

Centers for Disease Control and Prevention (CDC) Program Guidance for Implementing Certain Components of Syringe Services Programs, 2016

Introduction

The purpose of this document is to provide implementation guidance for programs directly funded by CDC interested in implementing new or expanding existing syringe services programs (SSPs) for persons who inject drugs (PWID). This program guidance was developed in accordance with the Department of Health and Human Services (HHS) Implementation Guidance to Support Certain Components of Syringe Service Programs, 2016 ([HHS SSP Guidance](#)).

As described in the 2012 summary guidance for prevention of HIV, viral hepatitis, STDs and TB for persons who inject drugs from CDC and HHS¹, 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 (STD) 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; and referral to integrated and coordinated substance use disorder services, mental health services, physical health care, social services, and recovery support services. A [directory of current SSPs](#) is maintained by the North American Syringe Exchange Network.

On December 18, 2015, President Barack Obama signed the Consolidated Appropriations Act, 2016, (Pub. L. 114-113),² which modified 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.

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>. Accessed on December 22, 2015.

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., experiencing, or at risk for, significant increases 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.

The HHS SSP guidance outlines the process for health departments to request a determination of need. For areas in which a determination of need has been made, this guidance details which SSP activities can be supported with CDC funds, which relevant CDC cooperative agreements can be used to support SSPs, and the process for how CDC funded programs can direct resources to implement new or expand existing SSPs. As always, requests to direct program funding to a different emergent activity are subject to approval from the CDC project officer and grants management officer.

Principles guiding the use of HHS funding for SSPs

As noted in the [HHS SSP Guidance](#), the following principles should be considered when planning, implementing, and evaluating an SSP:

- 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 program³ 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 medication 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 [sic] hepatitis A virus (HAV) and hepatitis B virus (HBV) vaccination;
 - Referral and linkage to and provision of substance use disorder treatment

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.

- (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 funding recipients should coordinate and collaborate with other local agencies, organizations, and providers involved in comprehensive prevention programs for PWID to minimize duplication of effort.
 - 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 or expand an existing SSP with prior approval from the respective federal agency.

Use of CDC Funds

The *Consolidated Appropriations Act, 2016 (P.L. 114-113)*, has modified the prohibition on federal funding for SSPs, and this change can be applied by CDC funded programs starting in Fiscal Year (FY) 2016 and can continue in future FYs, unless otherwise notified. CDC funded SSPs should be in accord with this guidance and remain subject to the terms and conditions as described in the recipient's Notice of Award. CDC funds can only be used to establish new or expand existing SSPs, with prior approval from the project officer and grants management officer. CDC funds cannot be used to supplant or replace state or other non-federal funds currently supporting SSP activities within a jurisdiction. In other words, CDC funds cannot be used to fund an existing SSP so that state or other non-federal funding can then be used for another program.

Applicable CDC Funding Opportunity Announcements

CDC has reviewed the scope of its various funding opportunity announcements (FOAs) to identify those whose awardees are best positioned to effectively support the implementation of SSPs in communities and to directly monitor local SSP activities to ensure compliance with national, as well as state and local laws, which vary by jurisdiction. As a result, two FOAs have been selected. Organizations receiving funds through these FOAs may request to direct funds to support SSPs. These applicable FOAs and their respective allowable SSP activities are outlined below.

- **PS12-1201, "Comprehensive HIV Prevention Programs for Health Departments"**
 - Allowed uses for funding include:
 - Personnel to support SSP implementation and management (e.g., program staff, as well as staff for planning, monitoring, evaluation, and quality assurance);
 - Supplies to promote sterile injection and reduce infectious disease transmission through injection drug use, exclusive of sterile needles, syringes and other drug

- preparation equipment;
 - Testing kits for viral hepatitis (i.e., HBV and 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, testing, treatment and care services, including antiretroviral therapy for HCV and HIV, pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), prevention of mother to child transmission and partner services; substance use disorder treatment, and medical and mental health care;
 - Educational materials, including information about: safer injection practices; reversing a drug overdose; HIV and viral hepatitis prevention, testing, treatment and care services; and mental health and substance use disorder treatment, including medication assisted treatment;
 - Male and female condoms to reduce sexual risk of infection with HIV and other STDs;
 - Referral to hepatitis A and hepatitis B vaccinations to reduce risk of viral hepatitis infection;
 - Communication, including use of social media technologies, and outreach activities designed to raise awareness about and increase utilization of SSPs; and
 - SSP planning and non-research evaluation activities.
- **PS14-004, “Reduce Hepatitis Infections by Treatment and Integrated Prevention Services (Hepatitis-TIPS) among Non-urban Young Persons Who Inject Drugs”**
 - Allowed uses for funding include:
 - Personnel to support SSP implementation and management (e.g., program staff, as well as staff for planning, monitoring, evaluation, and quality assurance);
 - Supplies to promote sterile injection and reduce infectious disease transmission through injection drug use, exclusive of sterile needles, syringes and other drug preparation equipment;
 - Testing kits for viral hepatitis (i.e., HBV and HCV) and HIV;
 - Syringe disposal services (e.g., contract or other arrangement for disposal of biohazardous material);
 - Navigation services to ensure linkage to viral hepatitis prevention, treatment and care services, prevention of mother to child transmission and partner services; substance use disorder treatment, and medical and mental health care;
 - Educational materials, including information about: safer injection practices; reversing a drug overdose; viral hepatitis prevention, testing, treatment and care services; and mental health and substance use disorder treatment, including medication assisted treatment;
 - Male and female condoms to reduce sexual risk of infection with HIV and other STDs;

- Referral to hepatitis A and hepatitis B vaccinations to reduce risk of viral hepatitis infection;
- Communication, including use of social media technologies, and outreach activities designed to raise awareness about and increase utilization of SSPs; and
- SSP planning and non-research evaluation activities.

During FY 2016, CDC resources to support allowable SSP activities must come from current CDC HIV and/or viral hepatitis program funding. Beginning in FY 2017, newly issued FOAs for HIV and viral hepatitis prevention programs will include guidance on the use of funding to support SSP activities. Below are the eligibility criteria and budgetary and programmatic requirements and restrictions.

Process for Requesting Use of CDC Funds for SSPs

STEP 1: As described in the [HHS SSP Guidance](#), state, local, territorial, and tribal health departments interested in directing federal funds to support SSPs must first demonstrate need in consultation with CDC. Health departments should provide CDC 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. The scope of the presented evidence should address the geographic area that will be served by the SSPs and include state, county, and city level data, as appropriate.

At any time, health departments may submit a request for CDC's determination of need to SSPCOORDINATOR@CDC.GOV, with a courtesy copy to their project officer. Within 30 days of receipt of this consultation request, CDC will notify the requestor whether the evidence is sufficient to demonstrate need for SSPs. If the evidence is sufficient, the requesting health department will receive notice of approval regarding determination of need for the jurisdiction. This notice may be used by state, local, territorial, or tribal health departments or eligible HHS funded recipients to apply to the respective federal agency for directing funds to SSPs. If the evidence is insufficient, no programmatic or budgetary changes will be authorized. However, jurisdictions may choose to revise and resubmit their request with additional evidence based on feedback from CDC.

Upon notification of CDC's concurrence with the jurisdictional need for SSPs, health departments and other eligible HHS funded recipients are strongly encouraged to discuss their plans to direct funds for SSPs with their respective federal funding agency. An HHS funded health department or other eligible recipient may elect to either (1) immediately request to direct FY16 funds to support SSPs or (2) delay its request to direct funds to support SSPs until a subsequent fiscal year.

Note: Only CDC directly funded, eligible awardees may submit a request to CDC to direct CDC funding to SSP activities.

CDC directly funded, eligible awardees seeking to direct FY16 funds for SSPs are strongly encouraged to request a determination of need according to the below deadlines. Adherence to these recommended deadlines will ensure adequate time to

have a determination of need request reviewed and process a subsequent request to direct FY16 funds for SSPs. If CDC directly funded, eligible awardees are unable to meet these deadlines, requests to direct funds for SSPs may be delayed until the next fiscal year.

- **For PS12-1201, “Comprehensive HIV Prevention Programs for Health Departments”**: These awardees should submit their requests for jurisdictional determination of need for SSPs by **May 27, 2016**
- **For PS14-004, “Reduce Hepatitis Infections by Treatment and Integrated Prevention Services (Hepatitis-TIPS) among Non-urban Young Persons Who Inject Drugs”**: These awardees should collaborate with their respective state health departments to submit requests for jurisdictional determination of need for SSPs by **May 27, 2016**

STEP 2: Upon notification of CDC’s concurrence with the need for SSPs within a jurisdiction, eligible CDC awardees may then discuss their plans to direct funds to support SSP activities with their project officer prior to submitting a proposal to the CDC Office of Grant Services (CDC/OGS). In accordance with CDC/OGS guidelines, eligible awardees must prepare a proposal which identifies the SSP activities that will be supported by CDC funds. The proposal should include 1) a proposed program plan and 2) a revised budget (see *Outline of Proposal to CDC* below for more details).

The proposal, including the proposed program plan and revised budget, must be submitted to CDC/OGS with a courtesy copy to the CDC project officer. This submission should include a copy of the CDC notification that the jurisdiction has sufficiently demonstrated need to use federal funding for SSP activities. Once approved by both the CDC/OGS grants management specialist and the CDC Project Officer, the requestor will receive a revised Notice of Award signed by the CDC/OGS grants management officer. Awardees must obtain this approval before using their awarded funding to implement any SSP activities.

- **For PS12-1201, “Comprehensive HIV Prevention Programs for Health Departments”**: Once the jurisdiction has obtained a CDC notification stating that the jurisdiction has sufficiently demonstrated need to use federal funding for SSPs, and following their decision to implement or expand existing SSPs, awardees should:
 - Develop a detailed program plan and budget describing the SSP activities that will be implemented in the jurisdiction. **All requests to direct FY16 funds to support SSPs must be submitted no later than 60 days following receipt of CDC approval of determination of need.**
 - Submit an addendum to the current Integrated HIV Prevention and Care Plan to include revisions to planned activities and priority populations as indicated by the addition of SSP components.
 - Send an additional courtesy copy of all requests to direct funds for SSP

activities to PS12-1201@CDC.GOV.

- **For PS14-004, “Reduce Hepatitis Infections by Treatment and Integrated Prevention Services (Hepatitis-TIPS) among Non-urban Young Persons Who Inject Drugs”:** Once the jurisdiction has obtained a CDC notification stating that the jurisdiction has sufficiently demonstrated need to use federal funding for SSPs, and following their decision to implement new or expand existing SSPs, awardees should:
 - Develop a detailed program plan and budget describing the SSP activities that will be implemented in the jurisdiction. **All requests to direct FY16 funds to support SSPs must be submitted no later than 60 days following receipt of CDC approval of determination of need.**

Step 3: CDC will approve or disapprove requests to direct funding to support SSPs activities within 30 days of receipt of all requested information. If seeking to implement SSP activities with FY16 funds, CDC strongly encourages eligible awardees to submit all requests according to the recommended submission deadlines.

After approving requests to direct funding for SSPs, CDC will work in partnership with awardees to determine the appropriate process measures related to SSPs. Awardees implementing new or expanding existing SSPs will need to collect basic SSP metrics information (e.g., number of syringes distributed, estimated number of syringes returned for safe disposal, number of persons tested for HIV or viral hepatitis, referrals to HIV, viral hepatitis and substance use disorder treatment).

Outline of SSP Proposal to CDC

All proposals to request the use of CDC funds to support SSPs should include the following elements, unless otherwise noted:

- Description of proposed new or expanded SSP related activities;
- Timeline for implementation:
 - Awardees without prior experience with SSPs should include preparatory activities as part of their timeline, including development of protocols and guidelines, and staff training.
- Impact on current activities funded under the respective FOA;
- Copy of existing protocols and guidelines for SSP related activities, if available;
- Budget and budget justification, proposed activities and measures;
- Description of current training and technical assistance needs related to planning, implementing, and evaluating SSPs, as appropriate; and
- Location of SSP related activities to be supported with federal funds.

Technical Assistance and Resources

Awardees should first review the [HHS SSP Guidance](#) and this guidance for instruction, tools, and resources. While requesting either 1) determination of need for SSPs or 2) authority to direct CDC funds to support SSPs, awardees should contact their project

officer to discuss specific needs for technical assistance. Project officers can provide guidance and facilitate access to capacity building assistance or other resources. Additional information about using CDC funds for SSPs is available at <http://www.cdc.gov/hiv/risk/syringes.html>.