

**HHS Implementation Guidance to Support Certain  
Components of Syringe Services Programs, 2016:  
Requesting a Determination of Need in Consultation with CDC**

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## SYRINGE SERVICES PROGRAMS

### Policies/Issues

The Affordable Care Act and HIV/AIDS

HIV/AIDS Care Continuum

Syringe Services Programs

## PREVENTING HIV AND HEPATITIS AMONG PEOPLE WHO INJECT DRUGS AND THEIR PARTNERS

The U.S. Department of Health and Human Services (HHS) is committed to working with grantees and partners to reduce the spread of HIV and viral hepatitis in the United States. The nation is experiencing a growing epidemic of illegal opioid drug use, which has also led to an increase in unsafe injection practices that put people who inject drugs (PWID) at risk of HIV and viral hepatitis.

<https://www.aids.gov/pdf/hhs-ssp-guidance.pdf>

needles,  
ID to exchange

used syringes for sterile ones have been demonstrated to be an effective component of a comprehensive approach to prevent HIV and hepatitis among PWID, while not increasing drug use.

In March 2016, HHS issued [guidance](#) (PDF 960 KB) for HHS-funded programs regarding the use of federal funds to implement or expand syringe services programs (SSPs) for people who inject drugs. The guidance is part of the bipartisan budget agreement President Obama signed into law in December 2015 which [revised a](#)

Service Locator  
Get Tested. Find Services.

## Objectives

- ❑ **Review HHS Implementation Guidance**
  - Determination of need in consultation with CDC
- ❑ **Provide practical information and tips for preparing requests for determination of need**

## Outline

- ❑ Background
- ❑ New legal authority for the use of federal funds for syringe services programs
- ❑ Determination of need in consultation with CDC
  - Jurisdictions **experiencing** increases in viral hepatitis or HIV infections
  - Jurisdictions **at risk** of increases in viral hepatitis or HIV infections
- ❑ Submission of requests for determination of need
- ❑ Additional resources

**BACKGROUND**

# HIV and Hepatitis C Infections among Persons Who Inject Drugs (PWID) in the United States

- ❑ HIV diagnoses attributed to injection drug use have been declining since the late 1980's<sup>1</sup>
  - Effective HIV prevention interventions
- ❑ Recent trends suggest increased risk for HIV and hepatitis C transmission attributed to injection drug use
  - Epidemic of prescription opioid use and increases in heroin use<sup>2,3</sup>
  - Increased prevalence of injection drug use among young people (<30 years)<sup>4</sup>
  - Incidence of acute hepatitis C infection increased from 2006 to 2012<sup>5</sup>
  - Large HIV outbreak among PWID in Southeastern Indiana<sup>6</sup>

<sup>1</sup>CDC: [www.cdc.gov/hiv/library/reports/surveillance](http://www.cdc.gov/hiv/library/reports/surveillance); <sup>2</sup>Maxwell JC. Drug Alcohol Rev 2011, 30:264-70; <sup>3</sup>CDC. Vital Signs. MMWR 2015, 64: 64(26):719-725; <sup>4</sup>Tempalski B et. al. PLoS ONE 2013, 8:e64789. <sup>5</sup>Suryaprasad AG et al. Clin Infect Dis 2014,59:1411-9; <sup>6</sup>Conrad C, et al. MMWR 2015, 64(16):443-4.

# Syringe Services Programs (SSPs)

- ❑ **Provide access to free sterile syringes and other injection equipment, safe disposal of used syringes, and syringe exchange**
- ❑ **Provide other health and supportive services**
  - Comprehensive risk reduction counseling
  - HIV and viral hepatitis screening and referral to treatment
  - Referral to substance use disorder treatment
  - Referral to medical and mental health care
- ❑ **Also known as syringe exchange programs (SEPs), needle-exchange programs (NEPs), needle and syringe programs (NSPs)**



# Effectiveness of SSPs in Reducing HIV Risk

- ❑ **First established in late 1980s in response to the HIV epidemic**
  - 204 known SSPs in the US in 2013<sup>1</sup>
- ❑ **Compelling evidence of SSPs effectiveness, safety and cost-effectiveness for HIV prevention among PWID<sup>2</sup>**
  - Reduction in injection risk behaviors
  - Reduction in HIV incidence
  - No increase in drug use (e.g., no increases in initiation, duration or frequency)
  - Additional benefits (e.g., enrollment in substance use disorder treatment, higher HIV treatment retention, reduced needle stick injuries among first responders)
- ❑ **Reach beyond enrolled SSP clients through secondary exchange and peer outreach**

<sup>1</sup>CDC. Syringe Services Programs for Persons Who Inject Drugs in Urban, Suburban and Rural Areas – United States, 2013. MMWR 2015; 64(48):1337-41.

<sup>2</sup>Wodak and Cooney (2006). Do Needle Syringe Programs Reduce HIV Infection Among Injecting Drug Users: A Comprehensive Review of the International Evidence. Substance Use & Misuse, 41:777-813.





**FEDERAL FUNDS CAN SUPPORT SSPs**

# Consolidated Appropriations Act, 2016 (P.L. 114-115): Federal funds can now be used to support SSPs

- ❑ **Modifies** the restriction on use of federal funds for SSPs
- ❑ Still prohibits use of federal funds for sterile needles or syringes for the injection of drugs
- ❑ Allows for federal funds to be used for other components of SSPs based on **evidence of a demonstrated need** by the health department and in consultation with CDC
  - Experiencing, or at risk for, increases in hepatitis infections or an HIV outbreak due to injection drug use

## What can federal funds be used for?

- ❑ Staff
- ❑ Supplies (e.g., alcohol pads, sterile water, cotton)
- ❑ Testing kits for viral hepatitis and HIV
- ❑ Syringe disposal services
- ❑ Navigation services to ensure linkage to services
- ❑ Provision of naloxone to reverse drug overdoses
- ❑ Communication, outreach and educational materials
- ❑ Condoms
- ❑ Planning and evaluation activities

## **Federal funds cannot be used for:**

- ❑ Needles and syringes for illegal drug injection**
- ❑ Other devices solely used for illegal drug injection (e.g., cookers)**

# How do I apply to re-direct federal funds to support SSPs?

## Step 1: Determination of need

- State, local, tribal and territorial health departments consult with CDC and provide evidence of need for SSPs

## Step 2: Application to federal agencies to direct funds

- State, local, tribal and territorial health departments and other HHS funding recipients apply to their respective federal agencies to direct funds to support approved SSP activities
- Each federal agency (e.g., CDC, SAMHSA) is developing its own guidance for the application process



# HOW TO DEMONSTRATE NEED?

## How to demonstrate need?

If **experiencing** increases in viral hepatitis or HIV infections

- ❑ Present data from surveillance that shows increases in:
  - Acute hepatitis C virus (HCV)
  - Acute hepatitis B virus (HBV)
  - HIV infections
  
- ❑ Provide evidence that the increase in infections resulted from injection drug use
  - Include data on transmission category
  - Epidemiologic surveys, or social or ethnographic community data

**Jurisdictions experiencing increases**



## Example of evidence for a jurisdiction experiencing increases

Outcome(s)	Data source	Geographic area	Assessment period beginning year and number or rate	Assessment period ending year and number or rate	Percent increase during the assessment period
Acute HCV	Viral Hepatitis Surveillance United States, 2013 (CDC, <a href="http://www.cdc.gov/hepatitis/statistics/2013surveillance/pdfs/2013hepsurveillancereport.pdf">http://www.cdc.gov/hepatitis/statistics/2013surveillance/pdfs/2013hepsurveillancereport.pdf</a> )	City A	Month: Jan-Dec Year: 2009  Value: 0.3 Units: cases per 100,00 population	Month: Jan-Dec Year: 2013  Value: 2.7 Units: cases per 100,00 population	800% increase over 5 years

## Example of evidence for a jurisdiction experiencing increases

- *Data submitted to CDC for the City of A indicate a 800% increase in annualized rates of acute hepatitis C infection from 2009 to 2013. During this period, data from at least three sources<sup>1-3</sup> suggest that the majority of these infections (>70%) resulted from injection drug use.*
  1. Zibbell, J.E., et al., *Increases in hepatitis C virus infection related to injection drug use among persons aged  $\leq$  30 years - Kentucky, Tennessee, Virginia, and West Virginia, 2006-2012.* *MMWR Morb Mortal Wkly Rep*, 2015. 64(17): p. 453-8.
  2. Suryaprasad, A.G., et al., *Emerging epidemic of hepatitis C virus infections among young nonurban persons who inject drugs in the United States, 2006-2012.* *Clin Infect Dis*, 2014. 59(10): p. 1411-9.
  3. Centers for Disease Control and Prevention. *Viral hepatitis surveillance -- United States, 2013.* 2014 (Accessed October 8, 2015).
- *During 2013, X County had a substantially higher rate of reported HCV cases compared with the City overall: 97 per 100,000 population compared with 69 per 100,000 population. We therefore believe that rates of acute HCV infection are rising throughout the City with an excess burden of disease in X County.*

Appendix 2. EXAMPLE OF A REQUEST  
FOR DETERMINATION OF NEED

## Tips for presenting strong evidence of need

### Tip 1: Data should be specific to the geographic area

- ❑ **The scope of the presented evidence should address the geographic area for which a determination is being requested**
  - County, city or other geographic area
  - State data as appropriate
  - Data from multiple jurisdictions, if relevant, is highly encouraged
- ❑ **If the request is for one jurisdiction the determination will apply to that jurisdiction**
  - Any new need in other geographic areas will require a new request of need to CDC
- ❑ **If multiple jurisdictions are affected the determination can be requested for entire state**
  - If CDC determination applies to the entire state, any new need in other geographic areas will not require a new request of need to CDC

## **Tip 2: Interpret data within the local context**

- ❑ **Interpret data in the context of local surveillance practices, disease patterns and long-term trends**
- ❑ **Current increases are above what is expected given past trends**
  - Example: 0 new HIV diagnoses reported between 2000 to 2013, but 5 new HIV diagnoses attributed to injection drug use reported in 2014 and 2015
- ❑ **Clarify that there have been no changes in surveillance practices to increase reporting that may artificially inflate numbers/rates**
  - Example: increased HIV testing efforts

## Tip 3: Increase in infections resulted from injection drug use

### □ Transmission category

- Risk factor most likely 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

- Example 1: Publications suggesting that a majority of acute HCV cases are due to injection drug use.
- Example 2: Qualitative interviews with recently diagnosed HCV patients found that all/most reported history of injection drug use

## Tip 4: Existing reports and publications

- ❑ Existing reports and publications of increases in HIV or viral hepatitis may be submitted as supportive evidence
- ❑ Example: MMWR report documenting an outbreak of hepatitis C infection
  - Also provide surveillance data, more recent data may be available



## **Jurisdictions at risk for increases**

## How to demonstrate need?

For jurisdictions **at risk** for – but not yet experiencing – increases

- ❑ Data should come from multiple sources
- ❑ Use local data when available
- ❑ Triangulate the data to provide evidence that there is likely an increase in injection drug use
- ❑ Outcomes proposed in the guidance are associated directly or indirectly with injection drug use



## **Example of outcomes for jurisdictions at risk for increases**

- ❑ Prevalence of injection drug use**
- ❑ Uptake of SSP services**
- ❑ Substance use disorder treatment admissions related to injection drugs**
- ❑ Drug-related crime**
- ❑ Drug-related overdose mortality**
- ❑ Emergency department or other medical care related to substance use**

## Example data sources

Drug use, injection drug use and uptake of SSP services

- Substance Abuse and Mental Health Services Administration (SAMHSA), National Survey on Drug Use and Health (NSDUH)
- Scientific surveys, syringe service program data, or social or ethnographic community data
- Community poison control data
- CDC, Youth Risk Behavior Surveillance System (YRBSS)
- SAMHSA, Treatment Episode Data Set (TEDS)
- State treatment admissions data
- Health care Cost and Utilization Project (HCUP)-State Inpatient Databases (SID)
- State hospital discharge files
- State or county arrest records

Substance use disorder treatment admissions related to injection drug use

Drug-related crime

## Appendix 1. Tools and Resources

Drug-related overdose mortality

- CDC, National Center for Health Statistics (NCHS)/National Vital Statistics System (accessible through Wide-ranging Online Data for Epidemiologic Research [WONDER])
- CDC, Web-based Injury Statistics Query and Reporting System (WISQARS™)
- State Vital Statistics System
- State or county Medical Examiner/Coroner files
- Healthcare Cost and Utilization Project (HCUP): State Inpatient Databases (SID)
- HCUP- State Emergency Department Databases (SEDD)
- State emergency department surveillance systems and EMS systems
- State hospital discharge data

Emergency department or other medical care related to substance use

## Example of a request for a jurisdiction at risk

Outcomes	Data source	Geographic area	Assessment period beginning year and number or rate	Assessment period Ending year and number or rate	Percent increase during the assessment period
Increase in Injection drug use among treatment admissions (any drug) to publicly funded programs	State Division of Alcohol and Drug Abuse	B County	Month: Jan-Dec Year: 2009  Value: 3,500 Units: number per year	Month: Jan-Dec Year: 2014  Value: 6,200 Units: number per year	77%
Heroin-related arrests	County arrest records	B County	Month: Jan-Dec Year: 2012  Value: 5,280 Units: number per year	Month: Jan-Dec Year: 2014  Value: 6,355 Units: number per year	20%
Drug overdose deaths	State Medical Examiner/Coroner files	B County	Month: Jan-Dec Year: 2009  Value: 9.8 per 100,000 Units: rate	Month: Jan-Dec Year: 2013  Value: 18.3 per 100,000 Units: rate	87%

## Example of how to synthesize the evidence

*The state of XX assessed 4 variables related to injection drug use in County B that together suggest an increasing trend in unsafe injection practices ....*

*The most direct indicator of injection drug use is the treatment admissions dataset. Treatment admissions related to injection drug use increased by 77% from 2009 to 2014. Admissions in the younger age group (15-24 years) increased. No new policing initiatives have been documented that may artificially inflate this trend.*

## Appendix 2. EXAMPLE OF A REQUEST FOR DETERMINATION OF NEED

*2,792 in 2014. On the other hand, drug overdose deaths involving opioids increased substantially (87%) between 2009 and 2013, with the largest increases among younger people (<30 years)...*

*The overall rates per 100,000 persons were....*

*Together these data suggest high and increasing levels of unsafe injection drug use in this jurisdiction, and particularly among young people (<30 years) who could greatly benefit from syringe service programs and harm reduction education to prevent future spread of viral hepatitis and HIV.*

## Tips for presenting strong evidence of need

### Tip 1: The more data sources, the better

- ❑ **Triangulation of multiple data sources is recommended because a single data source may be insufficient and lead to incorrect conclusions**
  
- ❑ **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**
  - Evidence from multiple data sources that indicate similar trends strengthen the conclusion of increases in injection drug use

## Tip 2: Use local data if available

- ❑ **Local data may be more timely and relevant**
- ❑ **Examples**
  - Instead of using federal datasets (e.g., SAMHSA TEDS) on admissions to substance use disorder treatment programs, use data from State agency that collects this information or from local treatment programs
  - Local SSP routine program data if available

## **Tip 3: Use more direct indicators of injection drug use**

- ❑ **More direct indicators of transmission risk related to injection drug use are more informative**
- ❑ **Examples of more direct indicators of drug injection**
  - Admissions to substance use disorder treatment for injection drug use
  - Arrest records for injection paraphernalia
  - ER admissions for injection related injury, such as severe skin and soft tissue abscesses or overdoses
- ❑ **Examples of less direct indicators of drug injection**
  - Prescription opioid prescribing patterns
  - Drug seizures by law enforcement

## **Tip 4: Use existing reports and publications**

- ❑ **Existing reports and publications documenting risk for potential increases in HIV or viral hepatitis may be submitted as supportive evidence**
- ❑ **Example: CDC's vulnerability assessment indicating a jurisdiction is at risk for an increase in HIV infections**
- ❑ **Need to provide additional data sources**
  - Example, more recent or local relevant data is available



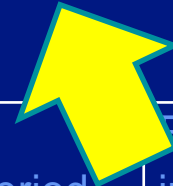


# **HOW TO PREPARE AND SUBMIT A REQUEST FOR DETERMINATION OF NEED?**

## How to prepare and submit a request?

- ❑ **Submit to CDC a request for determination of need that indicates:**
  - Whether the jurisdiction is (1) experiencing or (2) at risk of, but not yet experiencing increases in viral hepatitis or HIV infections due to injection drug use
  - Outcomes analyzed
  - Data sources
  - Geographic area covered
  - Assessment period (beginning year/date to end year/date)
  - Type of measure (e.g., number, rate)
  - Relative percent increase during the assessment period.
  - For jurisdictions at risk for increases, include a brief summary of how the data when taken together (i.e., “triangulated”) support this determination

## Example of a request for a jurisdiction at risk



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## Example of a request for a jurisdiction at risk

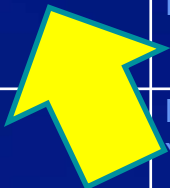
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	County report		Month: Jan-Dec Year: 2012	Month: Jan-Dec Year: 2014	



The request of determination of need can be for a country, city or state.

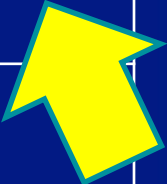
	Units: rate		Units: rate		
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## Example of how to synthesize the evidence

*The state of XX assessed 4 variables related to injection drug use in County B that together suggest an increasing trend in unsafe injection practices ....*

*The most direct indicator of injection drug use is the treatment admissions dataset. Treatment admissions*

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**Brief summary of how the data, when taken together (i.e., “triangulated”), support the determination of need**

*Op*  
*2,7*  
*between 2009 and 2013, with the largest increases among younger people (<30 years)...*

*The overall rates per 100,000 persons were....*

*Together these data suggest high and increasing levels of unsafe injection drug use in this jurisdiction, and particularly among young people (<30 years) who could greatly benefit from syringe service programs and harm reduction education to prevent future spread of viral hepatitis and HIV.*

## Where to send the request for determination of need?

- State, local, territorial, and tribal health departments should submit the request for need determination to:

**SSPCOORDINATOR@CDC.GOV**

## **What will be the process after I submit my request?**

- ❑ Within 30 days, CDC will notify if the evidence is sufficient**
- ❑ CDC will provide written documentation**
- ❑ Health department and others may then apply to direction funds to the respective federal agency**
- ❑ If the evidence is insufficient, no programmatic or budgetary changes will be authorized**
- ❑ Jurisdictions, may choose to revise and resubmit their request with additional evidence based on feedback from CDC**

# **ADDITIONAL RESOURCES**

## What if I have questions while preparing my determination of need?

- ❑ The HHS guidance has example data sources
- ❑ Initially, health departments should gather the data available and internally assess whether this data indicates possible increases
- ❑ If additional questions, submit requests for additional technical assistance to [SSPCOORDINATOR@CDC.GOV](mailto:SSPCOORDINATOR@CDC.GOV)
- ❑ Local health departments should request technical assistance from their state health department.

## CDC websites

- ❑ **CDC “Access to Sterile Syringes” website**
  - Resources and tools for data to assess local injection drug use
  - Links to existing guidance documents, reports and publications for planning and implementing SSPs
  - CDC guidance to request directing funds for SSPs
  - <http://www.cdc.gov/hiv/risk/syringes.html>
  
- ❑ **The AIDS.gov website hosts the HHS guidelines**
  - <https://www.aids.gov/pdf/hhs-ssp-guidance.pdf>

## Other resources

- ❑ **National Institute on Drug Abuse (NIDA) Community Epidemiology Work Group (CEWG), 1976-2014**
  - A network of local drug abuse experts who reported semiannually on drug trends and emerging issues in sentinel sites
  - Triangulate multiple data sources on drug use
  - Contact list for local drug abuse experts
  - <https://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-consortia/community-epidemiology-work-group-cewg>
  
- ❑ **NIDA National Drug Early Warning System (NDEWS), 2015-present**
  - Continues the work of CEWG
  - <http://www.ndews.org/>



**QUESTIONS?**