District Courts which have issued injunctions against aspects of the HHS 1557 rule held that HHS had acted arbitrarily and capriciously, in violation of the Administrative Procedures Act, by failing to take Bostock into account, although they concluded that they lacked the authority to vacate or modify Judge O’Connor’s orders. [122]

It should also be noted that Judge O’Connor is also the author of a 2018 ruling that the ACA is unconstitutional. [123] This ruling and subsequent appeals are discussed in §2.03[A][2][G], which immediately follows.

**HHS’ “conscience protection” rule.** In May 2019, HHS issued a final rule that gives health care providers and staff, and health plan sponsors and personnel, sweeping rights to opt out of “participating” in any health care procedure or activity to which they have a personal religious or moral objection. [124] The rule applied to any health care provider or institution, or health plan, that received federal financial assistance, and threatens providers and institutions who decline to accommodate “conscience-based” objections with curtailment of federal funding. The rule adopted a very broad interpretation of “participation” in a health care activity or procedure to which an individual is entitled to object—including even providing information or referrals to patients. Challenges to the rule were filed in federal courts in the Northern District of California, the Southern District of New York, the Eastern District of Washington, and the District of Maryland. On November 6, the Southern District of New York vacated the rule as violating the Administrative Procedure Act, and the Spending and Separation of Powers Clauses of the Constitution. [125] On November 19, the Northern District of California judge also vacated the rule, holding that it exceeded HHS’ authority under the federal statutes at issue. [126] On November 7, a third federal judge, in the Eastern District of Washington, vacated the rule from the bench; his written decision followed on November 21. [127] As of June 2020, the government has appealed both the New York and the California decisions. As this publication went to press, appeals filed by the government were pending in the Ninth Circuit [128] and the Second Circuit. [129] If the rule becomes final and is broadly enforced, it could interfere with HIV testing, treatment, and prevention efforts—particularly since many individuals living with HIV and many at elevated risk of HIV are members of stigmatized populations that have been subjected to widespread discrimination: gay and bisexual men, transgender persons, and persons with substance use disorders.

**G. Future of the ACA**

Since the passage of the ACA in 2010, there has been consistent opposition by many stakeholders to several of the law’s provisions. This has led to multiple legal challenges in the courts and multiple attempts to repeal parts of the law by legislation. The November 2016 election and resulting Republican control of the White House and majority in both chambers of Congress solidified efforts to repeal and replace parts of the law upon the inauguration of President Trump in January 2017. In addition, a number of lawsuits challenging aspects of the ACA remained ongoing in 2017, and rulemaking actions by federal agencies also proposed and sought feedback on changes to previously issued ACA regulations.

With respect to legislative efforts, although procedural limitations led Republican lawmakers to narrow the scope of the ACA provisions they sought to repeal, many of the reforms pursued in Republicans’ ACA repeal and replace efforts would have significantly amended or removed key provisions of the law, including those relating to essential health benefits and the Medicaid expansion.

In 2017, Republicans in the U.S. House of Representatives and Senate made several attempts to repeal and replace the ACA, but those efforts were unsuccessful. However, as part of the changes to the tax code in 2017, the ACA’s income tax on individuals who do not purchase health insurance was repealed, effective 2019. [130] A group of states hostile to the ACA subsequently filed a lawsuit arguing that the ACA’s minimum coverage requirement is no longer constitutional after repeal of the tax. They also argue that other provisions of the ACA, including protections for persons with preexisting conditions, are not severable from the minimum coverage
requirement and that the entire ACA is, therefore, unconstitutional. The Justice Department is now supporting the states’ position. Judge Reed O’Connor of the Northern District of Texas has ruled in the hostile states’ favor. The Fifth Circuit agreed with Judge O’Connor that the individual mandate/minimum coverage requirement was unconstitutional, but vacated the Judge’s ruling on the ACA as a whole and remanded the question of whether the ACA should survive the elimination of the individual mandate/minimum coverage requirement. The Supreme Court granted certiorari and is expected to decide the case in the October 2020 term – probably in the first half of 2021.

The three issues pending before the Supreme Court are: (1) whether the hostile states have standing to challenge the ACA, because the ACA minimum coverage provision no longer imposes a monetary penalty on those who do not have coverage; (2) whether the minimum coverage provision is constitutional under the Constitution’s Taxing Clause; and (3) even if the Court holds the minimum coverage provision is unconstitutional, whether it is severable from the rest of the ACA. The Trump Administration has argued to the Supreme Court that the entire ACA should be struck down.

In addition to the continued efforts to repeal and replace the ACA, the Trump Administration faces challenges in stabilizing the insurance markets and implementing provisions of the ACA. It also faces policy questions and litigation decisions relating to cost-sharing reduction payments, preventive services requirements, and other ACA implementation issues. The Administration has issued several rulemakings that many believe are intended to undercut the ACA’s mandated health plans (e.g., by delaying or stopping payments to insurers to compensate them for the requirement to shield consumers from certain costs). One such rulemaking, issued pursuant to Executive Order 13813, sought to increase access to short-term, limited-coverage plans, which are likely to appeal to younger, healthy persons and, therefore, increase costs in ACA-protected plans. The DC Circuit has ruled that such plans are within the legal authority of HHS.

[B] Antiretrovirals to Prevent HIV Infection: Pre-Exposure Prophylaxis, or PrEP

One of the greatest breakthroughs in the fight against the HIV epidemic emerged within the past decade: the discovery that the drugs used to treat the infection (antiretrovirals or ARVs) can also prevent transmission if taken according to prescription by uninfected individuals who are then exposed to the virus. The use of ARVs as a prophylactic measure is not entirely novel; post-exposure prophylaxis (PEP), reducing risk of infection immediately after exposure to HIV (e.g., via a needle stick in the workplace), is also based on the use of ARVs. And, of course, as discussed in §2.03[A], if an HIV-positive person’s viral load is undetectable as a result of ARV treatment, the virus is virtually untransmittable to others via sexual activity. However, using ARVs to prevent HIV in uninfected individuals rather than to treat HIV is a recent discovery and PrEP exactly does that. The first antiretroviral drug (Truvada) for use as PrEP was approved by the U.S. Food and Drug Administration (FDA) in 2012. Following several successful clinical trials, the CDC concluded that when taken pursuant to the daily dosage guidelines, PrEP reduces the risk of HIV infection via sexual intercourse in HIV-negative individuals by 90 percent for men who have sex with men (MSM) and for different-sex couples and by 70 percent for intravenous drug users. Subsequent studies have indicated much higher protective rates—perhaps close to 100 percent if there is complete adherence to the regimen.

While these results are quite promising and have renewed HIV prevention efforts, PrEP use needs to increase substantially in order to realize its full potential for reducing overall incidence of HIV infection. PrEP implementation on a wide scale has proved difficult for a number of reasons. Stigma and fear surrounding HIV, and sex, continue to limit PrEP use. Even when PrEP is initiated, several studies have found that identified categories of high-risk individuals (e.g., those who have multiple sexual partners and/or who use intravenous drugs) demonstrate imperfect adherence with the daily dosing regimen, making some providers reluctant to prescribe the drug. Certain tactics to improve adherence have proven effective, however, including distributing free pillboxes with the drug and sending automated text message reminders.
Adherence is particularly important not only to ensure effective prevention, but also because lack of adherence can have negative implications for ability to treat HIV, should it be contracted. Because PrEP is an ARV also used to treat HIV, those who become infected and continue taking PrEP before learning of their diagnosis risk developing resistance to a first-line treatment. Data indicate, however, that most individuals who are infected while on PrEP do not develop resistance if tested in time. Thus, patients taking PrEP must be tested for HIV every three months. In addition, more recent evidence suggests that PrEP may be effective even if taken only before and after unprotected sex, rather than every day. Nevertheless, some providers continue to believe that PrEP may exacerbate high-risk behavior, leading individuals to feel invincible to infection (although available data do not provide support for the assumption that PrEP use leads to increased levels of risky behavior among those who take it).

Despite implementation challenges, PrEP offers tremendous potential for slowing transmission of HIV. In a 2020 study surveying ten states with the greatest increase in PrEP coverage, researchers found the incidence of new HIV cases fell on average 4.0 percent. In 2020, the AIDS Vaccine Advocacy Coalition (AVAC) estimates 220,000-225,000 people are currently taking PrEP, meaning that only about 22 percent of the over one million people with a PrEP indication were on PrEP. Data further suggest that PrEP uptake to date is concentrated largely among urban MSM. Moreover, while PrEP use increased by 500 percent from 2013 to 2015, Black people accounted for only 10 percent of PrEP users. PrEP use is too low among Black and Latinx men who have sex with men (MSM), transgender people, women, people who inject drugs, and young people. Even so, use of PrEP appears to be growing. Previous federal administrations have emphasized the importance of widespread PrEP uptake as part of the National HIV/AIDS Strategy. As noted in §2.02[B], expansion of PrEP use is also a key element in the Trump Administration's initiative to end the HIV epidemic.

Substantial progress has been made in ensuring that PrEP is affordable for those who would benefit from it. It is covered by Medicare; by most if not all state Medicaid plans; and by many, if not most, private health insurance plans. Gilead, the manufacturer of Truvada, provides co-pay assistance for persons with health insurance and an assistance program for uninsured individuals. The company has also announced that it will donate up to 2.4 million bottles of the drug annually to the CDC in conjunction with the federal initiative to end the HIV epidemic. However, significant co-pay requirements in many health insurance plans, and the significant costs of the regular medical monitoring and testing that are the standard of care for individuals on PrEP, contribute to concerns about affordability expressed by many for whom PrEP is indicated.

One very important recent development is that, in June 2019, the U.S. Preventive Services Task Force issued a final “Grade A” rating for PrEP as a recommended prevention modality for individuals at high risk of HIV. A “Grade A” rating means: “The USPSTF recommends the service. There is high certainty that the net benefit is substantial.” Pursuant to the ACA and related law in some states, a prevention service that receives a USPSTF grade of A or B must often be covered by many health plans, without cost-sharing by covered individuals, after an interval of time after the recommendation, in this case 2021. However, there are as-yet unresolved issues with implementation. It is unclear whether the no-cost-sharing requirement applies only to the cost of the drug itself, or also to the costs of medical visits and tests that are indicated for patients on PrEP. Moreover, while the legal requirement appears to be self-implementing, many insurers, patients, and health care providers may be unaware of the requirement, and notice and enforcement efforts may be required. In June 2020, the California Insurance Commissioner issued a Notice to regulated carriers that provided health insurance, instructing them that, pursuant to the USPSTF rating and federal law, they are required to cover without cost-sharing not only the cost of the drug prescribed, but also the costs of associated medical visits and tests.

Further innovations may make the critical prevention modality of PrEP more accessible and affordable. The FDA has approved a generic version of Truvada, manufactured by a different company, which will be available in
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later 2020. A different drug for PrEP manufactured by Gilead, Descovy, was recently approved by the FDA for persons engaging in anal sex, but the FDA concluded there was insufficient evidence of its effectiveness for receptive vaginal sex because Gilead’s trials did not include a sufficient number of (cisgender) women. In May 2020, preliminary results from a large-scale study showed injectable cabotegravir PrEP may provide an easier alternative to taking daily pills of other prophylactic antiretrovirals. This finding marks the first time a large-scale clinical trial has shown an injectable, long-acting form of HIV prevention may be just as effective as the daily oral regimen of Truvada. Additional modalities are in development, including medications that can be taken less frequently, orally, or by skin patch.

One additional recent development is a dispute over patents for Truvada held by the U.S. government, and allegations that the CDC has allowed Gilead to systematically infringe those patents without paying royalties to the U.S. In response to growing pressure, the U.S. has filed a lawsuit against Gilead for patent infringement, seeking back royalties, trebled for knowing infringement, and ongoing royalties—including royalties for the new drug Descovy as well as for Truvada. The ultimate impact of this development on the cost of PrEP is uncertain.

[1] Access and Discrimination

ARV treatment (and PrEP) is priced at approximately $2,000/month, not including associated doctor visits and lab work. Patients’ out-of-pocket costs vary, however, depending on insurance status and coverage. For example, not all patients have insurance and, further, not all issuers are required to cover essential preventive services drugs (such as PEP and PrEP) under their plans. Consequently, access to PrEP may be limited because of financial means. Financial limitations are of particular concern because many high-risk communities, such as homeless youth, often are those who are most affected by such limitations.

Access may also be limited because of a physician’s reluctance to prescribe PrEP. In a 2014 survey of health practitioners, many of whom were HIV-specializing practitioners, 21 percent of respondents noted that they were not very likely to prescribe PrEP even to the highest-risk groups. Those with reluctance reported concerns about adherence to daily dose, commitment to follow-up care for monitoring and counseling, side effects, effectiveness of PrEP in preventing HIV, cost of treatment, and the effect on behavior (e.g., potentially emboldening a patient to engage in riskier behavior).

Explicit or unconscious biases may also increase the level of reluctance to prescribe PrEP based on race and/or gender, which may increase the risk of discriminatory prescription practices. For example, a study of medical students published in 2014 demonstrated that the participating medical students were less willing to prescribe PrEP to a Black HIV-negative gay male in a serodiscordant couple (as opposed to if the HIV-negative male were white), rating him more likely to engage in increased unprotected sex as a result of PrEP.

Studies also indicate that physicians have been reluctant to prescribe PrEP to adolescents. This likely is at least in part because, until recently, the FDA had only approved PrEP for those 18 and older, such that any prescriptions to minors necessarily would be off-label. However, that obstacle recently disappeared. In May 2018, the FDA amended its label for Truvada to approve the drug for any individual weighing 35 kg or more at risk of HIV due to sexual practices. Note that the average 13-year-old weighs significantly more than 35 kg.

No state expressly prohibits minors’ access to PrEP. Some physicians’ reluctance to prescribe PrEP to adolescents also appears to involve concerns about confidentiality. In addition, states’ laws vary as to whether minors have the authority to consent to medical care, which may also depend on the type of medical care. For example, some jurisdictions expressly allow some minors to consent to medical care for diagnosis and treatment.
of STIs; others allow only certain categories of minors to consent to medical care (e.g., those emancipated or serving on active duty in the military). [174]

Individuals on PrEP may also be subject to a heightened risk of discrimination. Although the ACA and implementing regulations include specific protections against discrimination in health care, these protections have certain limitations with respect to implementation and enforcement (see §2.03[A][2] & [F]) and, further, do not cover all types insurance (e.g., disability, long-term care, and life insurance). For example, in 2015, Mutual of Omaha Insurance Company allegedly denied a gay man long-term care insurance because of his use of PrEP. In response, GLBTQ Legal Advocates & Defenders filed a complaint in Massachusetts Superior Court alleging illegal denial of access to a place of public accommodation based on sexual orientation and disability. The case was removed to Federal District Court, and subsequently settled, with the insurer agreeing to revise its underwriting policies and to issue an insurance policy to the plaintiff. [175] This is the first publicly documented case of its kind. [176] However, reports of other individuals being denied disability or life insurance because they were taking PrEP [177] prompted California, New York, and Massachusetts regulators to issue guidance prohibiting such discrimination. [178] In March 2020, Maine passed a law to prohibit insurers from discriminating against individuals because they had been prescribed PrEP. [179] As of the summer of 2020, the Council of the District of Columbia was also reviewing a similar bill. [180]

Health insurer policies may also make access to PrEP more difficult. A number of health insurance carriers require pre-authorization for PrEP prescriptions. Some also require use of specified mail-order pharmacies for the drug. Protests against the resulting delays and unnecessary burdens have met with varying degrees of success.

Gilead's Truvada Co-Pay Coupon program currently covers up to $7,200/year of co-pays for eligible patients, with no monthly cap. However, an increasing number of insurers are adopting “co-pay accumulator” programs. These policies do not credit amounts paid by a pharmaceutical company for the patient's drug toward the patient's annual deductible, which forces the patient to bear substantial additional costs and discourages the patient from starting or continuing on PrEP. (Drug co-pay coupons are prohibited by Medicare and Medicaid as kickbacks, but permitted under commercial health plans.) The issues raised by this insurance practice are getting increasing public attention. They pit insurers’ concerns over pharmaceutical company incentives that may encourage unnecessary use of costly drugs against patient advocate and public health concerns over disincentives to engage in PrEP and other beneficial therapies. [181]

[2] Promoting Awareness

Certain jurisdictions have employed legislative efforts to increase awareness about PrEP. California was the first state to pass legislation related to PrEP education. In 2017, California Governor Jerry Brown signed into law AB2640, a landmark statewide law that requires the dissemination of PrEP-related information to high-risk HIV-negative persons during HIV post-test counseling. [182] The law is modeled after a similar law passed by the city of West Hollywood, CA, two years earlier. [183] At the end of 2016, Washington, D.C., launched a public-private partnership program to promote knowledge of PrEP to African American and Latino MSM and to transgender people of color, as well as PrEP and PEP general public education campaigns. [184] No similar legislative efforts have been undertaken to date at the federal level. [185] However, as noted in §2.02[B], the Trump Administration's initiative to end the HIV epidemic targets specific counties, states, and other jurisdictions where HIV incidence and prevalence is particularly high. Many, if not most, of these communities include large proportions of people of color. It remains to be seen how much emphasis HHS and the CDC—which are implementing the Administration's initiative—will focus specifically on racial and ethnic disparities.

Additional challenges include promoting and initiating similar programs in midwestern and southern states like Missouri and Texas. Both states have seen HIV incidence rates for at-risk communities increase, yet the political
climate may not be open to such programs. Other issues stem from the need for more provider education and awareness. Provider education (especially for primary care providers) is critical to expanding access to this prevention method; many primary care providers do not feel sufficiently informed to discuss PrEP with a patient. Thus, enacting laws that target a larger audience than just HIV testing clinics may be worth considering.

[C] HIV Testing and Confidentiality Requirements

After a reliable HIV antibody blood test became available in early 1985, states began regulating HIV testing and the use of test results or other HIV information by statutes requiring informed consent and imposing specific confidentiality standards. Since then, HIV-specific state laws have been supplemented by the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. §1320d, and its implementing regulations, including the Privacy Rule. The HIPAA Privacy Rule provides general confidentiality standards for protected health information, which is broadly defined to include "individually identifiable information" transmitted or maintained in electronic media or in any other form or medium. The Privacy Rule enhances the rights of patients in several respects, including a right to access personal health information, to amend such information, and to receive timely notification in the event of a breach of unsecured protected health information. The Privacy Rule contains several notable exceptions. Disclosures of protected health information do not require the patient's approval if they are communications between a patient's provider for the purposes of delivering or coordinating health care; communications needed for health center operations or payment; information sharing with government agencies for public health purposes (including HIV names reporting); and communications for certain law enforcement purposes. HIPAA protections do not preempt state laws that cover additional areas or that are stricter than HIPAA's provisions; thus, HIPAA's federal framework provides a floor but not a ceiling to privacy protections. For additional discussion of HIPAA, see Chapter 12.

Although testing for HIV and the maintenance of confidentiality can be viewed as two separate issues, in reality they are inseparable for most purposes: if an individual has been tested for HIV, the question of the use and control of the results of the test is unavoidable. Even the information that an individual has sought testing was once significant, given the potential for stigma attaching to an individual viewed as at risk for HIV (although this risk is declining as testing becomes a standard component of preventive medical care).

HIV testing is of positive medical and social significance, and it also poses significant potential for abuse, such as the testing of patients without their knowledge or consent. However, as research around prevention and treatment methodologies progress, testing has become increasingly less taboo and a standard element of a routine health screen. Testing is voluntary except for a select set of scenarios (e.g., inmates (at times), members of the military, Foreign Service, or Peace Corps). Occupational exposure and court-ordered scenarios can also result in mandatory testing, as discussed in §2.03[D] and [E].

In addition, many statutes regulate the process of testing, and mandate certain features of testing, such as post-test counseling, that may reduce the potential for psychological harm and distress experienced by those tested, can help ensure that patients are not mislead by unreliable or misinterpreted results, and require that the test results are provided to the patient in a timely manner. The enactment of confidentiality law provides the public with an important assurance that HIV information will not be publicly disclosed and thus result in discrimination. Nevertheless, breaches can occur. For example, in May 2017, the Spencer Cox Center settled a HIPAA enforcement action for $387,200 because employees had impermissibly disclosed a patient's HIV status, sexual orientation, and other protected health information to the patient's employer. HIPAA includes robust provisions relating to data security and breach notification in light of these risks.

Consent for an HIV test previously required separate informed consent, meaning that a patient was presented with a separate form for an HIV test than any other component of a series of blood tests. Today, every state but one allows for consent within a generalized laboratory consent form, provided that the patient checks a box indicating awareness that HIV will be included in the battery of tests. Moreover, CDC and WHO guidelines
encourage providers to offer HIV testing as part of routine laboratory screens to all patients, not only those deemed at risk. This is designed to reduce the stigma associated with receiving an HIV test and increase the number of patients tested (and there is some evidence that opt-out testing policies result in significantly higher screening levels).

**An emerging issue: Recency Testing.** The identification of persons newly infected with HIV is an important tool in ending the HIV epidemic. New “recency” tests, or recent infection testing algorithms (RITAs), have allowed researchers to identify whether individuals are newly infected with HIV by measuring that person's HIV viral load. Recency data, combined with geographic data, help practitioners identify clusters of recent infections, triggering a public health response. Recency tests have broad applications to: (1) determine the stage of the HIV infection; (2) estimate the proportion of those new HIV diagnoses that are recently acquired in a population; and (3) estimate the rate of HIV incidence in populations. There are many open questions about the practical implications of recency testing and the need for safeguards to protect individuals from undue criminal prosecution.

**An emerging issue: Molecular HIV Surveillance.** Recently there has been increased attention on “molecular surveillance” or “molecular epidemiology” as a tool for HIV prevention. When a person is diagnosed with HIV, the genetic code of their virus is sequenced to determine whether the virus is resistant to any antiretroviral drugs, and which drugs are indicated for the individual's treatment. This genetic information, which is provided in de-identified form to local and state health departments and to the CDC, can be compared to the information in the viral sequences obtained from other persons to identify “clusters” of related virus, and combined with other information to identify outbreaks of HIV transmissions in particular geographic areas and among specific populations. The information can then be used to target those areas or populations for prevention interventions. Researchers in 2019 observed that frequently transmitted HIV strains in larger clusters are associated with higher viral load, and they concluded that these strains are under selection to be more infectious and virulent. Those researchers hypothesized that early detection of growing clusters could counteract the later selection and propagation of more infectious and virulent HIV strains. As noted in §2.02(B), cluster detection technology is an important strategy in the federal government's recently announced "End the HIV Epidemic" initiative.

Concerns have been raised about possible breaches of confidentiality of individuals identified as belonging to such a “cluster,” and about possible uses of the information to investigate or prosecute individuals accused of transmitting HIV to others. As noted in §2.05 and in Chapter 7, many states have laws that criminalize transmitting HIV or exposing others to the virus. Although experts in molecular HIV surveillance agree that the technology cannot reliably indicate the direction of transmission between two or more HIV-positive individuals with the same virus, there is a danger that information obtained through cluster analysis could influence police, prosecutors, judges, or juries in unreasonable ways. There is a developing consensus that legal safeguards and policies need to be developed and implemented at the federal and state level to prevent this important prevention tool from misuse. In June 2020, the AIDS United Public Policy Council, consisting of more than 50 health care centers, public health agencies, advocacy organizations, and professional associations across the U.S., adopted a Consensus Statement urging the CDC and state and local public health authorities to take a number of specific actions to prevent unnecessary violations of individuals' privacy and to prevent illegitimate uses of surveillance data in law enforcement proceedings and civil litigation.

**[D] Testing of Pregnant Women and Newborns**

Providing antiretroviral therapy during pregnancy was shown to reduce perinatal transmission of HIV and thus was recommended for pregnant women with HIV. HIV testing was seen as a prerequisite to making this treatment option available. However, because mandatory testing could serve as a disincentive for women to seek prenatal care, the Ryan White CARE Act emphasizes pretest counseling and voluntary, although opt-out, HIV testing of pregnant women, consistent with the CDC's recommendations. To receive federal funding,
states must certify with the Department of Health and Human Services (HHS) that they have adopted these recommendations in implementing voluntary HIV testing and counseling. Note that while the potential cons associated with mandatory testing have been deemed to outweigh the benefit of identifying all women in need of PMTCT (Prevention of mother-to-child transmission), mandatory testing has been effective at reducing mother-to-child transmission: Cuba, which implemented a mandatory testing policy in the early days of the epidemic, was the first country to eliminate mother to child transmission.

[E] Testing Following Occupational Exposure

Although seeking to have oneself tested is the only way to determine whether HIV transmission has actually occurred as the result of a known injury or incident posing risk of exposure, persons at risk through occupational activities have often sought to have the source individual tested, to inform the risk benefit analysis associated with engaging in post-exposure prophylaxis. Many states that have adopted consent requirements for HIV testing also have adopted an exception pertaining to health care workers. For example, South Carolina allows nonconsensual testing of not just the source patient but also the health care worker and emergency response employee. Several states allow such testing, but only after a certification by a physician that the incident involved a significant exposure. In some states, once certification is completed, only “available blood” can be tested; without a court order, another specimen may not be obtained for that purpose without the patient's consent. Arkansas provides even greater access to patient HIV status by authorizing HIV testing without informed consent “when a healthcare provider, employee of a health care facility, or emergency response worker is involved in a direct skin or mucous membrane contact with the blood or body fluids of an individual which is of a nature that may transmit HIV, as determined by a physician in his or her medical judgment.”

Moreover, although not directly related to its purpose, the Ryan White CARE Act required the Secretary of Health and Human Services to develop a list of potentially life-threatening infectious diseases to which Emergency Response Employees (EREs) may be exposed in responding to emergencies. HIV is included on the secretary's list. The CARE Act then sets forth a process by which EREs at risk for exposure may seek to obtain information about the infectious status of the emergency victim.

[F] Court-Ordered Testing

State statutes that require HIV testing to be voluntary significantly limit the authority of courts to order HIV testing, and, in some cases, they have been interpreted to bar such testing. Some statutes do not directly authorize such testing at all, while others limit court-ordered testing and disclosure to circumstances in which the party seeking testing can demonstrate that he or she has had an exposure to body fluid of the source individual and that the exposure poses a significant risk of exposure to HIV. For additional discussion regarding involuntary testing in the criminal law context, see Chapter 7.

In a remarkable decision that goes against well-established medical and scientific standards, Syring v. Tucker, the Wisconsin Supreme Court ordered testing of a defendant in a civil action resulting from a biting incident six years earlier. On April 21, 1987, Tucker bit Syring. The bite broke Syring’s skin, and Tucker's saliva came into contact with his blood. Subsequently, Tucker stated, apparently on more than one occasion, that she had AIDS or was HIV positive. Syring commenced a lawsuit, which Tucker chose not to defend. He obtained a default award of $20,000 as compensatory damages for emotional distress and $10,000 as punitive damages. The trial court made it clear that the damage award was based on the assumption that Syring had not been infected with HIV, but that if he did show evidence of infection, he could seek a retrial on the damage issue. Syring also sought an order for Tucker to be tested for HIV. The trial court concluded that it did not have the authority to order such a test, and that ruling was summarily affirmed on appeal. On further appeal, the Wisconsin Supreme Court reversed, holding that ordering the testing was within the trial court’s “equitable authority,” was not barred.
by Wisconsin's statutory limitations on HIV testing and the use of HIV test results, and was “appropriate” and constitutional.

The reasons offered in support of the conclusion that testing is appropriate in such a case are hardly persuasive from a scientific point of view. Equally troubling is the court's resolution of complex medical and scientific issues, ranging from the significance and reliability of HIV antibody testing to Tucker's HIV antibody test result as relevant to Syring's pursuit of medical treatment, without reference to evidence supporting its conclusions in the record. First, the court considered the issue of whether HIV can be transmitted by saliva. In regard to that question, the court concluded, citing literature that is not fairly representative of the issue, that although the “greater weight of scientific opinion holds that HIV cannot be transmitted via saliva...scientific opinion does not appear unanimous” on that question. [216] Significantly, the court does not cite or explain the OSHA's workplace safety standard, which explicitly concludes that saliva, alone, does not pose a risk of HIV transmission. [217] Next, the court concluded, again counter to the prevailing weight of opinion, that Syring may in fact be infected with HIV, without that fact being detectable by antibody or other testing, even years after the potential exposure. [218]

A very similar case, Doe v. Burgos, [219] also involved testing to determine HIV status after a biting incident. Three-and-one-half years after the incident, and after testing negative for HIV herself, a correctional officer sought court-ordered HIV testing for the inmate accused of biting her. The correctional officer's demand for HIV testing was apparently brought pursuant to the Illinois AIDS Confidentiality Act, [220] which provides that written informed consent for HIV testing is not required in the case of a law enforcement officer's line-of-duty direct exposure to body fluids that may transmit HIV. The Act, however, was not in effect when the bite occurred, nor does it explicitly authorize court-ordered testing. In response to the correctional officer's lawsuit, the inmate provided documentation of a voluntary HIV test result indicating that she was negative for HIV antibodies. The trial court, however, for reasons not fully explained in the court's opinion, agreed with the correctional officer that this test result was not satisfactory because of concern that the blood specimen tested was not that of the inmate. The court ordered that more information be provided about the inmate's test or that the inmate be retested.

In other cases, however, the courts have rejected requests for HIV testing by determining that the results of testing simply would not bear on the issues in the case. In In re R. Children, [221] a child protective proceeding in which a father was alleged to have sexually abused his daughter, the court rejected the father's request for HIV testing to determine the daughter's status; her status was essentially irrelevant to the allegations of abuse against the father, given that the father was not alleged to have HIV or to have infected the daughter.

[G] Mandatory Reporting Standards

Since 1983, all states have required the reporting of diagnoses of AIDS, as defined by the CDC. Today, the requirement extends to HIV-positive test results. The reporting requirement, established by state infectious disease reporting laws or regulations, is typically imposed on the physician who initially diagnoses a patient with HIV and/or laboratories that process the test results. Where state health privacy or HIV-specific confidentiality standards apply, reporting requirements often are included as express exceptions to confidentiality. [222] In addition, the HIPAA Privacy Rule permits disclosures to public health authorities. [223] Diagnoses reported to state health departments include the patient's name/identity and may include other data, such as the patient's risk history and clinical status. Each state health department then transmits its data, but without patient identifying information, to the CDC.

Name-based reporting has not always been the norm; many states initially implemented code-based systems that did not identify patients by name. However, the 2006 reauthorization of the Ryan White CARE Act based the federal funding formula on name-based HIV test results as reported to and confirmed by the CDC, making name-based reporting of HIV test results the norm for all states. As of July 2017, all states and an additional
seven jurisdictions (District of Columbia, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, the Republic of Palau, and the U.S. Virgin Islands) had implemented name-based reporting.\[224\]

While mandatory reporting improves epidemiological data, enabling targeting of scarce resources to prevent HIV transmission,\[225\] data show that more individuals are willing to get tested when anonymity of results is guaranteed,\[226\] and some states require that anonymous testing be available.\[227\] Anonymous testing is different from testing that is confidential: in the former, but not the latter, no record is kept that identifies the individual who has been tested, and people being tested generally are referred to by number, or allowed to use a fictitious name. North Carolina abandoned anonymous testing, with the result that all HIV test results in the state are reportable. This action was challenged in ACT-UP Triangle v. Commission for Health Services.\[228\] The North Carolina Supreme Court rejected ACT-UP’s argument that confidential (but non-anonymous) reporting of HIV test results violates federal constitutional privacy protections. The court noted that both civil and criminal penalties are applicable for violations of confidentiality standards pertaining to the information. It should be noted that while anonymous testing is, of course, substantially more protective of individual privacy—records that are confidential could be disclosed erroneously or through deliberate unlawful acts—data on HIV infections generated through anonymous tests are not considered by federal authorities, and generally not by state authorities, in allocations of public funds (including allocations to states and localities under the Ryan White program; see §2.03[A][1]).

Footnotes


See, e.g., Christine Vestal, How the ACA Will Affect People with HIV and AIDS, USA Today (Oct. 28, 2013), https://www.usatoday.com/story/news/nation/2013/10/28/how-the-aca-will-affect-people-with-hiv-and-aids/3285897/ (noting that many states assumed that the ACA would lead to a reduction in state funding for programs such as Ryan White, and some thought the program would no longer be necessary).


statute required states to adopt the Medicaid expansion, the U.S. Supreme Court ruled in 2012 that the law's mandatory Medicaid expansion was unconstitutional, and, rather than striking down the law in its entirety, ruled that the appropriate remedy was to render the expansion optional to the states. Nat'l Fed. of Indep. Bus. v. Sebelius, 567 U.S. 519 (2012).

Johnson & Heisler, supra note [62], at 18.

Id. at 16.

Id.

Id. at 19.

Id. at 16.


See, e.g., President's 2018 Budget Threatens Access to Care and Quality of Life for People Living with HIV, AIDS United (May 26, 2017), https://www.aidsunited.org/Blog/?id=3585.


See Jennifer Kates et al., Assessing the Impact of the Affordable Care Act on Health Insurance Coverage of People with HIV, Kaiser Family Found. Issue Brief (Jan. 7, 2014), http://www.kff.org/hivaids/issue-brief/assessing-the-impact-of-the-affordable-care-act-on-health-insurance-coverage-of-people-with-hiv/ (“There were an estimated 406,970 nonelderly adults (ages 19–64) with HIV in care in January to April 2009. Medicaid was the largest source of insurance coverage (41%, including those dually covered by Medicare), followed by private insurance (30%). A much smaller share were covered by Medicare alone (6%), and 17% were uninsured. The remaining 5% were covered by other public sources.”).


Id. See §2.03[A][1], above, for additional discussion of the interaction between the Ryan White HIV/AIDS Program and the ACA.


See ACA tit. I, subtit. A & C, amending Public Health Service Act §§2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), and 2719A (regarding patient protections).

ACA §1302(b), codified at 42 U.S.C. §18022(b).


See ACA §§1311 & 1321.

State Health Insurance Marketplace Types, 2019, Kaiser Family Found., http://www.kff.org/health-reform/state-indicator/state-health-insurance-marketplace-types/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.


ACA §1302(d), (e), codified at 42 U.S.C. §18022; 45 C.F.R. §§156.140, 156.155.

ACA §1302(d); 45 C.F.R. §156.140.

ACA §1302(e); 45 C.F.R. §156.155. These plans provide essential health benefits and at least three primary care visits, but do not cover other services until after the annual cost-sharing limit is reached.


42 U.S.C. §§18081, 18082. The Trump Administration ended federal payments to insurance companies to reimburse them for CSR costs in 2017. However, the subsidies have continued. Insurers generally have added CSR costs to premiums, which means that federal premium subsidies for the affected consumers have increased. Therefore, CSR subsidies have continued, and the federal government is still paying for them, albeit in a different way. See, e.g., Louise Norris, The ACA’s Cost-Sharing Subsidies, HEALTH INSURANCE (Sept. 23, 2019), https://www.healthinsurance.org/obamacare/the-acas-cost-sharing-subsidies.


Public Health Service Act §2711, as amended by ACA; 29 C.F.R. §2590.715 - 2711.


Id. at 12846; see also 45 C.F.R. §156.125.

78 Fed. Reg. at 12846.

45 C.F.R. §92.207(b)(2).

81 Fed. Reg. at 31434 n.258.


U.S. Dep’t of Health & Human Servs., Office for Civil Rights, Administrative Complaint, Discriminatory Pharmacy Benefits Design in Select Qualified Health Plans Offered in Florida (May 29, 2014).


New York v. United States HHS, 414 F. Supp. 3d 475 (S.D.N.Y. 2019), appeal filed, No. 20-15398 (9th Cir.).

City and Cnty. of San Francisco v. Azar, 411 F. Supp. 3d 1001 (N.D.C.A. 2019), appeal filed, Nos. 20-15398 et al. (9th Cir.).


City and Cnty. of San Francisco et al v. Azar et al., 9th Cir. No. 20-15398 et al.
129 State of New York et al. v. HHS, 2nd Cir. No. 19-4254 (L).
132 Texas v. United States, 945 F.3d 355 (5th Cir. 2019).
145 See Jean-Michel Molina et al., On Demand PrEP with Oral TDF-FTC in MSM: Results of the ANRS Ipergay Trial, Conference on Retroviruses and Opportunistic Infections (Feb. 23–24, 2015).


Joanna Theiss, It May Be Here to Stay, But Is It Working? The Implementation of the Affordable Care Act Through an Analysis of Coverage of HIV Treatment and Prevention, 12 J. Health & Biomedical L. 109, 119 (2016).

A recent study that estimates the financial barriers to PrEP is Dawn K. Smith et al., Estimated Coverage to Address Financial Barriers to HIV Preexposure Prophylaxis Among Persons with Indications for Its Use, United States, 2015, 75 J AIDS 465 (Dec. 15 2017), http://journals.lww.com/jaids/Abstract/publishahead/Estimated_coverage_to_address_financial_barriers.96860.aspx.


In 2017, UnitedHealthCare announced restrictions on approval of PrEP, including regular preauthorization requirements. Individuals reported that they had been denied coverage of PrEP because they had engaged in “high risk homosexual behavior.” In the wake of publicity and advocacy by advocates for HIV organizations, the insurer has announced that it is withdrawing its restrictions. See, e.g., Brooke Sopelsa, United Apologizes, Reverses Truvada Policy After HIV Activists Push Back, NBC News (Aug. 5, 2017), https://www.nbcnews.com/feature/nbc-out/united-apologizes-reverses-truvada-policy-after-hiv-activists-push-back-n789801.


Cal. Health & Safety Code (CHSC) §120990 (West). Previously, CHSC §120990 required medical providers to “advise the patient of the need for periodic retesting, explain the limitations of current testing technology and the current window period for verification of results” and added that providers also “may offer prevention counseling or a referral to prevention counseling.” AB2640 amended CHSC §120990 to include a requirement to provide pamphlets about the effectiveness and safety of PrEP.


A recent decision by the U.S. Supreme Court may complicate the picture for legislative or regulatory efforts to mandate providers to provide specified information on PrEP to patients. See §2.06[A] (discussing the implications of National Institute of Family & Life Advocates v. Becerra, 138 S. Ct. 2361 (2018)).


David Tellalian et al., *Pre-exposure prophylaxis (PrEP) for HIV infection: results of a survey of HIV healthcare providers evaluating their knowledge, attitudes, and prescribing practices*, 27 AIDS Patient Care STDS 553 (2013).

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45 C.F.R. §160.103.

42 C.F.R. §§164 et seq.


In addition, some HIV testing is conducted at sites that may not qualify as HIPAA “covered entities” and thus would not be subject to HIPAA's rules. Accordingly, state privacy laws remain important in protecting the confidentiality of HIV test results and other health information.


212 42 U.S.C. §§300ff-81 through 300ff-90.

213 See, e.g., In re Harry G., 599 N.Y.S.2d 425 (Broome County Family Ct. 1993) (N.Y. informed consent law interpreted to bar testing of alleged perpetrator in child sex abuse proceeding in which there was no allegation that the perpetrator had AIDS), *aff'd on other grounds sub nom.* In re WW, 611 N.Y.S.2d 47 (App. Div. 1994). Cf. People v. Durham, 553 N.Y.S.2d 944 (Sup. Ct. Queens County 1990) (granting request for HIV testing as constitutional in sexual assault case).


215 498 N.W.2d 370 (Wis. 1993).

216 498 N.W.2d 370, 373.

217 See *Occupational Exposure to Bloodborne Pathogens*, 56 Fed. Reg. 64,004, 64,102–03 (Dec. 6, 1991); 29 C.F.R. §1910.1030(b)(l) (2014) (including saliva in dental procedures among human body fluids posing a risk of HIV infection because of the fact that saliva during such procedures is routinely mixed with blood, but not otherwise including saliva as an “other potentially infectious material”).

218 Compare Faya v. Almaraz, 620 A.2d 327, 337 n.9 (Md. Ct. App. 1993) (quoting and relying on CDC standard that HIV antibody testing is reliable to detect HIV infection six months after infection). Means of detecting HIV infection much sooner after infection are discussed in *Chapter 1*.


220 410 Ill. Comp. Stat. 305/7(c).

As with other health measures, there are significant disparities in the prevalence, diagnosis, access to treatment, and prevention of HIV/AIDS for racial and ethnic minorities. Socioeconomic, geographic, and cultural factors may also influence an individual's willingness or ability to seek diagnosis and treatment, and to maintain consistent treatment. Federal and state public health authorities track specific statistics to identify the disparities and tailor initiatives and programs to reduce them.

The Centers for Disease Control and Prevention (CDC), for example, uses a number of different measures to track and report on these disparities. The CDC maintains a website devoted to consolidating statistics, resources, and publications on health disparities in HIV/AIDS and other serious public health diseases. In 2018, for example, the CDC estimated that while Black people represented 13 percent of the population, they represented 41 percent of all new HIV infections. The CDC also reports that, in 2018, of the 1.1 million people over the age of 13 living with HIV, over 480,000 were Black. Similarly, Latinx people represented around 18 percent of the population in 2018, but accounted for 23 percent of HIV diagnoses. There are also regional/
geographic disparities, with certain sources reflecting trends of southern states driving the epidemic within the United States. [231]

There are many federal and state initiatives designed to address HIV/AIDS health disparities. [232] At the federal level, the Secretary's Minority AIDS Initiative Fund (now called the Minority HIV/AIDS Fund) was established by Congress in 1999 in response to concerns about the disproportionate impact of HIV/AIDS on racial and ethnic minorities in the United States. [233] The funding is allocated to HHS to support a wide range of activities designed to reduce HIV-related health disparities in racial and ethnic minorities, including grants to community organizations, research institutions, and local health departments. HHS also operates a distinct unit within the agency, the Office of Minority Health (OMH), whose mission is to improve “the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities.” [234] The OMH is responsible for leading implementation of the HHS Action Plan to Reduce Racial and Ethnic Health Disparities, a component of which addresses disparities associated with HIV/AIDS.

In addition to federal initiatives, several states have established their own efforts to examine and address racial disparities in HIV/AIDS treatment and prevention. In Florida, for example, the Department of Health runs the Minority HIV/AIDS Initiatives to coordinate interventions, strategies, and other initiatives with community organizations and other state entities. [235]

Available data suggest that much more is needed for federal and state efforts to address HIV/AIDS health disparities for racial minorities. For example, in May 2019, the CDC reported that, while rates of HIV infection among all women have declined since 2010, rates among black women remain higher than those among white women, even though black women account for only 13 percent of the population. [236] That report found that, although from 2010–2016 the largest decrease in new infections among women were for black women at 21 percent, 60 percent of new HIV infections among women were black women, indicating persisting disparities. The report notes that, even though the declines in HIV infection rates among black women signal some progress toward reducing racial disparities, “[t]ailored strategies to reduce disparities in incidence among women should address social and structural determinants, including inequitable access to health care, HIV-related stigma, and comparatively high background prevalence of certain sexually transmitted infections, that increase the risk for HIV infection among black women.”

Footnotes


232 For a list of federal initiatives to address racial and ethnic disparities in healthcare, some of which specifically address disparities associated with HIV/AIDS detection and treatment, see Inst. of Medicine, Comm. on Understanding Racial and Ethnic Disparities in Health Care, Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care, App. C (Brian D. Smedley, Adrienne Y. Stith, and Alan R. Nelson eds., 2003), https://www.ncbi.nlm.nih.gov/books/NBK220338/.


With respect to prevention efforts, criminal enforcement of the law is often mislabeled as a public health strategy when it intersects with health status. Criminalization of acts that could transmit HIV, for example, is a tactic the majority of states adopted when incidence of HIV was increasing most rapidly; nearly two-thirds of all state laws criminalizing HIV transmission (or acts that may risk HIV transmission) were passed between 1986 and 1995. Although the enactment of new laws targeting the transmission of HIV has declined since that time, and some states have repealed previously enacted HIV-specific laws, more than 30 states still have HIV-specific criminal statutes on the books as of July 2017. This criminalization tactic is not evidence based and in fact is not supported by health advocates. Because it is frequently labeled as a prevention tactic, however, it merits discussion here.

In the 1980s and 1990s, many states amended their criminal codes to explicitly criminalize intentional transmission of HIV (rather than rely on existing crimes, such as assault) in the wake of publicity around a few notorious incidents—for example, an instance in which a New York man knowingly infected 13 women in a series of rapes. That case, however, illustrates why criminal codes need not explicitly ban intentional transmission of HIV to make such activity punishable; he was sentenced for up to 12 years for rape and reckless endangerment. The consequences of explicitly criminalizing acts that risk HIV transmission are grave. For example, an Iowa statute prohibiting transmission was used to sentence a man to 25 years in prison and a lifetime registration as a sex offender after he was convicted of attempted transmission, even though the defendant both used a condom and had an undetectable viral load at the time of the encounter, and his sexual partner did not become infected. His sentence was overturned on appeal the same year in which Iowa became the first state to substantially amend its criminal HIV transmission law. Moreover, HIV-specific criminal exposure laws are disproportionately enforced against marginalized communities. For instance, a recent study by the Williams Institute at UCLA Law School of California's HIV-specific criminal laws found:

- the overwhelming majority of enforcement actions (95 percent) were against persons who had engaged in sex work or were suspected of sex work;
- two-thirds of enforcement actions targeted Black and Latino/a persons, although only one-half of persons with HIV/AIDS in California were Black or Latino/a; and
- 43 percent of enforcement actions targeted women, although they constituted only 13 percent of Californians living with HIV.
While most agree that intentional transmission of HIV should be a punishable offense, public health professionals argue that singling out sexual acts by people who know they have HIV in criminal statutes further stigmatizes the disease and may even deter individuals from seeking testing (because intentional transmission requires knowledge that one is HIV positive). Moreover, HIV-specific statutes often criminalize more than intentional transmission; many criminalize conduct without specific intent to transmit, without gradation for the severity of the risk of transmission, and without considering the use of effective preventative measures (e.g., condoms and PrEP). For example, in Mississippi, state law prohibits the exchange of any bodily fluids, even those that do not transmit HIV, such as saliva and feces. Florida's laws categorically prohibit HIV-positive individuals from having sex unless the other individual receives informed consent from the sexual partner (even if the individual is also HIV-positive).

For these reasons, a number of public health professionals have questioned such laws' connection to, or ability to advance, public health objectives. Because the criminal code allows for prosecution of truly intentional transmission without specific mention of HIV, criminalization is both unnecessary and counterproductive to the goal of prevention. Recently, the consensus among researchers and public health officials that antiretroviral treatment leading to viral suppression is perhaps the single most effective tool for preventing new transmissions has led a number of national and international experts to declare that the criminal law is an impediment to efforts to end the epidemic.

Potential conflict of public health and criminal law approaches: Molecular HIV Surveillance and Recency Testing as HIV prevention tools or as evidence of crime? As discussed in §2.03[C], an HIV prevention strategy that is receiving increasing attention at the CDC and in many state public health agencies is the genetic sequencing of HIV taken from recently diagnosed patients to identify “clusters” of genetically similar virus that indicate recent HIV outbreaks. There is a growing concern among advocates for people living with HIV and many public health professionals and medical providers that such information could be misused by prosecutors and misunderstood by judges and juries to implicate individuals in criminal HIV exposure or transmission cases. See §2.03[C] for more discussion.

PrEP and viral suppression due to successful antiretroviral treatment as potential defenses. Certain state laws provide for potential defenses to criminal liability for sexual acts by an individual who knows they are HIV positive. For instance, if such an individual takes measures that they believe, with good reason, eliminate the risk of transmission to the other person—for instance, by using a condom—then they would appear to lack the intent to transmit the virus. What if the accused HIV-positive individual had been informed by their medical provider that they were virally suppressed and, therefore, that the likelihood that they could transmit the virus to a sex partner was extremely low if not zero (see Section 2.03 of this chapter and Chapter 1)? Or what if the accused HIV-positive individual had been informed that their sex partner was on PrEP and, therefore, was protected from infection? Although such defenses have not, to date, been used successfully, they potentially could be interpreted to vitiate criminal liability, depending on specific statutory language. The following is an overview of certain defenses and a discussion of whether such defenses potentially could be interpreted or expanded to include the use of PrEP or viral suppression due to successful antiretroviral treatment.

Under some states’ laws, an HIV-positive individual can be liable only if the person has the intent to transmit the virus to the HIV-negative partner. One state with such laws is California. In 2017, that state amended its laws to provide that an HIV-positive individual can only be found liable if they “specifically intend” to transmit HIV to another person through engaging in “conduct that poses a substantial risk of transmission.” The statute defines conduct that poses a substantial risk of transmission as “an activity that has a reasonable probability of disease transmission as proven by competent medical or epidemiological evidence,” and expressly adds that “[c]onduct posing a low or negligible risk of transmission as proven by competent medical or epidemiological evidence does not meet the definition of conduct posing a substantial risk of transmission.”
The California law expressly allows an individual to negate intent by demonstrating that the HIV-positive individual took “practical means to prevent transmission.” Under the law, “practical means to prevent transmission” is defined as “a method, device, behavior, or activity demonstrated scientifically to measurably limit or reduce the risk of transmission of an infectious or communicable disease, including, but not limited to, the use of a condom, barrier protection or prophylactic device, or good faith compliance with a medical treatment regimen for the infectious or communicable disease prescribed by a health officer or physician.”

Iowa law similarly allows an individual to negate intent by demonstrating that the HIV-positive individual took “practical means to prevent transmission, or if the person informs the uninfected person that the person has a contagious or infectious disease and offers to take practical means to prevent transmission but that offer is rejected by the uninfected person subsequently exposed to the infectious or contagious disease.”

North Carolina recently amended its public health regulations to provide explicit exemptions from criminal liability for non-coercive sex, and for not disclosing HIV status to a sex partner, when the individual living with HIV is virally suppressed or when the sex partner is on PrEP:

(1) Persons diagnosed with HIV infection (hereafter “person living with HIV”) shall:

(a) refrain from sexual intercourse unless condoms are used except when:

(i) the person living with HIV is in HIV care, is adherent with the treatment plan of the attending physician, and has been virally suppressed for at least 6 months (HIV levels below 200 copies per milliliter) at the time of sexual intercourse;

(ii) the sexual intercourse partner is HIV positive;

(iii) the sexual intercourse partner is taking HIV Pre-Exposure Prophylaxis (PrEP)—antiretroviral medication used to prevent HIV infection as directed by an attending physician;....

(b) notify future sexual intercourse partners of the infection, unless the person living with HIV meets the criteria listed in Sub-item (1)(a)(i) of this Rule.

To date, California, Iowa, and North Carolina are the only states that have enacted legislation or public health regulations with specific and expressly stated language of this kind that can negate an individual’s intent under a criminal statute relating to HIV transmission on these bases. It is unclear whether other state criminal laws relating to HIV transmission would allow for defenses to the “intent” requirement under such laws based on the use of PrEP by the defendant's sexual partner or viral suppression/undetectability in the defendant due to the use of antiretroviral treatment. Given the demonstrated efficacy of PrEP, and antiretroviral treatment (accompanied with a health care provider's opinion that the individual is virally suppressed), courts and juries potentially could find (even without express language in the laws themselves) that an individual could not have had the intent to transmit the virus if the individual had knowledge of the partner's use of PrEP or if the individual believed their viral load to be suppressed or undetectable based on their health care provider's opinion or other information from their health care provider. Whether PrEP or the belief—or specific medical information reflecting—that an individual is virally suppressed/undetectable could preclude a finding of intent has yet to be tested in the courts.

Some states do not expressly specify a requisite level of intent in their HIV criminalization statutes, but do provide for affirmative defenses that potentially could be interpreted to provide for a PrEP or viral suppression defense. Two states' laws in particular—Minnesota and Nevada—potentially could allow for such an interpretation.

The Minnesota law provides for an affirmative defense if the HIV-positive individual “took practical means to prevent transmission as advised by a physician or other health professional.” Although “practical means” is not defined in the law, it is arguable that PrEP and/or other antiretroviral treatment could qualify.
However, whether the court or a jury would extend the defense to PrEP or antiretroviral treatment has yet to be determined.

Nevada’s statute criminalizes conduct that is “likely to transmit the disease to another person.” [258] Given that PrEP and antiretroviral treatment significantly reduce the likelihood of transmitting HIV when used in accordance with the prescribed regimen, a court or jury may find that an HIV-positive person does not engage in conduct “likely to transmit” HIV if the HIV-negative partner is on PrEP or the HIV-positive partner is on antiretroviral treatment. However, this interpretation likewise has yet to be tested.

Although other states may provide for additional iterations of potential defenses to criminal liability, it is unlikely that certain of these defenses provisions could be interpreted to include the use of PrEP or antiretroviral treatment. For example, Indiana's statute prohibits the exchange of bodily fluids. [259] Under the statute, using condoms would operate as an implicit defense because condoms prevent the exchange of bodily fluids. However, the use of PrEP or antiretroviral treatment would not satisfy this defense because PrEP or antiretroviral treatment does not prevent the exchange of bodily fluids. This likely is an area where case law will continue to develop.

Footnotes

237 For a survey of criminalized offenses specific to HIV, see Chapter 7, §7.03[H]. See also §2.05 for a discussion of potential application of HIV-specific criminalization laws and defenses in the context of pre-exposure prophylaxis (PrEP) treatment.

238 See HIV Laws That Address High-Impact HIV Prevention Efforts, CDC (July 18, 2019), https://www.cdc.gov/hiv/policies/law/statestates/; State-by-State Chart of HIV-Specific Laws and Prosecutorial Tools, Center for HIV Law & Policy (June 2020), http://www.hivlawandpolicy.org/sites/default/files/U.S.%20HIV%20Laws%20and%20Prosecutorial%20Tools%20%2C%20CHLP%20%282020%29_0.pdf; see also J. Stan Lehman et al., Prevalence and Public Health Implications of State Laws that Criminalize Potential HIV Exposure in the United States, 18 AIDS and Behav. 997 (2014) (discussing an analysis by CDC and Department of Justice researchers, which found that, by 2011, a total of 67 laws explicitly focused on persons living with HIV had been enacted in 33 states); id. (finding that HIV-specific laws vary as to which particular behaviors are prohibited or result in additional penalties—for example, in 24 states, laws require persons who are aware that they have HIV to disclose their status to sexual partners, and in 14 states, laws require such disclosure to needle-sharing partners).


239 See, e.g., Patricia Sweeney et al., Association of HIV Diagnosis Rates And Laws Criminalizing HIV Exposure in the United States, 31 AIDS 1483, 1486 (2017) (finding “no association between diagnosis rates and state criminal exposure laws”).


242 See Iowa Code §709C, repealed and replaced with Iowa Code §709D (a less strict criminal statute that includes other infectious diseases).


Recently, an individual challenged Ohio's HIV criminal law, which prohibits an HIV-positive individual with knowledge of their status from engaging in sexual conduct without disclosing their HIV status to the other person prior to engaging in the sexual conduct. The individual who challenged the Ohio law alleged that the provision violates the First Amendment of the U.S. Constitution and the Equal Protection Clause of the Fourteenth Amendment. The case was appealed to the Ohio Supreme Court, which upheld the Ohio law in October 2017. Specifically, the Ohio Supreme Court held that the statute does not violate the First Amendment, because it regulates conduct and not speech, and further found that the statute did not violate the Equal Protection Clause of the Fourteenth Amendment, because the state had a legitimate interest in preventing the transmission of HIV. See State v. Batista, No. 2016-0903, 2017 WL 4838768 (Ohio Oct. 26, 2017), http://www.supremecourt.ohio.gov/rod/docs/pdf/0/2017/2017-Ohio-8304.pdf.

For a discussion of prosecutions under nonspecific criminal statutes (i.e., general criminal laws not specific to HIV), such as those for assault, see Chapter 7, §7.03[B].

It should be noted that not all HIV advocates are in agreement as to whether legislation should be adopted, or other efforts pursued, to include defenses expressly based on the use of PrEP or use of antiretroviral treatment that results in a suppressed or undetectable viral load. Some advocates worry that a legislative strategy along these lines could exacerbate the health disparities and inequities currently present in the healthcare and criminal justice systems; in particular, inequities experienced with respect to access to treatments such as PrEP or antiretrovirals care and/or inequities in access to justice based on race and socioeconomic status. Because disparities exist in access to treatment (see Section 2.04 of this chapter), some advocates fear that defenses expressly based on the use of PrEP or viral suppression based on effective antiretroviral treatment potentially could exacerbate existing healthcare disparities and extend such disparities into the criminal prosecution context. The Center for HIV Law and Policy has issued a “Consensus Statement on HIV ‘Treatment as Prevention’ in Criminal Law Reform” related to this issue and the potential concerns that some advocates have raised. For more information, see Consensus Statement on HIV “Treatment as Prevention” in Criminal Law Reform, (July 13, 2017), https://www.hivtaspcrimlaw.org/the-consensus-statement.

AIDS and the Law - Skinner-Thompson, §2.06, INFORMATION ACCESS, CENSORSHIP, AND EDUCATION


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Education and prevention efforts in response to the HIV epidemic have been subject to control, censorship, and manipulation, largely as a result of conflicting political or ideological agendas. Educational efforts have necessarily introduced topics of a traditionally sensitive or private nature into public discourse, including issues concerning human sexuality (specifically, homosexuality and bisexuality, as well as adolescent sexuality) and illicit drug use. Despite some attempts to control or direct public discourse away from these important issues, it is fair to say that the epidemic has forced a significant change in what is acceptable in public discussion.

In HIV/AIDS education, the potentially controversial contents of the message on religious, moral, or political grounds is compounded by the fact that underlying scientific issues are often disputed, even where there is no reasonable ground for dispute. Thus, for example, recommending use of condoms as a means of preventing HIV transmission may be unacceptable to some on either a moral basis or as scientifically unsound, despite strong scientific evidence that condoms are effective in preventing HIV transmission. [260]

[A] Access to Information and Censorship

Attempts to ideologically influence and restrict public HIV education and dissemination of AIDS information have taken many forms and have occurred repeatedly. [261] In *Hummer v. Evans*, [262] for instance, a public school AIDS educator successfully challenged the termination of her contract, based on her advocacy for a prison inmate with HIV, as a violation of public policy. In July 2017, the Trump Administration slashed $213.6 million funding from a series of Obama-era grants to the Teen Pregnancy Prevention Program (TPPP), a program intended to reduce teen pregnancies, sexually transmitted infections, or other associated sexual risk behaviors. [263] Furthermore, a series of changes within the Trump Administration threatens the future of federal sex education programs. On April 20, 2018, the Administration announced it would overhaul the TPPP to more abstinence-focused programming. [264] Finally, according to a March 22, 2019 letter from Secretary Alex Azar, HHS plans to restructure the department to put Title X federal family planning and TPPP under the Office of Population Affairs headed by Diane Foley, who is known for her anti-choice and abstinence only advocacy. [265]

Federal HIV education efforts have been subject to congressional or administrative restrictions that often are not consistent with effective education. [266] Although there may be no legally recognized right to receive information or education on health issues, such as HIV transmission, from the government, in reality, governmental public health agencies are frequently the primary, if not exclusive, source of information. If those agencies do not directly undertake education efforts, they are frequently undertaken by nongovernmental agencies with government funds and the conditions attached to receipt of such funds. In that regard, Congress has specified that federally sponsored programs of education and information on AIDS “shall include information about the harmful effects of promiscuous sexual activity and intravenous substance abuse, and the benefits of abstaining
Moreover, federal funds may not be used to provide education and information "designed to promote or encourage, directly, homosexual or heterosexual sexual activity or intravenous substance abuse." Nonetheless, this limitation is not to be read to restrict the ability of an education program to provide "accurate information about various means to reduce an individual's risk of exposure" to HIV.

Congress has legislated that federally funded HIV/AIDS informational materials may not be obscene. Historical attempts by the CDC to administratively prohibit "offensive" terms or displays in federally funded HIV/AIDS education materials, however, were rejected as unconstitutionally vague and beyond the CDC's statutory authority in *Gay Men's Health Crisis v. Sullivan*. The CDC's standards were intended to screen out HIV/AIDS materials that might be offensive to a majority of the intended audience or to a majority of the adults outside the intended audience, unless the "potential offensiveness of such materials is outweighed by the potential effectiveness in communicating an important HIV prevention message."

The First Amendment has been used to ensure access to information in the interest of public health. For example, an AIDS advocacy organization successfully challenged the Massachusetts state transit authority's refusal to place advertisements for condoms in trolley cars, on the basis that the agency's decision constituted viewpoint discrimination against the content of the advertisements. Similarly, an Alabama statute was struck down for unconstitutionally infringing on freedom of speech by prohibiting state universities from funding any organization that "fosters or promotes a lifestyle or actions prohibited by the sodomy and sexual misconduct laws," including oral or anal sex between unmarried individuals. This law had been the basis for denial of funding to the Gay Lesbian and Bisexual Alliance, a student group at the University of Southern Alabama, including a request for funding to purchase World AIDS Day posters.

In other contexts, especially where younger students are involved, however, the First Amendment has not always trumped a school's decision to prohibit student organizations from using school grounds to promote HIV educational materials. For example, a Texas high school's refusal to allow a student group entitled the Lubbock Gay-Straight Alliance to meet on school grounds or to distribute flyers that included prevention messages survived First Amendment and equal protection challenges. The flyers directed students to websites that included information on the risk of transmission associated with oral sex, and guidance on how to use a condom and initiate safe-sex conversations, all of which the school (and court) deemed "obscene, indecent, and lewd" and contrary to the school's abstinence-only curriculum.

The First Amendment and government efforts to ensure that health care providers provide accurate information to patients. A recent decision by the U.S. Supreme Court may complicate legislative or regulatory efforts to mandate providers to provide accurate HIV-related information to patients. In *National Institute of Family & Life Advocates v. Becerra*, the Court ruled that two California laws violated the First Amendment: a law requiring certain licensed "pregnancy crisis centers" (religiously based and anti-abortion) to provide standardized, written information to patients about the availability of low-cost or no-cost abortions in California; and a law requiring unlicensed "pregnancy crisis centers" to provide written disclosures to patients that they are not licensed to provide medical services. The majority concluded that the laws in question were motivated by a "pro-choice" agenda—targeting entities and services providers who are opposed to abortion and requiring them to "speak" in ways that contradicted their beliefs and/or undermined their credibility. However, some of the majority opinion's language is quite broad and might be used by opponents of any law requiring healthcare providers to provide virtually any specified information to patients.

[B] Internet Information Control

The Internet has played a significant role in current HIV/AIDS education efforts and will continue to do so into the future. Educational information can be provided or obtained in private, and, if they so choose, the recipients may even remain anonymous. To the extent that Internet services are available from commercial service providers, educational institutions, or governmental organizations, political and geographical boundaries are not a barrier.
to the dissemination of information, even on a worldwide basis. Information can be made available in areas where it would not otherwise be available locally. For many users, both those who distribute information and those who receive it, the direct cost is insignificant, particularly in comparison to publication or retrieval of information in other media. New information can be made available far more quickly than by more traditional means. Furthermore, advocates for Internet HIV/AIDS education activities point out that the interactive nature of the medium enhances the value of the Internet for HIV/AIDS education, providing opportunities for debate about issues not available in other media, particularly in terms that would not be acceptable in many other forums. Legislative attempts to regulate the availability of information on the Internet, primarily to protect minors from exposure to sexually explicit materials, have resulted in several cases involving rulings relevant to Internet HIV/AIDS education efforts.

The discussion of AIDS prevention issues, particularly on the Internet, opens scientific discourse to a broad public, ranging from professional scientific researchers and scholars to AIDS activists to persons whose interest is only casual. Like the sexual content in safe-sex messages or other materials made available in other contexts ranging from school curricula to mass-transit bus advertisements, the character of the information is fairly considered scientific. For example, the identification of sexual behaviors that are believed by medical experts to transmit or prevent transmission of HIV is a science-based message. However, to be understood and accepted, that essentially scientific message may be expressed in language that some persons may find to be patently offensive.

The recent advent of geosocial network dating applications (or apps) which cater to the LGBTQ community has also generated new opportunities to promote HIV/AIDS education. These apps use geographic triangulation technology to produce potential nearby matches. Individuals may use the applications for what would traditionally be defined as dates, or may use them to seek sexual activity. One of the most prominent LGBTQ-oriented dating applications is Grindr. Other dating applications such as Tinder are widely used by both the heterosexual and the LGBTQ community. According to Tinder, 10 million people use the app daily. [277]

In some cases, certain researchers have reported a correlation between the proliferation and widespread use of these dating applications and the rise of STI rates in the United States. [278] Seeking to address this concern, some applications have participated in or developed their own educational campaigns to inform their users of the risks of unprotected sexual intercourse, and ways to prevent and treat STIs such as HIV. For example, upon opening the Grindr application, a user may receive a pop-up message informing the user about PrEP, where and how it can be obtained, and where the user can find more information about the HIV prevention method. [279] Grindr users can also signal that they use PrEP by stating that they are explicitly on the medication or by sharing a blue pill emoji with other users. [280] It is also possible for app users to explicitly indicate their HIV status.

Not only have dating applications like Grindr been engaged in HIV awareness and treatment campaigns, but they have also partnered with the CDC and with AIDS foundations to help provide access to testing to sexual health resources. [281] Dating applications, like Grindr, Tinder, and others, may play an increasingly important role in HIV/AIDS treatment and prevention education moving forward.

Despite the potential benefits of geosocial applications for enhancing awareness, treatment, and prevention of HIV/AIDS and other STDs, they can also pose a threat to the privacy of LGBTQ people. For example, data breaches pose a threat to all users, and LGBTQ people living in countries where homosexuality is condemned risk being outed and persecuted by the ability of anti-LGBTQ organizations to manipulate the geographic triangulation capability of these applications. [282] Recent reports from the United States also indicate that applications such as Grindr have allegedly been used by some to lure unsuspecting LGBTQ people into traps, where they are assaulted. [283] Thus, it is important to bear in mind that while these applications may benefit the LGBTQ community by helping connect and educate those who use the apps, they can also be employed to endanger user privacy, safety, and well-being.

[C] Communications Decency Act of 1996
Legislation enacted by Congress in 1996 attempted to prohibit the availability of “indecent” and “sexually explicit” information or materials on the Internet to persons under the age of 18. The Communications Decency Act of 1996 (CDA), included as a provision in the Telecommunications Act of 1996, was intended to prevent minors from being exposed to pornography. Numerous plaintiffs, including the American Civil Liberties Union, Internet service providers, news organizations, software manufacturers, public interest groups, and individual users, including AIDS information providers, challenged the CDA.

In *Reno v. American Civil Liberties Union*, the Supreme Court struck down the CDA as unconstitutional. The Court noted several examples of HIV/AIDS information on the Internet as relevant to its decision—“AIDS prevention” as a topic discussed in one of the thousands of Internet newsgroups; “safer sex instructions that Critical Path posts to its website, written in street language so that the teenage receiver can understand them, are available not just in Philadelphia, but also in Provo and Prague” as an example of the ways that information providers cannot control the dissemination of information posted at websites—and noted that the Critical Path AIDS Project, an educational organization that maintains an Internet website, as well as other organizations “regard[s] charging listeners to access their speech as contrary to their goals of making their materials available to a wide audience free of charge” and is thus antithetical to verifying the age of users by requiring credit cards or similar means. Although the court noted the vagueness of the CDA's terms “indecent” and “patently offensive,” which it deemed relevant to the issue of the statute's over breadth, the Court did not base its ruling specifically on the CDA's vagueness. Instead, the court concluded that the anti-indecency provision of the CDA “effectively suppresses a large amount of speech that adults have a constitutional right to receive and to address to one another.” Subsequent and much narrower legislation, the Children's Internet Protection Act, which requires libraries and K-12 schools to protect children from harmful online content as a condition of federal funding, was upheld as constitutional by the Supreme Court.

**[D] School-Based HIV/AIDS Education and Prevention Programs**

HIV/AIDS school education programs have been particularly controversial in some areas of the country. Frequently, conflicts have arisen regarding the content of such programs in specific regard to whether sexual abstinence should be the exclusive educational message, or whether adolescents should learn about the risks of HIV infection and means by which to reduce risk of transmission, as part of sexual education modules. The evidence squarely points to the efficacy of the latter approach; abstinence-based programs are not effective at reducing teen pregnancy or high-risk behavior.

School policies and programs are traditionally left to the states and local school boards, although federal funds often are attached to restrictions on curricula development.

In the early days of the HIV epidemic, the CDC issued guidelines in 1988 that emphasized that school programs should provide education that enables and encourages young people to abstain from sex “until they are ready to establish a mutually monogamous relationship within the context of marriage.” However, the CDC also recommended that school systems, in consultation with parents and health officials, should provide AIDS education programs that address preventive types of behavior, including the use of latex condoms, although the CDC stopped short of suggesting that condoms be made available to students. The National Commission on AIDS recommended that “[c]omprehensive HIV prevention should include information, exploration of values and attitudes, skill building, and access to health care and social services, including condom availability.” Also, the commission noted that both abstinence messages and skills building about other means of reducing risk of HIV transmission, such as use of condoms, should be included.

Nonetheless, the federal government has funded abstinence-only education programs for many years, and requirements that states use funding for such education were strengthened with respect to HIV/AIDS education in the George W. Bush Administration, even though the Government Accountability Office issued a formal report...
stating that such curricula provided students with incomplete and inaccurate information. A critical review of the federal abstinence-only-until-marriage funding program concluded that these programs deny children basic information that could protect them from HIV infection and discriminate against gay and lesbian children, thus interfering with fundamental rights to information, health, and equal protection under the law.

Today, HHS offers a menu of various evidence-based sex education programs, some of which are exclusively abstinence based. To date, however, there has been little new funding streams or other real-world mechanisms for implementing comprehensive curricula that includes all forms of risk reduction available to sexually active adolescents. The Patient Protection and Affordable Care Act, enacted in 2010, created the Personal Responsibility Education Program, which is defined, in part, as a program that is designed to "educate adolescents on…both abstinence and contraception for the prevention of pregnancy and sexually transmitted infections, including HIV/AIDS." Such federally funded programs must be evidence-based, medically accurate, effective programs or must substantially incorporate elements of effective programs that have been proven on the basis of rigorous scientific research to change behavior to delay sexual activity and increase condom or contraceptive use for sexually active youth. Federal legislation that would support more Comprehensive Sex Education has been introduced into Congress the past few years, but has yet to be enacted.

At the state level, most mandate some form of HIV education in public schools, but very few require that school systems ensure that curricula are medically accurate. As of June 2020, only 28 states and Washington, D.C. mandate both sex education and HIV education. States such as California have adopted legislation mandating AIDS education for junior and senior high schools but do not include distribution of condoms as part of the program. Parents have in some instances successfully challenged policies that make sexual education that includes HIV/AIDS education a mandatory component of a child's curriculum. In one case alleging that New York State could not require children to participate in education about HIV/AIDS, the state was unsuccessful in defending its curriculum on the basis of the importance of education to the public's health. Other challenges that have been brought to enjoin schools from exposing children to "pro-gay" content have squarely failed as being based in nothing more than "highly speculative and attenuated" theories.

Footnotes


Other sexual intercourse-oriented applications for gay and bisexual men, such as Scruff, have also adopted similar efforts. See Christina J. Sun et al., Acceptability And Feasibility of Using Established Geosocial and Sexual Networking Mobile Applications to Promote HIV And STD Testing Among Men Who Have Sex with Men, 19 AIDS Behav. 543 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4359067/.


287 521 U.S. 844, 851.

288 521 U.S. 844, 854 (footnote omitted).

289 521 U.S. 844, 857 n.23.

290 521 U.S. 844, 874.


292 For more information about such programs, see SEICUS SexEdLibrary, http://www.sexedlibrary.org.


Harm reduction strategies are those that reduce negative consequences of illicit or high-risk behavior (e.g., intravenous drug use, sex work). These strategies are often controversial because they can be construed (often erroneously) as endorsing or even promoting the activity rather than seeking to eliminate the harm altogether. However, these strategies are critical to HIV prevention if one assumes that these behaviors can never be eliminated and would otherwise result in very high rates of transmission. Three examples include targeted outreach to sex workers, syringe exchanges for intravenous drug users, and school-based condom distribution programs.

[A] Sex Work

Individuals who engage in sex work are at extremely high risk for infection with HIV, and they can pass on HIV to a multitude of customers, making channels of sex work appear as hot spots of rising incidence. Harm reduction strategies seek to educate sex workers on the risks associated with HIV, and equip them to engage in risk reduction (e.g., condoms, PrEP, frequent testing). Because prostitution is illegal in the United States and in many countries in which HIV incidence has been rapidly increasing, groups seeking to engage sex workers in harm reduction strategies must overcome barriers associated with the fear of prosecution, stigma, and harassment that make sex workers less likely to access medical attention and social services.

There is a consensus among public health authorities that criminalization of consensual, adult sex work, and the attendant police practices are barriers to HIV prevention and treatment. The criminal justice system exacerbates stigma and marginalization of sex workers and discourages HIV testing, engagement in care, and prevention. Decriminalization of sex work would likely result in lower HIV infection rates—as well as better health and well-being for sex workers who are HIV positive. In early 2018, the U.S. Court of Appeals for the Ninth Circuit upheld California’s laws criminalizing sex work against a constitutional challenge. In addition to challenges in the courts, efforts at legislative reform on the state and local level may be assisted by a recent policy brief in favor of decriminalization by Amnesty International, together with extensive supporting research on the experience in other countries. A bill to repeal all D.C. laws criminalizing consensual sex work involving legal adults was introduced in the District of Columbia Council in 2019. A hearing was held on the bill in October 2019 and generated considerable support for and opposition to the bill, and decriminalization of sex work generally. As a result, Council members announced that the bill would not move forward. However, advocates for sex workers potentially face a new challenge with the enactment in early 2018 of the Allow States and Victims to Fight Online Sex Trafficking Act (FOSTA). The law creates and expands criminal and civil liability for online platforms and their owners, managers and operators, and online speakers, who directly or indirectly promote, facilitate, or assist in prostitution or sex trafficking. While well-intentioned, the law threatens to reach not only those who are involved in non-consensual or coercive sex trafficking, but individuals engaged in consensual sex work through online platforms (which generally are much safer than street work) and those who assist them (for instance, by providing information and resources to help make sex work...
A lawsuit challenging FOSTA in U.S. District Court for the District of Columbia was dismissed for lack on standing on September 24, 2018. However, on January 24, 2020, the U.S. Court of Appeals for the D.C. Circuit reversed the lower court ruling and found the plaintiffs established their Article III standing.

In 2003, Congress enacted the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act, providing substantial funding to nongovernmental organizations working to stem HIV transmission around the world. The Act required all recipients of funds to actively denounce prostitution and sex trafficking, including by posting a statement on any organizational website. Public health professionals working in these organizations challenged this provision, arguing that it undermined their ability to engage in harm reduction with high-risk sex workers, and further, taking such an anti-sex work position could antagonize local governments. While the organizations could have structurally split to take advantage of the funds while not changing their core policies, they did not want to take anti-sex work positions that undermined their core beliefs. In 2013, the U.S. Supreme Court struck down this funding restriction on First Amendment grounds, finding that the government could not require agencies to adopt and actively promote its beliefs with respect to sex work. However, in June 2020 the Court ruled that the government could enforce the funding restriction against the foreign affiliates of the same U.S.-based NGOs consistent with the First Amendment.

[B] Syringe Exchanges

Sharing “injection drug equipment” (e.g., syringes and needles) has been recognized since the beginning of the HIV epidemic as a significant source of HIV transmission routes. According to the CDC, in 2015, 6 percent of the diagnoses of HIV in the United States were attributable to injection drug use, and an additional 3 percent were attributable to male-to-male sexual contact and injection drug use. This represents a decline in HIV cases attributable to injection drug use; annual HIV diagnoses among people who inject drugs decreased by 48 percent overall from 2008 to 2014. However, transmission by injection drug use remains a significant problem; at the end of 2013, an estimated 103,100 men and 68,200 women were living with HIV attributed to injection drug use.

To address the problem of HIV transmission through injection drug use, the National Commission on AIDS (subsequently replaced by the Presidential Advisory Council on HIV/AIDS) long ago recommended not only the removal of legal barriers to the “purchase and possession of injection equipment,” but also the overall expansion of drug treatment programs. The National Commission on AIDS focused federal leadership to address the issues of drug use and HIV and increased funding of research and epidemiological studies of drug use and HIV transmission. The National Commission on AIDS urged all levels of government and the private sector to mount “a serious and sustained attack on the social problems that promote licit and illicit drug use in American society.”

The National Commission on AIDS’ early efforts spawned programs that today advocate for and provide sterile needles or syringes (both activities are referred to here as syringe access). Typically, in the setting of syringe-exchange programs, the intravenous drug user is required to return a used syringe or needle in order to obtain a sterile one. As rates of transmission via injection drug use spiked in the 1990s, the number of syringe access programs grew rapidly, growing incrementally thereafter. As of 2017, the North American Syringe Exchange Network reported that 264 syringe-exchange programs existed in 35 U.S. states.

Syringe-exchange programs provide several benefits to the public. First, syringe-exchange programs are associated with a reduction in HIV prevalence and incidence rates. Second, syringe-exchange programs are far less costly than the cost of treating a person once he or she is infected with HIV. Finally, syringe-exchange programs frequently provide one of the few effective means of public health outreach to intravenous drug users, and these programs can serve as a means of getting addicted drug users into treatment programs. New York State's syringe-exchange program serves as a prime example of these benefits. A large number of intravenous drug users have participated in the program (171,582 from 1992 to 2013), demonstrated...
positive changes in behavior (e.g., reduced sharing of needles, no increase in drug use), and received referrals
to other service programs (such as HIV test sites and drug treatment programs). Those who participated in
the program had a 1.6 percent rate of HIV seroconversion per year, compared to 4.7 to 7.2 percent for high-
frequency injectors not in syringe-exchange programs. [328]

However, syringe-exchange programs have been questioned on several grounds. [329] First, insofar as the
programs are viewed as receiving the government's endorsement, they appear to officially condone illicit drug
use, and they may even encourage an increase in illicit drug use, contrary to the government's commitment
against such activities. Second, given the limitations on resources, syringe-exchange funding is questioned
because that funding could go directly to rehabilitation programs or other services. Finally, syringe-exchange
programs are viewed by some as bringing criminal law standards into contempt, insofar as federal or state laws
are viewed as criminalizing the activities of such programs.

Further, political and financial support for syringe access programs is generally low. Although the National
Research Council recommended in the 1990s that the surgeon general certifies that federal funds be made
available to support syringe-exchange programs, [330] federal officials took no action to make federal funds
available for syringe-exchange programs. The federal government instituted a ban on federal funding for syringe
access programs under the Ryan White CARE Act of 1990. [331] The ban was in place until 2009, was reinstated
in 2011, and was partially lifted once again in 2016. [332]

Not only is federal funding for syringe access programs sparse, but the legal framework surrounding the
access programs is complex. The sale of sterile needles or syringes is criminalized under federal law, though
exemptions are available for those authorized by State law. [333] State legislatures and public health officials
have responded to the issue of needle exchange in a number of ways. Some programs function legally without
explicit authorization, based on interpretations of state or local public health laws. [334] Other programs operate in
the over 20 states that have explicitly legalized needle-exchange programs. [335]

Numerous states prohibit the possession of drug paraphernalia, including needles and syringes, [336] and state
or local government and foundation sources that might wish to support syringe-exchange programs cannot,
because their action would be directly or indirectly supporting criminal activities. Thus, individuals—frequently
volunteers—who staff the syringe access programs can face prosecution for their activities. Furthermore,
individuals who receive the needles face potential arrest going to or from needle-exchange sites. However,
individuals facing prosecution for their activities in regard to syringe-exchange programs have occasionally been
successful in obtaining acquittals in several cases by arguing a necessity defense, based on the theory that
their actions in distributing needles avoids the greater harm of HIV transmission. [337], [338], [339] Furthermore,
individuals facing prosecution for their participation in syringe-exchange programs have escaped liability where
the court found there was no probable cause to arrest the individuals just because they possessed drug residue
in spent syringes while those individuals were exchanging the spent syringes or because they possessed
syringes after receiving new syringes from in an exchange program. [340]

**Developments at the federal level:** In seeking to reduce transmission of HIV and other infectious diseases
resulting from the sharing of syringes, public health advocates and others broadened their agenda from
supporting syringe-exchange programs to also including syringe “deregulation” more generally. Deregulation
allows legal access to syringe purchase in pharmacies, allowing physicians to prescribe syringes and making
syringes available for purchase in vending machines. [342] At least 19 states have established regulations on the
retail sale and possession of syringes. [343]

The Trump Administration's initiative to end the HIV epidemic, discussed in §2.02[B], acknowledges that syringe
exchange programs play a critical role in preventing new infections and in identifying individuals with HIV and
engaging them in care. [344] It remains to be seen how federal officials in the current Administration will navigate
the complex legal issues discussed above, or how much actual financial, technical, and logistical support they will actually provide in jurisdictions where injection drug use is a significant driver of the epidemic.

Furthermore, Philadelphia has led efforts to establish a “supervised injection site” in the city, as a way to address an epidemic in overdoses and to better engage persons with substance use disorders in health care and support services. The initiative, directed by Safehouse, a nonprofit agency, would establish a facility in south Philadelphia where individuals could ingest substances (which they would bring themselves) in a safe environment, staffed by trained persons who could assist in the event of an overdose, and by others who would offer support, mental health, and substance use disorder treatment services. The initiative has the support of the Philadelphia Commissioner of Public Health and Commissioner of Behavioral Health, and former Pennsylvania Governor Edward Rendell. In February 2019, the U.S. Attorney in Philadelphia filed a civil lawsuit against Safehouse and its Executive Director, seeking a declaratory judgment that the initiative was in violation of the Controlled Substances Act. On October 2, 2019, in a ground-breaking decision, the district court ruled in favor of Safehouse. The court held that when enacting the Controlled Substance Act's prohibition of “manag[ing] or control[ling] any place…for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance,” Congress did not contemplate safe injection sites. The court concluded that because Safehouse's purposes were to save lives, help people reduce substance use, and advance the public health (rather than to facilitate the use of controlled substances) the statute was not violated. The government will certainly appeal, and the U.S. Attorney has threatened to take action to close the site if it opens before all appeals have been exhausted. In February 2020, Safehouse abandoned its efforts to open its supervised injection site in South Philadelphia after facing community resistance and the cancellation of its lease. Safehouse is currently considering its next moves and a possible future home for the site.

[C] Condom Distribution Programs in Schools

Condom distribution programs in schools have become increasingly common, especially in cities with high rates of HIV transmission, and to some extent in surrounding suburban neighborhoods. Condom distribution programs (via school nurses, vending machines) have been shown to be effective, and advocacy concerning their availability has been shown not to increase sexual activity among adolescents. Condom distribution programs are controversial and have been challenged on the grounds that parental consent should be required before a school may distribute to minors, especially if introduction of condoms would be the first time a minor was confronted with the concept of sexual activity. However, programs have largely survived challenges on these grounds (i.e., interference with a parent's right to control a child's upbringing and free exercise of religion challenges); courts have reasoned that school-based programs do not need to notify parents if a child requests or receives condoms, and do not need to provide parents with the option to opt out from a child being able to access counseling around sexually transmitted diseases when made available via the school nurse. As one court reasoned, “[p]arents have no right to tailor public school programs to meet their individual religious or moral preferences.” Other courts have gone even further, reasoning that provision of condoms without parental consent is akin to provision of medical services. Courts are divided, however, on whether or not condoms constitute medical services, for which parental consent is required except as where exempted (e.g., abortion). One court concluded that they do not, and thus found no basis for requiring parental consent. Another, however, reasoned that condoms can be considered health services—not merely education. The program in question—based in New York City—survived the legal challenges brought against it by amending its policies to allow parents to opt out of allowing their child to request and receive condoms. Arkansas' school policy requires written parental consent for students to receive condoms in schools that choose to make them available.
Footnotes


317 Woodhull Freedom Found. v. United States, 948 F.3d 363, 374 (D.C. Cir. 2020). The U.S. Court of Appeals for the D.C. Circuit held that two of the plaintiffs, Andrews and Koszyk, had standing to bring suit. *Id.* at 374. The D.C. Circuit concluded Andrews satisfied the injury standing requirement, because Andrews’ website allowed sex workers to share information about products or services they commonly use—such as PayPal or other payment processors—falling within FOSTA’s proscription on facilitating sex work. *Id.* at 372–74. The D.C. Circuit also concluded Koszyk satisfied the injury and redress standing requirements, because Koszyk demonstrated FOSTA caused Craigslist to remove Koszyk’s sex-work personals-pages advertisements and that a favorable decision would create a significant increase in likelihood that he would obtain relief—Craigslist would reinstate its personals pages if FOSTA was invalidated, thus allowing Koszyk to repost his sex-work advertisements. *Id.* at 374.


319 Agency for Int'l Dev. v. All. for Open Soc'y Int'l, 207 L. Ed. 2d 654 (U.S. June 29, 2020).

320 The National Commission on AIDS, citing CDC statistics, reported in 1991 that 32 percent of all adult and adolescent AIDS cases were related to injection drug use; 70 percent of all pediatric AIDS cases related to a mother at risk for HIV infection were directly related to the mother's exposure to HIV through injection drug use or sex with an injecting drug user; 71 percent of all female AIDS cases were linked directly or indirectly to injection drug use; 19 percent of male AIDS cases were directly linked to injection drug use; and an additional...
7 percent of male AIDS cases were linked to both homosexual/bisexual contact and injection drug use. The Commission also reported that in New York City alone, there were an estimated 200,000 injection drug users, half of whom are HIV positive, but there were only 38,000 publicly funded treatment slots. National Comm’n on AIDS, Report: The Twin Epidemics of Substance Use and HIV 4–5 (1991). By the end of 1995, injection drug use was the second most frequently reported risk behavior for HIV infection, and 36 percent of AIDS cases reported to the CDC were directly or indirectly attributed to injection drug use. AIDS Associated with Injecting-Drug Use—United States, 1995, 45 CDC Morbidity and Mortality Wkly. Rep. 392 (1996).


See Syringe Exchange Programs—United States, 1994–1995, 44 CDC Morbidity and Mortality Wkly Rep. 684 (1995). The North American Syringe Exchange Network reported an 82 percent increase in syringe exchange programs between 1993 and 1995. Fifty-five percent of programs were categorized as legal (operating in a state that had no law requiring a prescription to purchase a hypodermic syringe or had an exemption to the state prescription law allowing operation of the program), 32 percent as illegal but tolerated (operating in a state that has a prescription law, but having received a vote of approval from a local elected body), and 13 percent as illegal/underground (operating in a state that has a prescription law and without support from local elected officials). Id. The status of a program affects the degree to which it can promote harm reduction, with legal programs more likely than illegal ones to offer onsite HIV counseling and testing.


Nat'l Research Council & Inst. of Medicine, Preventing HIV Transmission: The Role of Sterile Needles and Bleach 7 (Jacques Normand et al. eds., 1995).


See Scott Burris et al., The Legal Strategies Used in Operating Syringe Exchange Programs in the United States, 86 Am. J. Pub. Health 1163 (1996) (survey of reported and unreported prosecutions of syringe-exchange workers showing nine cases resulting in acquittal and two cases resulting in conviction).

In Roe v. City of New York, 151 F. Supp. 2d 495 (S.D.N.Y. 2001), a class-action challenging police harassment of syringe-exchange participants in New York City, the court found that the plaintiff-injection drug users had standing to challenge the police department's alleged practice of targeting for arrest drug users who frequented legally authorized syringe-exchange sites in areas known for high levels of illicit drug activity. The plaintiffs alleged that police would stop and arrest syringe-exchange participants on their way to exchange sites, when they were likely to be carrying injection equipment containing unusable drug residue. Id. at 501. The plaintiffs further claimed that the police department practice created a fear of arrest that led to a decreased use of syringe-exchange sites and an increased sharing of syringes, which in turn led to an increased blood-borne disease transmission. Id. The court granted declaratory judgment to the plaintiff syringe-exchange program participants on the basis that there was no criminal law liability for possession of a controlled substance in New York, when that controlled substance is the drug residue remaining in a used syringe or syringe possessed by an exchange participant. Roe v. City of New York, 232 F. Supp. 2d 240 (S.D.N.Y. 2002). The court noted that it would be bizarre to conclude that the New York legislature intended to permit the creation of syringe-exchange programs in order to reduce the distribution of used syringes, while at the same time frustrating that goal by making participation illegal. Id. at 257.

In L.B. v. Town of Chester, 232 F. Supp. 2d 227 (S.D.N.Y. 2002), a syringe-exchange participant challenged the legality of his arrest in Orange County, New York, for possessing syringes he had obtained from the exchange program in New York City. The court ruled similarly as it did in Roe v. City of New York, finding that once the syringe-exchange participant identified himself as such and provided identification authenticating his participation, there was no probable cause for arrest. Id. at 234. Moreover, in ruling on the defendant-police officers' motion for summary judgment based on their claim of qualified immunity, the court concluded that it was objectively unreasonable for the officers to have believed they had probable cause for arrest. Id. at 236–37.


Id. (Board of Directors and Advisory Committee).


In the early 1980s, motivated by a desire to protect the safety of the nation's blood supply, the FDA responded to the HIV/AIDS crises by indefinitely deferring (i.e., prohibiting) the donation of blood by any man who had sex with another man since 1977. The FDA's deferral policy also prohibits donations from anyone who has ever exchanged sex for money or drugs, or engaged in nonprescription injection drug use. The need for a lifelong deferral policy, as applied to MSM, has been criticized because the tests used to detect (and then exclude) blood donations that contain HIV are incredibly effective and because the policy does not rely on individual assessments of risky behavior (e.g., number of recent partners), but instead isolates and discriminates against a particular minority group—gay and bisexual men and transgender women, regardless of engagement in high-risk behavior. [359]

In 2015, the FDA eliminated what was a lifetime ban on MSM from donating blood, imposing instead a one-year deferral period (requiring a man who had sex with another man to wait at least one year before donating blood). [360] This still amounts to a perpetual ban, so long as an individual is sexually active, including those who have been in monogamous relationships for years. Critics argue the one-year period is unnecessarily long, given that
tests are able to detect HIV infection within weeks of exposure. Nonetheless, the change in federal law reflects one more step toward evidence-based policy making.

Moreover, in July 2016, the FDA signaled it was open to reconsidering even the one-year deferral policy, and requested public comment on alternative blood donor deferral policies. The FDA specifically invited scientific comments on: whether it is feasible to screen potential donors for specific behaviors that would pose a significant risk of HIV infection during the “window period” (the period of time between infection and when current test would reveal the infection); which specific behaviors should be the subject of screening; how those behaviors can reliably be detected through a revised donor questionnaire or other means; and what the specific deferral period(s) should be for persons who have engaged in those behaviors. A number of blood donation centers and others in the blood industry; health centers and health policy experts; and HIV advocacy organizations submitted comments in late 2016. In 2017, the FDA’s position was that further relaxation on restrictions on blood donations by gay and bisexual men—for instance, use of questions to screen for specific sexual behaviors associated with a higher risk of HIV transmission—would require a study to demonstrate impacts on the blood supply. The FDA developed a pilot study to test the effectiveness of questions focused on individual risk behavior as a way of protecting the safety of the blood supply without unnecessarily stigmatizing all gay and bisexual men. In February 2017, the American Bar Association House of Delegates adopted a policy statement urging the FDA to promulgate a new deferral policy that is based on sound evidence and protects the safety of the blood supply without stigmatizing gay and bisexual men by excluding them regardless of their specific behaviors.

In light of the coronavirus disease 2019 (COVID-19) pandemic, the FDA announced in April 2020 it was relaxing restrictions on gay men being allowed to donate blood—instead of one year, MSM need only wait three months to donate blood. The FDA claims its policy change is “[b]ased on recently completed studies and epidemiologic data,” and the policy changes “are expected to remain in place after the COVID-19 pandemic ends, with any appropriate changes based on comments” submitted to the FDA. Although the three-month blood deferral policy reduces blood-donation restrictions on MSM, it still presents a barrier to MSM who have not engaged in recent sexual activity posing a significant risk of HIV infection. In its April 2020 revised guidance, the FDA stated that it “remains committed to further investigating individual risk assessment as an alternative to time-based deferrals” and noted that it had recently initiated “[a] study of this approach.”

Footnotes
AIDS and the Law - Skinner-Thompson, §2.09, RESTRICTING SEXUALLY ORIENTED COMMERCIAL ACTIVITIES


Last Updated: 12/2020

The HIV epidemic has provided government officials with a new rationale for attacking sexually oriented commercial activities, by utilizing not the criminal law but coercive civil legal authority instead. The risk of HIV transmission has been proffered in support of regulation or closure of businesses that foster or promote sexual activities on their premises. Although the sexual activities themselves are frequently not commercial in nature, they occur in settings that are commercial (e.g., bookstores, movie theaters, and bathhouses).

The U.S. Supreme Court has upheld the regulation of sexually oriented commercial establishments on the theory that such regulation is a constitutionally appropriate means of limiting the negative “secondary effects,” possibly including HIV transmission. Courts have upheld laws that prohibit enclosure of viewing areas (of videos or dancers) on the basis that privacy afforded to such activity increases high-risk sexual activity. Bathhouses and sex clubs have been similarly prohibited based on the theory that they facilitate engagement in high-risk sexual activity. More recently, public health authorities have started to target such gathering places with prevention messages (e.g., education on transmission and distribution of condoms) rather than discourage their operation. For example, Los Angeles requires that bathhouses and sex clubs undergo quarterly inspections, pay annual fees, and offer onsite free testing and counseling for HIV, free condoms, and information on safe sex.

Footnotes

367 Criminal law prohibitions on commercial sexual activities such as prostitution are covered in Chapter 7. Although some courts have concluded that prostitution offenses occur on the premises of commercial businesses and thus justify their closure, that does not appear to be the primary commercial purpose of the businesses.


369 Doe v. City of Minneapolis, 898 F.2d 612 (8th Cir. 1990).


AIDS and the Law - Skinner-Thompson, Chapter 2 HIV AND PUBLIC HEALTH LAW


**AIDS and the Law - Skinner-Thompson, §2.10, REGULATION OF MEDICINAL MARIJUANA**


**Last Updated: 12/2020**

HIV/AIDS medications frequently produce severe nausea and weight loss as side effects. Many patients have sought to obtain marijuana on a medically approved basis to counteract these side effects as well as to provide relief from chronic pain for HIV/AIDS patients with sensory neuropathy. [373] In July 2016, the Food and Drug Administration (FDA) approved a new form of dronabinol, which is indicated for the treatment of anorexia associated with weight loss in patients with AIDS and contains a synthetic delta-9-tetrahydrocannabinol (TCH), a main component of marijuana. [374] The older capsule formulation of dronabinol is a Schedule III controlled substance, [375] while the newer oral solution formulation has been assigned to Schedule II. [376] Such classifications allow physicians to prescribe dronabinol as appropriate for patients with AIDS.

Despite the availability of dronabinol since 1985, marijuana itself has been listed on Schedule I of the Controlled Substances Act. [377] Drugs on Schedule I, the most restrictive classification, are statutorily defined as those with “no currently accepted medical use in treatment” [378] and consequently are only available under federal law for “research, chemical analysis, or [the] manufacture of other drugs.” [379]

In 1999, a study of the scientific literature concerning medical use of marijuana was released by an independent panel of experts under the auspices of the Institute of Medicine. The study, which had been requested by the Office of National Drug Control Policy, concluded that the active ingredients in marijuana are useful in treating nausea and weight loss associated with AIDS, and that marijuana was not a “gateway drug” leading to the use of “harder” drugs. The study recommended increased government support to speed the development of cannabinoid drugs, but, noting the toxicity of marijuana smoke, it also recommended that patients who did not respond to other treatments and did not have a concern about the long-term effects of smoking marijuana should be permitted to smoke it. [380] In early 2006, however, the FDA issued an intergovernmental advisory stating that “no sound scientific studies supported medical use of marijuana” and criticizing state referenda as inconsistent with the FDA’s regulatory role. [381] Advocates for medical marijuana denounced the FDA advisory as politically motivated and contradicted by the 1999 IOM study, which the FDA's advisory did not reference. [382] One such organization, Americans for Safe Access, filed suit against HHS and the FDA, challenging the government position that marijuana has no accepted medical value. [383] Although the case was ultimately unsuccessful, the FDA now formally recognizes the potential medical benefit of marijuana derived drugs and supports research on such. [384] As evidence of its support, the FDA, which reviews all human research protocols that involve marijuana, cites its coordination with other federal agencies that are involved in marijuana research. [385]
Nonetheless, challenges to the classification of marijuana as a Schedule I drug (i.e., defined as having no medical utility) continue to fail. In 2016, the *Drug Enforcement Administration* (DEA) denied a 2011 petition by the governors of Washington and Rhode Island to remove marijuana and “related items” from Schedule I and reassign those items as medical cannabis in Schedule II. In accordance with rescheduling provisions, the DEA requested a scientific and medical evaluation and scheduling recommendation from the *Department of Health and Human Services* (HHS). After concluding that marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision, HHS recommended that marijuana remains in Schedule I. The DEA followed HHS's recommendation and declined to reschedule marijuana.

Notwithstanding federal resistance, the use of marijuana for medical treatment has been legalized in 33 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands. Another 13 states allow for use for specified medical conditions only (e.g., certain kinds of cancer or seizure disorders, as opposed to at a physician's determination of need).

In addition, federal enforcement trends, described as “resource allocation” decisions, are shifting with regard to federal criminal prosecutions relating to medical marijuana. A 2009 memorandum issued by the U.S. Attorney General's office states that the Department of Justice “is committed to the enforcement of the Controlled Substances Act in all States” based on the congressional determination “that marijuana is a dangerous drug, and the illegal distribution and sale of marijuana is a serious crime and provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels.” Accordingly, the “prosecution of significant traffickers of illegal drugs, including marijuana, and the disruption of illegal drug manufacturing and trafficking networks continues to be a Department of Justice core priority.” However, the memorandum also states:

> As a general matter, pursuit of these priorities should not focus federal resources...on individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana. For example, prosecution of individuals with cancer or other serious illnesses who use marijuana as part of a recommended treatment regimen consistent with applicable state law, or those caregivers in clear and unambiguous compliance with existing state law who provide such individuals with marijuana is unlikely to be an efficient use of limited federal resources.

Nonetheless, in 2011, U.S. attorneys in several states, including Arizona, Colorado, Hawaii, Montana, Rhode Island, Vermont, and Washington, sent letters to state officials warning that medical marijuana farms and dispensaries, those buying or selling marijuana for medical purposes pursuant to state law, and even state employees who authorized such programs or landlords that provide space to such programs could face federal criminal prosecution and various civil penalties.

On February 27, 2017, Attorney General Jefferson Sessions established the Department of Justice's Task Force on Crime Reduction and Public Safety, which was tasked with reviewing existing violent crime related policies in the areas of charging, sentencing, and marijuana. As of the summer of 2020, the Task Force has not recommended any new policies, but rather a continuation of the previous Administration's marijuana-related policies established in 2009.

**Footnotes**


Dispensing of Controlled Substances to Residents at Long Term Care Facilities, 75 Fed. Reg. 37463, 37565 (June 29, 2010).


FDA, FDA and Marijuana (June 19, 2018), http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421163.htm.


