POLICY AND PROCEDURE NOTICE: PPPN-067
SYRINGE SERVICES PROGRAMS

Summary and Purpose of PPN: To guide the administration of the Ryan White Part A Program to ensure compliance with regulations related to the use of federal funds for Syringe Services Programs (SSPs).

Authority:

- Consolidated Appropriations Act, 2016 (Pub. L. 114-113)
- 45 CFR 75.351-75.353
- 74 CFR 74.51(a)
- 2 CFR 215.51(a)
- 2 CFR 75 Subpart F – Audit Requirements
- HIV/AIDS Bureau, Division of Metropolitan HIV/AIDS Programs & Division of State HIV/AIDS Programs National Monitoring Standards for Ryan White Part A and Part B Grantees: Universal – Part A and B
- NOA Program Specific Terms
- Fulton County Ryan White Part A Contract/Agreement
- GAO Report on Oversight of Ryan White Part A/B Grantees https://careacttarget.org/library/gao-report-oversight-part-ab-grantees
- Fulton County Ryan White Part A Contract/Agreement

Policy and Procedures:

The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed by President Barack Obama in December 2015, modifies the ban on the use of federal funds to support programs distributing sterile needles or syringes (referred to as SSP) for Department of Health and Human Services (HHS) Programs, including Health Resources and Services Administration (HRSA) Programs. Federal funds may not be used to purchase sterile needles or syringes for the purpose of injecting illegal drugs. However, federal funds may be used to support various components of SSPs as outlined in the Department of Health and Human Services Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016 https://www.hiv.gov/sites/default/files/hhs-ssp-guidance.pdf

Department of Health and Human Services Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016

Introduction

The purpose of this document is to provide implementation guidance for programs directly funded by the Department of Health and Human Services (HHS) interested in implementing or expanding syringe services programs (SSPs) for persons who inject drugs (PWID). As described in summary guidance from the Centers for Disease Control and Prevention (CDC) and HHS[1], the term SSPs includes provision of sterile needles, syringes and other drug preparation equipment and disposal services, as well as some or all of the following services: comprehensive sexual and injection risk reduction counselling; HIV, viral hepatitis, other sexually transmitted diseases (STDs) and tuberculosis (TB) screening; provision of naloxone to reverse opioid overdoses; referral and linkage to HIV, viral hepatitis, other STDs and TB prevention care and treatment services, referral and linkage to hepatitis A virus (HAV) and hepatitis B virus (HBV) vaccination, as well as referral to integrated and coordinated f substance use disorder, mental health services, physical health care, social services, and recovery support services.

On December 18, 2015, President Barack Obama signed the Consolidated Appropriations Act, 2016 (Pub. L. 114-113),[2] which modifies the restriction on use of federal funds for programs distributing sterile needles or syringes (referred to as SSPs, or as syringe exchange programs) for HHS programs. The Consolidated Appropriations Act, 2016, Division H states:

> SEC. 520. Notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug: *Provided,* That such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with State and local law.

While the provision still prohibits the use of federal funds to purchase sterile needles or syringes for the purposes of hypodermic injection of any illegal drug, it allows for federal funds to be used for other aspects of SSPs based on evidence of a demonstrated need (i.e.,

[1] CDC. (2012) Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance from CDC and the U.S. Department of Health and Human Services. MMWR;61(RR05):1-40.

[2] https://www.congress.gov/114/bills/hr2029/BILLS-114hr2029enr.pdf

experiencing, or at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use) by the state or local health department and in consultation with the CDC. This guidance details what can be supported with federal funds and what criteria will be used to determine demonstrated need.

Principles guiding the use of HHS funding for SSPs

- Programs that use federal funding for SSPs must adhere to federal, state and local laws, regulations, and other requirements related to such programs or services. State and local laws may vary and will impact the ability of federally funded recipients to implement these programs.
- Recipients should coordinate with and work toward obtaining cooperation from local law enforcement officials when implementing SSPs.
- SSPs, as they are implemented, should be a part of a comprehensive service program[3] that includes, as appropriate:
  - Provision of sterile needles, syringes and other drug preparation equipment (purchased with non-federal funds) and disposal services;
  - Education and counseling to reduce sexual, injection and overdose risks;
  - Provision of condoms to reduce risk of sexual transmission of viral hepatitis, HIV or other STDs;
  - HIV, viral hepatitis, STD and TB screening;
  - Provision of naloxone to reverse opioid overdoses;
  - Referral and linkage to HIV, viral hepatitis, STD and TB prevention, treatment and care services, including antiretroviral therapy for hepatitis C virus (HCV)and HIV, pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), prevention of mother-to-child transmission and partner services;
  - Referral and linkage to hepatitis A virus (HAV) and hepatitis B virus (HBV) vaccination;
  - Referral and linkage to and provision of substance use disorder treatment (including medication-assisted treatment for opioid use disorder which combines drug therapy (e.g., methadone, buprenorphine, or naltrexone) with counseling and behavioral therapy);
  - Referral to medical care, mental health services, and other support services.
- Recipients should ensure that SSPs supported with federal funds provide referral and linkage to HIV, viral hepatitis, and substance use disorder prevention, care and treatment services, as appropriate.
- HHS recipients should coordinate and collaborate with other local agencies, organizations, and providers involved in comprehensive prevention programs for PWID to minimize duplication of effort.

[3] CDC. (2012) Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance from CDC and the U.S. Department of Health and Human Services. MMWR; 61(RR05):1-40.

- SSPs are subject to the terms and conditions incorporated or referenced in the recipient's federal funding.
- Federal funds can only be used to establish a new SSP or expand an existing SSP with prior approval from the respective federal agency.

Use of Federal Funds

Funds may be used to support various components of SSPs[4] including, but not necessarily limited to, the following:

- Personnel (e.g., program staff, as well as staff for planning, monitoring, evaluation, and quality assurance);
- Supplies, exclusive of needles/syringes and devices solely used in the preparation of substances for illicit drug injection, e.g., cookers;
- Testing kits for HCV and HIV;
- Syringe disposal services (e.g., contract or other arrangement for disposal of biohazardous material);
- Navigation services to ensure linkage to HIV and viral hepatitis prevention, treatment and care services, including antiretroviral therapy for HCV and HIV, PrEP, PEP, prevention of mother to child transmission and partner services; HAV and HBV vaccination, substance use disorder treatment, recovery support services and medical and mental health services;
- Provision of naloxone to reverse opioid overdoses;
- Educational materials, including information about safer injection practices, overdose prevention and reversing a opioid overdose with naloxone, HIV and viral hepatitis prevention, treatment and care services, and mental health and substance use disorder treatment including medication-assisted treatment and recovery support services;
- Condoms to reduce sexual risk of sexual transmission of HIV, viral hepatitis, and other STDs;
- Communication and outreach activities; and
- Planning and evaluation activities.

Note: Not all of the components listed above will be supported by all HHS agencies; use of funding will depend on each HHS agency's authorities, policies and procedures as well as state and local laws and regulations. Approval to use federal funds to support SSPs will be contingent on <u>first</u> demonstrating need, in consultation with CDC.

Process for demonstrating need in consultation with CDC

[4] CDC. (2012) Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance from CDC and the U.S. Department of Health and Human Services. MMWR;61(RR05):1-40.

State, local, territorial, and tribal health departments should consult with CDC by providing evidence that their jurisdiction is (1) experiencing or, (2) at risk for a significant increase in viral hepatitis infections or an HIV outbreak due to injection drug use.[5] The scope of the presented evidence should address the geographic area that will be served by the SSPs and include county, city and state level data, as appropriate.

First, jurisdictions should assess if they are *experiencing* significant increases in viral hepatitis or HIV infections. For jurisdictions *experiencing* significant increases in viral hepatitis or HIV infections, state or local health departments may use multi-year data from surveillance systems to demonstrate an increase in acute hepatitis C virus [HCV], acute hepatitis B virus [HBV], or HIV infections (Table 1a). Health departments must also provide evidence that the significant increase in infections resulted from injection drug use. Such evidence may include transmission category (i.e., risk factor most likely to have been responsible for transmission of HIV infection, HCV or HBV) collected as part of routine case reporting, epidemiologic surveys, scientific data, or social or ethnographic community data. Health departments should assess any significant increases within the context of local surveillance practices, disease patterns and long-term trends.

Second, for jurisdictions *at risk for* – but not yet experiencing – significant increases in viral hepatitis or HIV infections due to injection drug use, data should come from multiple sources that when triangulated (combined) provide compelling evidence that there is likely an increase in injection drug use in the jurisdiction. Multiple data sources are recommended because a single data source may be insufficient. For example, increases in arrests for syringe and drug possession may be due to increased enforcement by the police force, or additional human resources for drug enforcement units. Similarly, increases in emergency department visits for drug-related overdoses may be due to new hospital initiatives to improve reporting or greater awareness of the condition among staff responsible for reporting. Evidence from multiple data sources, that when considered together, indicate likely increases in injection drug use provides reassurance that the problem assessment is accurate.

CDC recently conducted analyses to identify a set of outcomes associated with acute HCV infection, a proxy for unsafe injection drug use. Tables 1b illustrates some of these outcomes and data sources that may be useful as evidence. In addition, health departments may use local data sources not listed in these tables and that provide valuable insights unavailable from national or state sources. Examples of data triangulation are available in the National Institute on Drug Abuse Community Epidemiology Work Group reports (see http://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-

[5] The state executive branch agency responsible for the administration of discretionary and/or formula grant funds authorized by Title V, Part B, Subpart 1 of the Public Health Service (PHS) Act and Title XIX, Part B, Subpart II of the PHS Act (42 U.S.C. 300x-21) awarded by Substance Abuse and Mental Health Services Administration, as applicable, must contact the state health department, if the agency believes a determination is warranted.

consortia/community-epidemiology-work-group-cewg/meeting-reports/area-reports-june-2014). Health departments are encouraged to conduct similar analyses to provide evidence of increases in injection drug use in their jurisdictions.

Table 1.a Requested outcomes for jurisdictions *experiencing* significant increases in viral hepatitis or HIV infections*

Outcomes	**Example Data Sources**
Acute HCV or HBV attributed to injection drug use	• National Notifiable Disease Surveillance System (NNDSS) • State or local surveillance systems • Multi-year cohort studies of persons who inject drugs (PWID)
HIV infections attributed to injection drug use	• National HIV Surveillance System (NHSS) • State or local surveillance systems • Multi-year cohort studies of PWID

* Must provide evidence that increases resulted from injection drug use; such evidence may include transmission category from case reporting, existing published data and reports, surveys, or social or ethnographic community data.

Verification:

- Site visit.

Approved June 2019

Reviewed: April 2021

See "Corrective Action Plan Form"