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A Syndemic Approach to STD 340B Correctional Facility Partnerships

for Health Department
Prevention Programs

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Glossary

TERM	DEFINITION
Correctional Facility	A jail, prison, or other detention facility used to house people who have been arrested, detained, held, or convicted by a criminal justice agency or a court; any place used for the confinement of persons charged with or convicted of a crime or otherwise confined under a court order.
Covered Entity	A facility or program that is listed in the 340B statute as eligible to purchase medication through the 340B program.
Jail	A type of correctional facility generally used to detain people awaiting trial or sentencing. For those who have been sentenced, jail sentences are usually shorter than those incarcerated in a prison. Jails also house smaller populations than prisons and are often under the jurisdiction of a local law enforcement agency.
340B Patient Definition	This definition must be met for individuals to be eligible to receive 340B medications: (1) The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care, and (2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the covered entity, and (3) the individual receives health care services or range of services from the covered entity which is consistent with the service or range of services for which grant funding has been provided to the entity.
Prison	A type of correctional facility that incarcerates individuals convicted of a crime. State prisons are operated by individual states which have their own legislation regarding the prison system. Federal prisons are overseen by the Federal Bureau of Prisons and have different purposes and security levels.
Section 318	Section 318 of the Public Health Service Act authorizes federal funding for sexually transmitted diseases and other prevention and control projects and programs. This section of the Public Health Service Act can be found here: https://www.govinfo.gov/content/pkg/COMPS-8773/pdf/COMPS-8773.pdf

TERM	DEFINITION
Social Determinants of Health	Conditions in the environment where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. Learn more here: https://health.gov/healthypeople/priority-areas/social-determinants-health
Status Neutral Approach	People living with HIV and/or hepatitis and people who could benefit from HIV and hepatitis prevention services are not two distinct populations but, rather, a group of people with similar medical and social service needs. Adopting a status neutral and whole-person approach to people in need of prevention and care services can address these similar needs, along with HIV and hepatitis-related stigma and discrimination.
Syndemic Approach	Syndemics are epidemics—of diseases or health conditions, such as viral hepatitis, sexually transmitted infections (STI), substance use, and behavioral health issues—that interact with each other and by that interaction increase their adverse effects on the health of communities that face systematic, structural, and other inequities. In addition, social determinants of health (SDOH) such as racism, homophobia, and poverty interact with syndemic conditions and diseases. While SDOH are not epidemics per se, they are social factors that can exacerbate the negative impact of linked epidemics. These syndemics contribute to excess disease burden and ongoing health disparities. Collectively addressing these intersecting conditions and SDOH can result in better infectious disease prevention and care outcomes by prioritizing the whole person. Learn more here: https://www.cdc.gov/hiv/division-of-hiv-prevention/strategic-plan/dhp-cross-cutting-focus-areas-and-the-strategic-framework.html

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Introduction

According to the [Centers for Disease Control and Prevention \(CDC\)](#), the prevalence of HIV, viral hepatitis, and STIs is significantly higher among people who are incarcerated when compared with the general population. Risk factors for acquiring viral hepatitis, HIV, and sexually transmitted infections (STIs) are common among incarcerated populations. These include lack of access to harm reduction strategies including condoms, sterile syringes and injection equipment, and engaging in commercial, survival, or coerced sex. Many individuals who are incarcerated have limited access to health care before incarceration, and most have battled a multitude of social determinants of health throughout their lives. The CDC provides specific screening, vaccination, and treatment [recommendations for correctional and detention settings](#) that give guidance for appropriate viral hepatitis-, HIV-, and STI-related services during intake and throughout the period of incarceration. **Addressing communicable diseases in correctional settings is vital to address the overall syndemic of viral hepatitis, HIV, and STIs.** Because of the high prevalence of viral hepatitis, HIV, and STIs in correctional facilities and the opportunity for [high-impact interventions](#) to be implemented, many health department viral hepatitis, HIV, and STI programs (prevention programs) have established collaborative partnerships with correctional facilities in their jurisdiction.

With almost [two million people incarcerated](#) in the United States, testing and treatment within correctional settings is a high-impact intervention promoted by CDC and mandated by statute in multiple states. To provide screening and treatment for viral hepatitis, HIV, and STIs, correctional facilities often need support, guidance, and resources from health department prevention programs. When a prevention program provides support in the form of direct funding or in-kind contributions from a federal funding source authorized by [Section 318 of the Public Health Service Act \(PHSA\)](#), this partnership deems the correctional facility eligible to participate in the [340B drug pricing program](#) with an STD designation. Participating in the 340B drug pricing program provides a correctional facility with access to deeply discounted medications that enable the correctional facility to contain prescription drug costs and consequently maximize their budgets to expand testing, treatment, and care to further address the syndemic of viral hepatitis, HIV, and STIs.

340B Eligibility

Health department prevention programs often form financial relationships with correctional facilities to provide viral hepatitis, HIV, and STI services. STD 340B eligibility for correctional facilities becomes possible through government grants, subcontracts, or memorandums of understanding (MOUs) in which eligible Section 318 funding or support is provided to the correctional facility. Prevention funding under the statutory authority of Section 318 include*:

- [PS21-2103](#): Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments
- [PS18-1802](#): Integrated Human Immunodeficiency Virus (HIV) Surveillance and Prevention Programs for Health Departments
- [PS21-2010](#): Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States
- [PS19-1901](#): Strengthening STD Prevention and Control for Health Departments

**Additional CDC funding opportunities are authorized by Section 318 and program administrators should reference grants, cooperative agreements, or notice of funding opportunity (NOFO) documents to determine statutory authority and STD 340B eligibility.*

Prevention programs often award Section 318 funding to correctional facilities for:

- Personnel to implement disease intervention, partner services, outbreak response readiness, and other grant-specific activities and functions
- Specimen processing and testing for HIV, viral hepatitis, and STIs
- Hepatitis A/B vaccinations
- Materials and supplies for the prevention, treatment and care of viral hepatitis, HIV, and STIs
- Other services as determined by the prevention program

It is important to note that HRSA considers in-kind contributions provided through Section 318 programs as STD 340B eligible support (<https://www.hhs.gov/guidance/document/340b-drug-pricing-program-frequently-asked-questions>). These in-kind contributions must be paid for by qualifying Section 318 grant funds and may be in the form of real property, equipment, supplies, other expendable property, and goods and services directly benefitting and specifically identifiable to the project or program (HRSA). **In-kind contributions provided by health department prevention programs to correctional facilities include:**

- Condoms and lubricant
- Educational brochures
- Educational programming to incarcerated individuals regarding the transmission, prevention, and treatment of viral hepatitis, HIV, and STIs
- Medical education and training to correctional facility staff on viral hepatitis, HIV, and STI treatment and care
- Partner services and linkage to care for individuals diagnosed with viral hepatitis, HIV, and STIs
- Testing support that may include HIV/HCV rapid test kits, laboratory allocations, and confirmatory testing
- Health department staff embedded within the facility to assist with viral hepatitis, HIV, and STI services
- Other in-kind services as determined by the prevention program and paid for by the qualifying grant funds

Prevention Program Collaboration and Service Integration

Health departments receive multiple Section 318 qualifying grants across viral hepatitis, HIV, and STI prevention programs. This means that there are numerous programs, potential partnerships, and opportunities for 340B eligibility to be conferred to correctional facilities. Health department prevention program administrators should work together to establish the most strategic partnership with correctional facilities within their jurisdiction and utilize the best funding opportunity available to support a syndemic approach and implement integrated public health interventions. Regardless of which Section 318 qualifying grant is providing eligibility, health department administrators should ensure the correctional facility leverages the 340B Drug Pricing Program to address their population's unique needs and the current syndemic of viral hepatitis, HIV, and STIs.

Participating in the 340B Programs is crucial to providing cost-effective services within the scope of the grant, as viral hepatitis, HIV, and STIs all require treatment. Once a correctional facility is an eligible STD 340B covered entity, health department prevention programs should ensure the correctional facility understands the scope of the grant that is providing eligibility and the expectations of a syndemic approach. This means that prevention program administrators should work together to identify mutually beneficial activities and prevention strategies that facilitate comprehensive delivery of services for all syndemic epidemics including viral hepatitis, HIV, and STIs.

Examples of a syndemic approach include:

- Ensuring risk assessments conducted by correctional facilities include overlapping behavioral questions that encompass viral hepatitis, HIV, and STIs
- Setting expectations that screening and treatment policies are in place that address all aspects of the syndemic
- Encouraging the correctional facility to treat people holistically, addressing social and economic barriers

It is especially important for HIV and viral hepatitis treatment and care program administrators to work closely with prevention programs to ensure uninterrupted access to HIV, hepatitis B, and hepatitis C treatment within correctional facilities. Medicaid, Medicare (including employer sponsored and individual plans) and [The Ryan White HIV/AIDS Program](#) are typically unavailable to people while they are incarcerated, leaving correctional facilities responsible for significant medication costs, which may lead to haphazard treatment and care policies.¹ While discussing and implementing STD 340B eligible partnerships with correctional facilities, it is essential that prevention programs consider the treatment and care of people with HIV and/or viral hepatitis. An STD 340B designation can be used for HIV and viral hepatitis treatment once the 340B patient definition has been met. Participation in the 340B program with an STD designation may increase access and quality of treatment for people with HIV and/or viral hepatitis who are incarcerated.

Partnership Management

Correctional facilities are not 340B eligible on their own. Correctional facilities need to partner with a hospital or grantee who receives 340B eligible funding in order to be 340B eligible. Health department prevention program administrators, as grantees, should steward these partnerships with care. Through formal partnerships, prevention programs have the opportunity to implement or expand syndemic services and measure the public health impact the 340B program has on viral hepatitis, HIV, and STIs. Prevention program administrators can establish clear expectations regarding syndemic services within the scope of their grants of in-kind contributions, receive meaningful aggregate data that will help evaluate efforts and work with the correctional facility to implement impactful prevention programming. It is recommended that prevention programs establish [memorandums of understanding](#) (MOUs) that outline and formalize these crucial partnerships.

NEW PARTNERSHIPS	EXISTING PARTNERSHIPS
<p>May be initiated by either the prevention program or the correctional facility and may include learning about program objectives and opportunities for partnership</p>	<p>May currently exist as a formal or informal partnership across different prevention programs or with specific program staff (with or without agreements in place)</p>
BENEFITS OF ESTABLISHING AN MOU	
<ul style="list-style-type: none"> • Bring awareness to STD 340B eligibility and realize STD 340B program potential • Formalize or improve the partnership, setting clear expectations • Include 340B elements into partnership agreements, including data sharing • Expand, offer, or improve treatment and prevention services within the facility • Engage the correctional facility on health department prevention program planning, outbreak response, and syndemic action and elimination plans 	

¹ RWHAP recipients and subrecipients may use Federal funds (and/or associated 340B program income/ rebates) to provide medical or support services to PLWHIV incarcerated in Federal or State prisons on a transitional basis only, notably linkage to and continuity of care associated with parole. For low-income PLWHIV incarcerated in other correctional systems, including city and county jails, RWHAP funds may also be used to provide well-defined HIV care and treatment services that are not otherwise available on a short-term basis, which may involve the duration of incarceration for some individuals. See HRSA HAB [Policy Clarification Notice 18-02](#) to learn more.

Whether the prevention program is developing a new partnership with a correctional facility or expanding or formalizing an existing partnership to include 340B considerations, it is important to identify key stakeholders within the correctional facility and discuss 340B eligibility, syndemic approaches, pharmacy operations, and compliance elements.

It is recommended that health department prevention programs take the following steps when establishing an STD 340B partnerships with a correctional facility:

1. Identify and engage with key stakeholders within the correctional facility and those that will be solely responsible for the administration of the 340B program. This may include the warden, chief operations officer, medical director, pharmacy director, and other staff directly involved in 340B program operations
2. Prevention program staff should be aware of whom the correctional facility's authorizing official and primary contact will be
3. Ensure the correctional facility knows about the 340B Program and notify them when they receive funding or in-kind contributions that were purchased with qualifying Section 318 funding
4. Share STD 340B educational materials and resources to build the correctional facility's 340B capacity
5. Work together to establish a contract or MOU and the timeline for 340B registration. Ensure the correctional facility is aware of quarterly registration periods and that they have the grant number and NOFO number needed for registration
6. Ensure the health department staff person listed on the notice of award (NOA) for the grant or cooperative agreement providing eligibility is aware of the correctional facility's 340B enrollment as they will verify eligibility to HRSA
7. Provide guidance regarding the STD 340B patient definition and what is considered a service within the scope of the CDC NOFO that is providing eligibility and ensure the [syndemic approach](#) is implemented
8. Provide syndemic best practices and guidance for program collaboration and service integration, including overlapping risk factors and following CDC testing recommendations
9. Understand how the correctional facility is meeting and documenting the 340B patient definition
10. Set clear expectations regarding oversight and compliance and ensure the correctional facility knows they are solely responsible for compliance with 340B Program requirements, including annual recertification
 - HRSA Office of Pharmacy Affairs (OPA) administers the 340B drug pricing program, and health departments do not need to audit correctional facility STD 340B covered entities for compliance unless agreed to in a contract or MOU
11. Health department prevention programs should **never** serve as a correctional facility's authorizing official or primary contact, create an account or register the facility on their behalf, attest to the correctional facility's compliance, or create 340B policies or procedures for the correctional facility
12. Prevention programs should implement or update contracts and agreements to account for 340B considerations

340B Cost Savings

Incarcerated individuals are not insured, eliminating the possibility of generating 340B revenue for correctional facilities. However, participation in the 340B program does provide correctional facilities with up-front cost savings. With these up-front cost savings, correctional facilities have the opportunity to expand activities within budgets or reallocate funding. Reducing the cost of medications alleviates stress on limited budgets and provides opportunities to address syndemic comorbidities and social determinants of health. Correctional facilities may have the opportunity to implement innovative programs and policies with 340B cost savings.

While there is currently no statutory regulation pertaining to STD 340B program revenue and savings, STD-covered entities should use 340B savings for activities that promote the purpose of their qualifying funding. STD 340B cost savings should be reinvested back into a viral hepatitis, HIV, or STI program, directly benefit patients, and include a syndemic approach. **Correctional facilities should reinvest their 340B cost savings into syndemic programming that:**

- Expands testing and follows CDC testing recommendations
 - This may include utilizing 4th generation HIV tests
 - Providing testing to everyone regardless of age or gender
 - Offering antibody testing and nucleic acid amplification tests (NAT) for HCV
 - Providing multi-site STI testing
 - Implementing universal opt-out testing on intake and interval retesting throughout the duration of incarceration
- Expands treatment
 - Providing first-line therapies
 - Removing exclusionary criteria
 - Providing medication to continue treatment upon release
- Implements prevention programs within the facility
 - Provides safer sex supplies, safer tattooing & piercing supplies, and safer injection supplies
- Treats substance use disorders while incarcerated and upon release
- Provides Narcan within the facility and naloxone upon release
- Supports linkage to care including bridging services to ensure engagement in HIV, STI, or viral hepatitis prevention or care following release
- Provides sufficient staffing to support expanded syndemic services which may include administrators, pharmacists, clinicians, mental health professionals, case managers, educators, and disease intervention specialists
- Provides supportive services that address the social determinants of health, health disparities and recidivism
 - This may include food, transportation, and housing vouchers, ongoing case management, and other activities identified by the unique needs and circumstances of the correctional facility and jurisdiction

Documenting the Public Health Impact

When a correctional facility utilizes an STD 340B designation, they have access to deeply discounted medications for their 340B eligible patients, in turn saving hundreds of thousands of dollars and maximizing their medical budgets. Prevention programs and correctional facilities should work together to document the public health impact of their STD 340B partnership, including how syndemic services have been expanded and improved within the facility. This may include the correctional facility sharing success stories and aggregate data with the prevention program, such as the number of individuals screened and treated for viral hepatitis, HIV, STIs, and additional syndemic services implemented with savings attributed to 340B Program participation. Through an MOU or contract, prevention programs can ensure they receive these data elements and public health impact reports as needed, which may be quarterly, bi-annually, or annually.

340B Considerations

Once enrolled in the 340B program, correctional facilities are responsible for compliance with all 340 Program requirements. As 340B covered entities, correctional facilities should maintain comprehensive, written 340B policies and procedures. These should contain program requirements, methodologies for routine self-auditing, and internal corrective action. Correctional facilities participating in the 340B program should also maintain in-house pharmacy inventories, contract pharmacy agreements, wholesaler account agreements, and their 340B OPAIS record. The prevention of medication diversion is also a primary compliance element, and correctional facilities are responsible for ensuring that 340B Program medications are only dispensed to 340B Program-eligible patients (see 340B Patient Definition) and that 340B Program medications are not resold or transferred. Correctional facilities should review [HRSA's program integrity guiding principles](#) to maximize oversight and manage compliance risk.

340B Patient Definition

Each patient who receives 340B medications must meet the 340B patient definition. Viral hepatitis, HIV, and STIs are overlapping epidemics with overlapping risk factors, and each of these health concerns directly affects the others. It is important that prevention programs do their best to ensure CDC testing, treatment, and care recommendations are being implemented across their correctional facility partnerships for viral hepatitis, HIV, and STIs. Correctional facilities should ensure the 340B patient definition is being met by providing the scope of services outlined by the grant providing 340B eligibility while keeping syndemic approaches in mind. While each CDC NOFO has a different scope, each NOFO supports the syndemic approach.

To be eligible to receive 340B medications, patients must receive health care services other than medications from the 340B covered entity. Patient eligibility is met when (1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care, and (2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the covered entity, and (3) the individual receives health care services or range of services from the covered entity which are consistent with the service or range of services for which grant funding has been provided to the entity.

Below is a table comparing 340B patient definition elements with correctional facility compliance and implementation:

340B PATIENT DEFINITION	CORRECTIONAL FACILITY PRACTICE
<p>The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s healthcare</p>	<p>It is the legal requirement and responsibility of correctional facilities to provide adequate medical care to those incarcerated within their facilities. The correctional facility (including their medical contractor if applicable) maintains medical records for all incarcerated individuals.</p>
<p>The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the covered entity</p>	<p>Correctional facilities have medical personnel on staff or pay a medical contractor to provide medical and health care services. When a correctional facility utilizes a paid contractor for medical services, the correctional facility should be the covered entity, not the medical contractor, as the responsibility for the care provided to the incarcerated individuals remains with the correctional facility regardless of medical contractor turnover.</p>
<p>The individual receives a health care service or a range of services from the covered entity which is consistent with the service or range of services for which grant funding has been provided to the entity</p>	<p>To be 340B eligible, incarcerated patients must receive health care services or a range of services that are in line with the grant. This means screening and treatment of viral hepatitis, HIV, and STIs upon intake and throughout the duration of incarceration per CDC guidelines.</p>

Purchasing Medications

Some correctional facilities have in-house pharmacies or pharmacy licenses, which allows them to purchase 340B medications directly from a wholesaler. Other correctional facilities use contract pharmacies, which serve as an extension of the correctional facility’s 340B Program and provide patients access to prescription medications. Correctional facilities that have a central pharmacy and multiple housing locations should consult with Apexus to seek guidance to determine the need to register multiple physical locations.

Eligible Medications

Covered 340B medications are outlined in statute and further clarified by [Apexus FAQ #1367](#). There is no designated medication formulary for the 340B Program, and manufacturers participating in Medicaid and Medicare Part B must offer all covered outpatient medication at or below the 340B ceiling price. The term covered outpatient drug is defined in section 1927(k) of the Social Security Act. The Centers for Medicare & Medicaid Services provides a list of medication that are reported by manufacturers under the Medicaid Drug Rebate program and thus subject to a 340B ceiling price, which can be found here: <https://data.medicaid.gov/dataset/0ad65fe5-3ad3-5d79-a3f9-7893ded7963a>

Once the 340B patient definition is met and a patient is 340B eligible, correctional facilities can utilize 340B for every medication that is clinically indicated for that patient enabling correctional facilities to address the syndemic within their walls, including treating viral hepatitis, HIV, STIs, and co-occurring medical conditions including substance use disorder (SUD), mental health conditions, and other chronic health conditions.

Resources

- American Academy of Family Physicians, Incarcerations and Health: A Family Medicine Perspective, <https://www.aafp.org/about/policies/all/incarceration.html>
- American Association for the Study of Liver Diseases, HCV Testing and Treatment in Correctional Settings, <https://www.hcvguidelines.org/unique-populations/correctional>
- At-A-Glance: CDC Recommendations for Correctional and Detention Settings, <https://www.cdc.gov/correctionalhealth/rec-guide.html>
- CDC Recommendations for Correctional and Detention Settings, <https://www.cdc.gov/std/treatment-guidelines/correctional.htm>
- CDC STI Treatment Guidelines, 2021, Persons in Correctional Facilities, <https://www.cdc.gov/std/treatment-guidelines/correctional.htm>
- Columbia Mailman School of Public Health, Public Health in Prison, <https://www.publichealth.columbia.edu/public-health-now/news/public-health-prison>
- HRSA Policy Clarification Notice #18-02, <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/pcn-18-02-people-who-are-incarcerated.pdf>
- HRSA's Ryan White HIV/AIDS Program, Addressing the HIV Care Needs of People with HIV in State Prisons and Local Jails, <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/resources/hrsa-justice-tep.pdf>
- NASTAD, 340B for Viral Hepatitis Programs: 340B Drug Pricing Program Guidance, <https://nastad.org/resources/340b-viral-hepatitis-programs-340b-drug-pricing-program-guidance-webinar-series>
- National Institute of Justice Centers for Disease Control and Prevention, Public Health/Corrections Collaborations: Prevention and Treatment of HIV/AIDS, STDs, and TB, <https://www.ojp.gov/pdffiles/169590.pdf>
- National Library of Medicine, HIV Treatment in US Prisons, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2953806>
- National Library of Medicine, Prevention of Hepatitis C by Screening and Treatment in U.S. Prisons, <https://pubmed.ncbi.nlm.nih.gov/26595252>
- National Library of Medicine, Prevalence of STIs and Associated Risk Behaviors in Prisons: A Systematic Review, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9478043>
- NCSD, 340B and Ending the Epidemics, <https://www.ncsddc.org/resource/340b-and-ending-the-epidemics>
- U.S. Department of Justice, Census of State and Federal Adult Correctional Facilities, <https://bjs.ojp.gov/content/pub/pdf/csfac19st.pdf>

The purpose of this document is to provide guidance to health department prevention programs providing and correctional facilities as it pertains to the 340B designations authorized by Section 318 of the Public Health Service Act. This guidance is written based on the best understanding of NASTAD and its contractors. Covered entities should refer to the 340B statute, HRSA published guidance and HRSA policy releases for additional guidance. Covered entities should also use their own judgment and legal counsel to assist in ensuring compliance with 340B Program requirements. The materials herein do not constitute, and should not be treated as, professional advice regarding compliance with laws or regulations. This is not a legal document and should not be used to substitute the 340B statute, 340B program regulations, HRSA published guidance, HRSA policy releases, and other relevant resources. Liability for compliance with 340B Program requirements resides solely with the covered entity.