

**Indiana State Department of Health**  
**Syringe Exchange Program Guidance for Local Health Departments**  
**Version 2.0**

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## Introduction

Syringe exchange programs (SEP), also known as syringe access (SAP) or needle exchange (NEP) programs, are a harm reduction intervention that have been in existence since the late 1980s and have been scientifically proven to reduce transmission of HIV, hepatitis B and C, and other blood-borne pathogens in people who inject (PWI). The primary objectives of SEPs are to:

- Provide a clean syringe for each injection instance to reduce the potential for transmission of HIV, hepatitis B and C, and other blood-borne pathogens.
- Provide an entry point for substance abuse treatment and care and other resources as appropriate to the individual.

There are a number of considerations that communities should examine as they consider establishing an SEP. As each community is different, each SEP will reflect the needs of the community while taking into account local culture and resources. This guidance is designed to provide a starting point for communities seeking information about SEPs or considering this intervention for their own community.

## Syringe Exchange Programs in Indiana

Syringe Access Programs became legal in the state of Indiana, under certain circumstances, when Senate Enrolled Act 461 (SEA 461) was signed into law in May 2015, and later codified at I.C. 16-41-7.5.

Prior to the passage of SEA 461, in January 2015, the Indiana State Department of Health (ISDH) began the process of identifying an outbreak of HIV disease in PWI in southeastern Indiana. In response to the outbreak, the Governor issued Executive Order 15-05, declaring a public health emergency in Scott County and allowing Scott County to request an SEP as part of a broad disease control and prevention plan for a period of 30 days. Scott County officials completed this request and opened the first legal SEP in the state of Indiana on April 4, 2015. The Executive Order was renewed in mid-April and SEA 461 passed both houses of the General Assembly later that month. Under the new law, the Scott County Health Department requested the continuation of their SEP and the Indiana State Health Commissioner approved it for a period of one year. Since that time, several more Indiana counties have availed themselves of the new law in response to HIV and hepatitis C epidemics.

There are no state funds available to support the development, implementation, and/or evaluation of syringe access programs.

## Considerations for Local Health Departments

The complete language of the law allowing for the establishment of SEPs in Indiana is provided in the next section of this document along with a checklist for drafting a proposal. As local health officials read through the requirements in the law and begin to consider if an SEP is appropriate for their county, there are a number of items to consider. It is important to remember that although a county may have an HIV or hepatitis C epidemic, they are not *required* to operate an SEP. The goal of any county should be to identify and respond to communicable disease and drug use issues before an epidemic exists and thus not need an SEP. The determination as to whether an SEP is needed should be made after careful review of the data and consideration of a number of factors. The following are questions to consider:

- Does your county or municipality meet the criteria set forth in the law?
  - o Does the county have an epidemic of HIV, hepatitis C, or both?
  - o If so, is intravenous drug use the primary mode of transmission?
- What measures has the county taken to control the epidemic?
  - o Have they been effective? If not, can you identify specific factors or barriers?
  - o What other measures might be considered in place of or in addition to the establishment of a SEP as part of a comprehensive public health response?
- Based on what you know about the epidemic in your jurisdiction, is an SEP a medically appropriate method of harm reduction?
- How will the SEP be funded, staffed, and which model will work best for our community?
- Where is the most appropriate place to physically locate the SEP, related supplies and other components given the expected number and needs of participants? Is this location secure and does it offer confidential entry and exit? Have you considered a mobile unit alone, or in combination with a fixed location?
- Who are the community partners that provide substance abuse treatment and support, housing, transportation, food, HIV, STD, and/or hepatitis C testing, medical and mental health services, insurance enrollment, and other services or referrals that the injecting community may need?
- What view does the community at large have about SEPs? How will you educate the community at large about the potential for a SEP in the area?
- How will law enforcement and public health work together to ensure a balance between upholding laws and supporting public health?
- How will you work to develop trust in the community and the assess needs of the injection drug-using community?
- In addition to syringe exchange and substance abuse treatment and support referrals, what other resources and referrals will the SEP offer? For example, will wound care kits and Pre-Exposure Prophylaxis (PrEP) be provided?
- Will sharps containers be provided to participants for safe disposal of used syringes? If not, how will used syringes be disposed of, and how will this be paid for?
- Who will be accountable for medical oversight of the SEP? What must medical oversight entail in your county?
- Are there local laws or ordinances that should be considered as they relate to SEPs?

- Does your community have any unique characteristics that should be considered (for example; acts as a regional hub or center, access to public transportation, etc.)

## Indiana State Syringe Exchange Program Law

### Indiana Senate Enrollment Act 461

#### Chapter 7.5. Communicable Disease: Syringe Exchange Program

<http://iga.in.gov/legislative/2015/bills/senate/461#document-d1a62251>

#### Chapter 7.5. Communicable Disease: Syringe Exchange Program

Sec. 1. As used in this chapter, "local health department" refers to: (1) a local health department established under IC 16-20; or (2) the health and hospital corporation created under IC 16-22-8.

Sec. 2. As used in this chapter, "program" means a syringe exchange program operated under this chapter.

Sec. 3. As used in this chapter, "qualified entity" means any of the following: (1) A local health department. (2) A municipality (as defined by IC 36-1-2-11) that operates a program within the boundaries of the municipality. (3) A nonprofit organization that operates a program and has been approved by official action to operate the program by: (A) the local health department; (B) the executive body of the county; or (C) the legislative body of a municipality for the operation of a program within the boundaries of the municipality.

Sec. 4. (a) A qualified entity may operate a program only in a county where a public health emergency has been declared. However, a qualified entity may not operate a program outside of the jurisdictional area of the governmental body that approved the qualified entity. (b) A qualified entity that meets the requirements in subsection (a) and complies with the requirements of this chapter may operate a program.

Sec. 5. Before a qualified entity may operate a program in a county, the following shall occur: (1) The local health officer or the executive director must declare to the executive body of the county or the legislative body of the municipality the following: (A) There is an epidemic of hepatitis C or HIV. (B) That the primary mode of transmission of hepatitis C or HIV in the county is through intravenous drug use. (C) That a syringe exchange program is medically appropriate as part of a comprehensive public health response. (2) The legislative body of the municipality or the executive body of the county must do the following: (A) Conduct a public hearing that allows for public testimony. (B) Take official action adopting the declarations under subdivision (1) by the local health officer or the executive director in consideration of the public health for the area that the body represents. (3) The legislative body of the municipality or the executive body of the county that took official action under subdivision (2) notifies the state health commissioner of: (A) the body's actions under subdivision (2); (B) the request that the state health commissioner declare a public health emergency; and (C) other measures taken concerning the epidemic that have proven ineffective. (4) The state health commissioner has declared a public health emergency for the county or municipality.

Sec. 6. A qualified entity that operates a program under this chapter must do the following: (1) Annually register the program in a manner prescribed by the state department with the: (A) state department; and

(B) local health department in the county where services will be provided by the qualified entity if the qualified entity is not the local health department. (2) Have one (1) of the following licensed in Indiana provide oversight to the qualified entity's programs: (A) A physician. (B) A registered nurse. (C) A physician assistant. (3) Store and dispose of all syringes and needles collected in a safe and legal manner.

(4) Provide education and training on drug overdose response and treatment, including the administration of an overdose intervention drug. (5) Provide drug addiction treatment information and referrals to drug treatment programs, including programs in the local area and programs that offer medication assisted treatment that includes a federal Food and Drug Administration approved long acting, nonaddictive medication for the treatment of opioid or alcohol dependence. (6) Provide syringe and needle distribution and collection without collecting or recording personally identifiable information. (7) Operate in a manner consistent with public health and safety. (8) Ensure the program is medically appropriate and part of a comprehensive public health response.

Sec. 7. (a) The following may terminate the approval of a qualified entity: (1) The legislative body of the municipality, the executive body of the county, or the local health department that approved the qualified entity. (2) The state health commissioner, if the state health commissioner determines that the qualified entity has failed to comply with section 6 of this chapter. (b) If a person described in subsection (a)(1) or (a)(2) terminates the approval of a qualified entity, the person shall notify the other person with authority to terminate that is described in subsection (a) of the termination.

Sec. 8. A state agency may not provide funds to a qualified entity to purchase or otherwise acquire hypodermic syringes or needles for a program under this chapter.

Sec. 9. (a) A law enforcement officer may not stop, search, or seize an individual based on the fact the individual has attended a program under this chapter. (b) The fact an individual has attended a program under this chapter may not be the basis for probable cause by a law enforcement officer.

Sec. 10. A program shall file a quarterly report with the state department. The report must contain the following information listed on a daily basis and by the location, identified by the postal ZIP code, where the program distributed and collected syringes and needles: (1) The number of individuals served. (2) The number of syringes and needles collected. (3) The number of syringes and needles distributed. The state department may request that a qualified entity supply additional information concerning the program operated by the qualified entity.

Sec. 11. (a) If the state health commissioner receives a request to declare a public health emergency under this chapter, the state health commissioner shall approve, deny, or request additional information concerning the request under section 5 of this chapter not later than ten (10) calendar days from the date the request is submitted to the state health commissioner. If additional information is: (1) requested by the state health commissioner; and (2) provided by the entity seeking the declaration; the state health commissioner shall approve or deny the request not later than ten (10) calendar days from the submission date of the additional information. (b) A public health emergency declared under this section may remain in effect for not more than one (1) year from the date the public health emergency is declared. However, the state health commissioner may renew the declaration of a public health emergency upon the request of the executive body of the county or the legislative body of the municipality that requested the initial declaration.

Sec. 12. Before November 1 of each year, the state department shall submit a report concerning syringe exchange programs operated under this chapter to the governor and to the general assembly in an electronic format under IC 5-14-6.

Sec. 13. This chapter may not be construed to preclude the governor from taking any action within the governor's authority.

Sec. 14. This chapter expires July 1, 2019.

## **National Resources**

There are a number of national organizations and resources available to local health departments considering an SEP when determining the most appropriate model for their community.

### **National Alliance of State and Territorial AIDS Directors (NASTAD) and Urban Coalition for HIV/AIDS Prevention Services (UCHAPS)**

~ Syringe Services Program Guidelines for Development and Implementation for State and Local Health Departments

<http://www.uchaps.org/assets/NASTAD-UCHAPS-SSPGuidelines-8-2012.pdf>

### **Harm Reduction Coalition**

~ Harm Reduction Coalition Resource Page

<http://harmreduction.org/our-resources/>

### **North American Syringe Exchange Network**

~ National Directory of Syringe Exchange Programs and Resources

<https://nasen.org/>

### **New York State Department of Health**

~ Syringe Access and Disposal Guidance -

[https://www.health.ny.gov/diseases/aids/consumers/prevention/needles\\_syringes/](https://www.health.ny.gov/diseases/aids/consumers/prevention/needles_syringes/)

### **New Jersey State Department of Health**

~ Syringe Access Program Report/Information-

<http://www.nj.gov/health/aids/sapreport.shtml>

### **Seattle and King County Drug Use and Harm Reduction Resources**

~ Access and Disposal Resources and Harm Reduction Materials for Users

<http://www.kingcounty.gov/healthservices/health/communicable/hiv/HarmReduction.aspx>

## **Indiana State Department of Health Resources**

The Indiana State Department of Health has a number of resources available to local communities to assist in determining if an HIV and/or HCV epidemic is occurring in their area and technical assistance to include but not limited to program planning, implementation, and evaluation is available for those counties and municipalities considering a SEP.

### **I.) Spotlight on HIV/STD/Viral Hepatitis Semi-Annual Reports**

Semi-annually, the ISDH compiles the Spotlight Report and disseminates it via the ISDH website and presentations at the HIV Community Planning Group and other stakeholders as appropriate.

The most recent Spotlight Report as well as those for previous years is available at the following web address: <http://www.in.gov/isdh/23266.htm>

### **II.) County Profiles**

The ISDH has created a profile of each county's HIV, STD, and hepatitis data for use in better understanding trends of disease over time and to support counties and municipalities in determining if they meet the requirements to apply for a SEP program. These profiles have been provided to each county health department and are available online at <http://www.in.gov/isdh/26680.htm> .

### **III.) Data Requests**

As noted, any entity can request data from the ISDH Office of Clinical Data and Research by utilizing the form found at <http://www.in.gov/isdh/23266.htm> or by calling, 317-233-7406.

### **IV.) ISDH Technical Assistance – SEP Support Staff**

ISDH technical assistance is available to local health departments (LHD) to support the establishment of SEPs in local communities. ISDH SEP technical assistance is provided by public health officials with experience in harm reduction interventions, and HIV, STD, and viral hepatitis prevention and testing strategies. Those LHDs requesting technical assistance should contact the ISDH Division of HIV, STD, Viral Hepatitis at 317-233-7499. The needs of the LHD will then be assessed and the appropriate ISDH staff member(s) will be engaged to work with the LHD to meet their needs.

The ISDH technical assistance can assist with all aspects of program planning, implementation, and evaluation; however, state employees will not operate or staff SEPs. SEPs must be operated by LHDs, a municipality, or nonprofit entities with which the LHD has a contractual relationship.

## Syringe Exchange Program (SEP) Menu of Options

The following chart provides a menu of potential options for operating a SEP under Indiana SEA 46.

Citation: Syringe Services Program Guidelines for Development and Implementation for State and Local Health Departments

<http://www.uchaps.org/assets/NASTAD-UCHAPS-SSPGuidelines-8-2012.pdf>

| <b>Registration Model</b>  | <b>Transaction Models</b>  | <b>Delivery Methods</b>   |
|--|--|---|
| <p><b>* Unique Identifier-</b> At registration participants provide demographic data for program planning and monitoring purposes. Per SEA461, no personally identifiable information may be collected or maintained. A unique identifier is then provided to the participant. The identifier is presented at each time of exchange.</p> <p>A registration card may be provided to program participants containing their unique identifier. This card may be presented during SEP transactions and in the event that law enforcement officials request proof of SEP participation.</p> | <p style="text-align: center;"><b>The goal is 100% syringe coverage – 1 clean syringe for <u>every</u> injection of <u>every</u> PWI.</b></p> <p><b>*Negotiation Based</b> - Work with participant to identify number needed for specified period of use (week, month)</p> <p><b>*One for One</b> – Participants are provided one syringe for every syringe brought in for proper disposal.</p> <p><b>*One for One Plus</b> – Participants are provided one syringe for every syringe brought in for proper disposal and an additional amount negotiated with the SEP.</p> | <p><b>* Storefront</b> – Transactions take place in an office or storefront.</p> <p><b>* Mobile/Street</b> – Transactions take place in a mobile unit at prescheduled times and locations.</p> <p><b>* Peer Delivery</b> – “Champion(s)” are identified and provide delivery to participants based on a schedule (or are “on call” in some communities.) This option is to be used in conjunction with another model (e.g.; storefront).</p> <p><b>* Pharmacy</b> – Transactions take place in participating pharmacies. Participants typically pay for the syringes obtained.</p> <p><b>* Pharmacy Voucher</b> –SEP provides participants with vouchers to obtain syringes from participating pharmacies as a component of multi-stakeholder agreements.</p> |
| <p><b>All SEPs MUST include counseling and/or referral for substance abuse treatment, HIV, STD, -and viral hepatitis testing, medical care, and other resources (i.e. food, housing, etc.) See additional requirements for Indiana SEPs in I.C. 16-41-7.5-6.</b></p>   |  |   |

## **Syringe Exchange Program Development Checklist for Local Health Departments**

- The local health officer or executive director has declared to the executive body of the county or municipality that (1) there is an epidemic of HIV and/or hepatitis C, (2) the primary mode of transmission of HIV and/or HCV is intravenous drug use, (3) and that an SEP is a medically appropriate response as part of a comprehensive control and prevention plan.
- The legislative body of the county or municipality has (1) conducted a public hearing allowing public testimony, (2) taken official action to request a public health emergency and request permission to operate an SEP from the Indiana State Health Commissioner, and (3) provided a plan for the implementation and evaluation of the SEP.
  - This request must include the following;
    - The above declaration by the local health officer or executive director.
    - The previous and current efforts taken to control and prevent transmission of disease to date.
- The local health officer or executive director and legislative body of the county or municipality should include the following elements to their syringe access plan to the Indiana State Health Commissioner in order for the proposal to be considered.
  - SEP short and long term goals and objectives.
  - Specify ownership of the SEP.
    - County Health Department.
    - County Commissioners.
    - Other entity.
  - The source of funding for the SEP.
  - The specific population that the SEP will serve.
  - The non-identifiable way in which participants will be monitored.
  - The location(s) of the SEP in the community.
    - Indicate if a mobile unit or satellite locations will be used.
  - The method by which participants will receive substance abuse treatment and care referrals, HIV, STD, viral hepatitis testing including any partner entities.
  - The transaction model to be used.
  - The method by which sharps and medical waste will be disposed.

- A list of other resources or materials that will be provided to participants.
  - Wound care kits.
  - Overdose prevention resources.
  - Others identified at the local level.
- The method by which the SEP will provide overdose prevention education and resources.
- Provide an explanation as to the comprehensive public health response that preceded and will accompany the SEP. Potential response activities may include but are not limited to, the following:
  - HIV, STD, viral hepatitis education and outreach,
  - Establishing or increasing counseling and testing for HIV, STDs, viral hepatitis,
  - Providing health navigators to assist with insurance enrollment.
  - Providing access to resources including but not limited to birth certificates, identification cards, and/or vaccinations.
  - Access to behavioral health services.
- The Indiana State Health Commissioner has given permission for the implementation of the SEP.
- The SEP is implemented at the local level.
- Under SEA 461, the operating entity of the SEP must provide quarterly reports to the ISDH including the following listed on a daily basis and by the postal zip code where the SEP operates:
  - The number of participants served.
  - The number of syringes and sharps collected.
  - The number of syringes and sharps distributed.
- Annually, and upon request, the operating entity of the SEP must provide the ISDH with a status report for the evaluation of the SEP.
- Annually or upon expiration of the SEP operating period the operating entity of the SEP will provide the Indiana State Health Commissioner with a request for renewal, if desired, in accordance with the requirements of the law.



**Michael R. Pence**  
Governor

**Jerome M. Adams, MD, MPH**  
State Health Commissioner

## Indiana Syringe Exchange Program (“SEP”) Review and Guidance Pursuant to I.C. 16-41-7.5

|   |  |   |   |   |
|---|--|---|---|---|
| County Submitting Request:<br><br>_____ | Date of County’s Initial Submission to ISDH:<br><br>____/____/____ | ISDH’s Initial Reply to County Due/Sent:<br><br>____/____/____ (Date Due)<br><br>____/____/____ (Date Sent) | ISDH Requested County to Submit Additional Information (yes/no):<br><br>_____ |   |
|   | Date of County’s 2nd Submission to ISDH:<br><br>____/____/____     | ISDH’s 2nd Reply to County Due/Sent:<br><br>____/____/____ (Date Due)<br><br>____/____/____ (Date Sent)     | ISDH Approved (yes/no)?<br><br>_____  | Effective Dates of Public Health Emergency:<br><br>____/____/____ (becomes effective)<br><br>____/____/____ (expires) |
| Reviewer: _____                         |  |   |   |   |
| <b>Reference to</b>                     | <b>Statutory Requirement</b>                                       | <b>Guidance on Statutory Requirement</b>  | <b>Compliant</b>  | <b>Comments</b>   |

| Statute                              |  | with the Requirement? (yes/no)   |
|--------------------------------------|--|--|
| IC 16-41-7.5-3<br>Qualified Entity   | <p>A QE means any of the following:</p> <p>A local health department (“LHD”);</p> <p>A municipality that operates the SEP within its boundaries;</p> <p>A nonprofit organization that operates a program and has been approved by official action to operate the program by:</p> <p>(1) the LHD;</p> <p>(2) the executive body of the county; or</p> <p>(3) the legislative body of a municipality for the operation of a program within the boundaries of the municipality.</p> | <p><i>Only a <u>qualified entity</u> (“QE”) may operate an SEP. The entity submitting a proposal to operate an SEP must meet the statutory definition of a “qualified entity” (“QE”).</i></p> <p><i>Most counties operate the SEP through their LHD, but the LHD or county may choose to contract with a 3<sup>rd</sup> party nonprofit to operate the SEP. In this instance, the county or LHD must take official action to approve the nonprofit as evidenced by a board resolution or equivalent. Relationships with 3<sup>rd</sup> party nonprofits should be outlined in detail in a contract that requires the 3<sup>rd</sup> party to comply with each enumerated element of the statute.</i></p> |
| IC 16-41-7.5-4(a)<br>Location of SEP | <p>A QE may operate an SEP only within a county where a public health emergency has been declared and <u>may not operate an SEP outside</u></p>  | <p><i>A QE may not operate an SEP outside of the jurisdictional area of the governmental body that approved the QE and declared the public health emergency. For example, a county SEP must operate and provide</i></p>  |

|  |   |  |
|--|---|--|
|  | <b>of the jurisdictional area of the governmental body that approved the QE.</b>  | <i>services only within its county borders. The same applies to a city, town or other municipality. However, there is no limitation imposed by law on an SEP serving persons that have an outside county of residence but who come to the county SEP seeking services.</i>   |
| <b>IC 16-41-7.5-4(b)</b>                             | <b>A QE that meets the requirements in (a) and complies with the requirements of this chapter may operate a program.</b>  | <i>In order to operate an SEP, a QE must remain continuously compliant with <u>all</u> requirements of I.C. 16-41-7.5.</i>   |
| <b>IC 16-41-7.5-5(1) Requirements to Operate SEP</b> | <b>Before a QE may operate a program, the following shall occur:<br/>(1) The local health officer (“LHO”) or the executive director must declare to the executive body of the county or the legislative body of the municipality the following:</b> | <i>Before an SEP can begin operating, the LHO, County/Municipality and the State Health Commissioner have several responsibilities to perform. The first step is for the LHO to draft a letter or other form of communication directed to the County Commissioners that includes several required declarations or attestations that are stated in a manner that is substantially identical to the language in the statute.</i> |
| <b>IC 16-41-7.5-5(1)(A)</b>                          | <b>There is an epidemic of hepatitis C or HIV.</b>  | <i>The first declaration required of the LHO in the letter relates to the existence of an <u>epidemic of hepatitis C, HIV or both</u>. There is often a high rate of hepatitis C/HIV co-infection, but not always. The LHO must state in his/her declaration whether one or both are present.</i>  |
| <b>IC 16-41-7.5-</b>                                 | <b>That the primary mode of</b>   | <i>Secondly, the LHO must declare in the</i>   |

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5(1)(B)

**transmission of hepatitis C or HIV in the county is through intravenous drug use.**

*letter that the primary mode of transmission of the communicable disease is via intravenous drug use.*

IC 16-41-7.5-5(1)(C)

**That a SEP is medically appropriate as part of a comprehensive public health response.**

*Lastly, the LHO must declare that, in his/her medical opinion, implementing a SEP is “medically appropriate as part of a comprehensive public health response.”*

*A SEP is meant to be only part of a larger, comprehensive, public health plan and not the sole element of harm reduction. The county should plan for other medically appropriate activities based upon the needs of the population to be served.*

*Counties may consider the following as examples of medically-appropriate elements of an SEP: testing, referrals to treatment programs, developing a comprehensive assessment for intake, raising awareness, giving supplies, training, gathering support from community partners, referrals to auxiliary services such as food and housing as appropriate.*

IC 16-41-7.5-5(2)

**The legislative body of the municipality or the executive body of the county must do the following:**

*Now that the LHO has submitted his/her declarations to the County Commissioners, the Commissioners must act upon them by involving the community in the decision to operate an SEP.*

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**IC 16-41-7.5-5(2)(A)**

**Conduct a public hearing that allows for public testimony.**

*The law requires that a public hearing be held whereby the citizens have a chance to hear the proposal, testify and ask questions. The county should include in its SEP proposal either written minutes of the public meeting, or a written attestation (in the form of a letter, declaration, or otherwise), that the public meeting occurred, when, where, time, and whether meaningful opportunity for public comment was provided.*

**IC 16-41-7.5-5(2)(B)**

**Take official action adopting the declarations under (1) made by the LHO or the executive director in consideration of the public health for the area that the body represents.**

*After the public hearing has been held, the Commissioners must formally agree with and adopt or pass the declarations made by the LHO. This "official action" taken by the county should be in writing in the form of a letter, declaration, resolution or otherwise that will accompany the SEP proposal.*

**IC 16-41-7.5-5(3)**

**The legislative body of the municipality or the executive body of the county that took official action under (2) then notifies the State Health Commissioner of:**

**Its actions under (2); the request that the state health commissioner declare a public health**

*The county, as part of their SEP proposal, should include a letter addressed to the State Health Commissioner that outlines the steps they have taken to hold a public meeting and to adopt the declarations of the LHO, to request that the State Health Commissioner declare a public health emergency, and an explanation of other measures taken concerning the epidemic that have proven ineffective. The county should describe any and all efforts that proved to be ineffective, regardless of*

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|                              |   |   |
|------------------------------|---|---|
|                              | <b>emergency; and other measures taken concerning the epidemic that have proven ineffective.</b>            | <i>whether those efforts were discontinued or are ongoing.<sup>1</sup></i>  |
| <b>IC 16-41-7.5-5(4)</b>     | <b>The State Health Commissioner has declared a public health emergency for the county or municipality.</b> | <i>The State Health Commissioner signs a letter declaring a public health emergency for the county, and includes the date on which the emergency will commence and expire. The emergency may be declared for a period not to exceed one (1) year, but may be renewed upon request of the executive body of the county or the legislative body of the municipality that requested the initial declaration.</i><br><br><i>The State Health Commissioner must respond within 10 calendar days by denying the request, approving and declaring the emergency, or requesting more information. (see IC 16-41-7.5-11)</i> |
| <b>IC 16-41-7.5-6 Duties</b> | <b>A QE that operates a program under this chapter</b>  | <i>ISDH has developed a confidential, web-based SEP Database for the purpose of</i>   |

<sup>1</sup> PROPOSAL DRAFTING: When submitting a proposal to the State Health Commissioner, consider also including the following as applicable: short and long-term goals of the SEP; funding source(s); characteristics/demographics of the specific population that the SEP will serve; the location(s) of the SEP services and whether mobile/satellite and/or stationary locations will be used; the method by which participants will receive substance abuse treatment, care referrals and HIV/STD/HCV testing; the name of the transaction model or type you plan to use; sharps/medical waste disposal method; list of resources to be provided to participants (wound care kits, overdose prevention, naloxone, etc.), method of providing overdose prevention education; detail about previous and ongoing efforts such as education/outreach, counseling, testing (in jails and otherwise); providing ancillary social services such as access to birth certificates, identification cards or vaccinations; behavioral health services; perceived barriers to past and future success and plans to mitigate same; staffing particulars and information about partners; identification of medical oversight personnel; methods that will employed to ensure that the SEP is to be operated in a manner consistent with public health and safety; and how you will ensure the program is medically appropriate as part of a comprehensive public health response.

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**must do the following:**

**(1) Annually register the program in a manner prescribed by the state department; and**

**(2) Have one of the following licensed in Indiana provide oversight to the QE's programs: (a) A physician; (b) A registered nurse; (c) A physician assistant.**

**(3) Store and dispose of all syringes and needles collected in a safe and legal manner.**

**(4) Provide education and training on drug overdose response and treatment, including the administration of an overdose intervention drug.**

**(5) Provide drug addiction treatment information and referrals to drug treatment programs, including programs in the local area**

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*registration, data entry and reporting. SEPs are required to utilize this database in order to comply with IC 16-41-7.5-6. Training and User Access is available through ISDH SEP Support Staff. A SEP must include in their proposal, the identity of the person who will serve in a medical oversight role. It will be this person's responsibility to ensure that the SEP is operated in a medically appropriate way. This person will take into account the needs of the community when staffing the SEP, and put into place appropriate policies and procedures, as well performing other functions as deemed appropriate by the county.*

*The SEP should establish guidelines and implement practices that ensure the safety of all concerned, to include, at a minimum, Universal Precautions.*

*See Training/Treatment Resources on <https://optin.in.gov/>*

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**and programs that offer medication assisted treatment that includes a federal Food and Drug Administration approved long acting, nonaddictive medication for the treatment of opioid or alcohol dependence.**

**(6) Provide syringe and needle distribution and collection without collecting or recording personally identifiable information.**

*The SEP Database will help the SEP to maintain confidentiality. The SEP should put into place all reasonable policies and procedures necessary to ensure the confidentiality of SEP participants, as well as provide training and obtain signed confidentiality forms from all Users.*

**(7) Operate in a manner consistent with public health and safety.**

**(8) Ensure the program is medically appropriate and part of a comprehensive public health response.**

*The SEPs medical supervisor should play a key role in ensuring medical appropriateness and educating staff on the right standard of care for the SEP. It is important to provide SEP services as an integral part of the county's overall plan to combat the epidemic. It is not expected that the SEP be the only method of reducing harm, but instead, be part of a larger and comprehensive approach to public health.*

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**IC 16-41-7.5-7 (a) The following may**

|  |  |  |
|--|--|--|
| <b>Termination</b>                           | <p>terminate the approval of a QE:</p>   |  |
|  | <p>(1)The legislative body of the municipality, the executive body of the county, or the local health department that approved the QE;</p> <p>(2)The state health commissioner, if the state health commissioner determines that the QE has failed to comply with section 6 of this chapter;</p> <p>(b)If a person described in (a)(1) or (a)(2) terminates the approval of a QE, the person shall notify the other person with authority to terminate that is described in subsection (a) of the termination.</p> |  |
| <b>IC 16-41-7.5-8<br/>Use of State Funds</b> | <p>A state may not provide funds to a QE to purchase or otherwise acquire hypodermic syringes or needles for a program under this chapter.</p>   | <p><i>Indiana state law precludes any state agency, including ISDH, from subsidizing the acquisition of syringes/needles. The state law substantially mirrors a federal ban on direct funding of syringes and needles.</i></p> |
| <b>IC 16-41-7.5-9<br/>Program</b>            | <p>(a)A law enforcement officer may not stop,</p>  | <p><i>Counties are permitted to exercise discretion in their law enforcement</i></p>   |

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**Attendees; law Enforcement**

**search, or seize an individual based on the fact the individual has attended a program under this chapter.**

**(b)The fact an individual has attended a program under this chapter may not be the basis for probable cause by a law enforcement officer.**

*activities when arresting/prosecuting individuals who are viably participating in a SEP. Current participation is often evidenced by possession of a participation card, but a card is not mandatory.*

**IC 16-41-7.5-10 Program Reports**

**A SEP must file a quarterly report with the state department. The report must contain the following information listed on a daily basis and by the location (by ZIP code), where the program distributed and collected syringes and needles:**

**(1)The number of individuals served;**

**(2)The number of syringes and needles collected; and**

**(3)The number of syringes and needles distributed.**

*ISDH will collect quarterly reports. Some of the data may be stored and easy to submit from the SEP Database, whereas other information may need to be compiled and submitted using other means. Information on the number of individuals served, the number of syringes collected, and the number of syringes distributed needs to be compiled on a per day basis and identified by the ZIP code of the location where distribution took place (not the ZIP code of participants' residence).*

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**The state department may request that a QE supply additional information concerning the SEP operated by the QE.**

*It is likely that, as SEPs gain traction, ISDH and state legislatures will seek additional information. There is no statutory limitation on ISDH's ability to request information regarding a county's SEP.*

**IC 16-41-7.5-11(a)  
Request for Public Health Emergency; Approval and Denial; Expiration**

**(a) If the state health commissioner receives a request to declare a public health emergency under this chapter, the state health commissioner shall approve, deny, or request additional information concerning the request under section 5 of this chapter not later than ten (10) calendar days from the date the request is submitted to the state health commissioner. If additional information is: (1) requested by the state health commissioner; and (2) provided by the entity seeking the declaration; the state health commissioner shall approve or deny the request not later than ten (10) calendar days from the submission date of the additional information.**

*ISDH has a team of qualified individuals who begin review of a SEP proposal upon receipt. The team submits its recommendations to the state health commissioner. ISDH communicates directly with the LHD/county regarding any deficiencies and requests for more information. If no further information is required, a decision is made within ten days. Ultimately, the decision as to whether the proposal supports a declaration of a public health emergency is communicated both verbally and in writing to the LHD/county.*

*It is important to note that once a SEP proposal is received by the state health commissioner, a response is due from him/her within ten (10) calendar days (holidays and weekends are included in the calculation).*

*The ten (10) calendar days begin to accrue once the state health commissioner is in receipt of the additional information requested. Holidays and weekends are included in the calculation.*

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**(b)A public health emergency declared under this section may remain in effect for not more than one (1) year from the date the public health emergency is declared. However, the state health commissioner may renew the declaration of a public health emergency upon the request of the executive body of the county or the legislative body of the municipality that requested the initial declaration.**

*Letters of approval to a QE should include the start and stop dates of the one (1) year period. The county may submit a formal request for renewal prior to the end of the one (1) year period. A request for renewal should be accompanied by supporting documentation and submitted in a timely fashion (approximately 60 days prior to the termination of the initial one (1) year period) in order to give ISDH ample time for review without causing a lapse in the emergency declaration.*

**IC 16-41-7.5-12 Before November 1 each year, the state department shall submit a report concerning syringe exchange programs operated under this chapter to the governor and the general assembly in an electronic format per IC 5-14-6.**

**IC 16-41-7.5-13 This chapter may not be construed to preclude the governor from taking any action within the governor's authority.**

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## **Indiana State Department of Health Syringe Exchange Program Database Access Procedure**

### **Background and Purpose:**

Syringe Exchange Programs (“SEP”) approved by the State Health Commissioner under IC 16-41-7.5 are required to annually register with ISDH. They must also collect, maintain and report on specific data regarding SEP participants. This procedure provides a framework by which ISDH can promote and support SEP registration and data collection and ensure data security and confidentiality in partnership with approved SEPs.

### **Definitions:**

**Syringe Exchange Program (“SEP”):** SEPs, also known as syringe access or needle exchange programs, are a form of harm reduction intervention whereby clean syringes, supplies and other services are provided to injection drug users to reduce the potential transmission of blood-borne pathogens, such as HIV, hepatitis C virus, and hepatitis B virus.

**Qualified Entity (“QE”):** A QE is (1) a local health department; (2) a municipality (as defined by IC 36-1-2-11) that operates a program within the boundaries of the municipality; (3) a nonprofit organization that operates a program and has been approved by official action to operate the program by:

- (A) The local health department;
- (B) The executive body of the county; or
- (C) The legislative body of a municipality for the operation of a program within the boundaries of the municipality.

**SEP Support Staff:** SEP Support Staff is ISDH staff that is dedicated to the task of supporting SEP program administration throughout Indiana.

**SEP Database:** SEP Database is the ISDH-created, secure web-based database used to store and track data collected and maintained by each approved SEP.

**SEP Database Users (“Users”):** Users are persons duly authorized by the SEP to enter data and/or access the SEP Database in a confidential manner in order to perform duties on behalf of the SEP.

### **Process:**

- The State Health Commissioner approves a county’s proposal to provide syringe exchange services under IC 16-41-7.5 and declares a public health emergency. By virtue of this act, the county becomes a Qualified Entity (“QE”) for the purpose of operating an SEP.
- The QE provides to SEP Support Staff the *SEP Database User Request/Approval Form* and signed *Confidentiality and Release of Liability Statement* for each User with a need to access the SEP Database. The forms will include, at a minimum, the reason for access, an authorized signature, and dates that each User’s access is authorized, to include dates of access commencement and termination.
- SEP Support Staff will verify each request and record, track and store all completed forms and other necessary documentation in a confidential manner, and coordinate commencement and termination of access with the ISDH Office of Technology and Compliance.
- SEP Support Staff and the QE will establish a time, location, and roster for SEP Database training.
- Before the training, SEP Support Staff, together with the ISDH Office of Technology and Compliance, will create a Gateway account and communicate usernames/passwords to each User via the email addresses provided.
- SEP Support Staff will conduct the SEP Database training.

- The QE will immediately notify SEP Support Staff in the event a User's access is to be terminated earlier than previously indicated.
- SEP Support Staff will appropriately manage access to the SEP Database and ensure that related policies and procedures are updated and distributed as needed.
- In the event of a breach or potential breach of confidential information stored in the SEP Database or otherwise belonging to or about a SEP participant, the QE and/or SEP Support Staff will immediately alert the ISDH Office of Legal Affairs.

**CONFIDENTIALITY AND RELEASE OF LIABILITY STATEMENT**  
**\_\_\_\_\_ County Health Department (“LHD”)**

I. Confidentiality of Health and Proprietary Information. The following statement concerns the confidentiality of personal, proprietary, medical, epidemiological and/or Protected Health Information (PHI) and other information or data reported to, generated, maintained or owned by or otherwise in the possession of, the LHD (together known as “Confidential Information”). This statement applies to all, employees or agents thereof (“Employees”) and non-employees such as visitors, vendors, contractors, volunteers, students and student interns (“Non-Employees”) who are providing services, visiting, and/or shadowing with or on behalf of the LHD that may come into possession of Confidential Information in any form whatsoever.

Except as provided by law, all such Confidential Information, regardless of how obtained, shall be secured and maintained in a strict and confidential manner. Furthermore, Confidential Information may be used only in furtherance of assigned duties and will not be disclosed to others or discussed with third parties without the prior written consent of the LHD. Please be advised that there are serious penalties for violating the aforementioned statement including, but not limited to, the following:

1.1 Federal Penalties. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its related Privacy and Security Standards, directly address the protection and confidentiality of PHI. PHI may not be used or disclosed by Employees or Non-Employees unless required, permitted, or specifically authorized by the LHD under these guidelines. Penalties for violation of HIPAA may include civil monetary penalties and federal criminal penalties.

1.2 State Penalties. Except as provided by IC 16-41-8-1, medical, or epidemiological information involving a communicable disease as set forth under 410 IAC 1-2.3, shall not be used or disclosed by Employees or Non-Employees and shall be secured and maintained in a strict and confidential manner. Failure to appropriately maintain and secure such information may result in the imposition of penalties provided under IC 16-41-8-1 or otherwise.

1.3 Other Penalties. Unauthorized uses or disclosures of Confidential Information by Employees or Non-Employees to include inappropriate access, misuse, theft, destruction, alteration, or sabotage of such information, may result in immediate removal from the premises and/or revocation of current and future visiting/working privileges, and may lead to legal action and/or a duty to mitigate damages.

II. Waiver of Liability. The undersigned acknowledges and agrees to hold the LHD, its agents and employees, harmless from any and all acts or harm that may occur to his/her person or property while visiting or working on the premises and/or off-site.

**I, the undersigned, acknowledge that I have read and understand the aforementioned statement and agree to abide by its terms.**

\_\_\_\_\_  
Name (print)

Circle One:      Employee      Non-Employee

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Indiana State Department of Health**  
**Syringe Exchange Program Renewal Process and Template**

**I. Introduction**

This document serves as a supplement to the Syringe Exchange Renewal Procedure outlining the process that counties should complete when requesting a renewal of the public health emergency declaration by the State Health Commissioner.

**II. General Guidance**

- a. All documentation should be submitted at least 60 days prior to the end of the then current public health declaration.
- b. All documents should be sent electronically to Tami Barrett ([tbarrett@isdh.in.gov](mailto:tbarrett@isdh.in.gov))
- c. All documents should be type written.
- d. All documents with multiple pages should be numbered.

**III. Template**

- Cover letter including the following information:
  - o The name and contact information of the primary point of contact for the SEP.
  - o The name of the Qualified Entity (QE) currently operating the SEP and the name of the individual providing medical oversight as described in the Renewal SOP.
    - It should be specifically noted if the individual providing medical oversight and/or the QE changed.
  - o A brief narrative highlighting the strengths and challenges faced by the SEP in the previous year.
    - Examples of this may include: Number of participants transitioned into substance abuse treatment and/or medical care, new or strengthened community partnerships, challenges developing trust within the community and/or among potential participants, etc.
  - o Discussion of previous year's goals and goals for the upcoming year including the process used to develop those goals.
  - o Any needs for technical guidance and/or support.
  - o Any information that you would like to share or feel might be helpful in assessing the progress of the SEP to date.
  - o The length of time that the county is requesting to continue to operate the SEP, which may not exceed one (1) year.
  
- A written statement from the local health officer ("LHO") or the executive director to the executive body of the county or the legislative body of the municipality to the effect that: (a) the epidemic of Hepatitis C and/or HIV remains in effect; (b) the primary mode of transmission of Hepatitis C and/or HIV in the county is through intravenous drug use; and (c) an extension of the SEP is medically appropriate as part of a comprehensive public health response.
  
- The LHO shall also state whether he/she recommends that the SEP continue to operate in substantially the same manner as previously approved, or in the alternative, a statement that sets forth any changes proposed to the operation of the SEP to curtail the epidemic.
  
- A copy of the most recent quarterly report required by I.C. 16-41-7.5-10 that has been updated to include data gathered from that report to the date of submission, as well as

other evidence or narrative available to demonstrate the SEP's impact on the health of the persons served and curtailment of the epidemic.

- An attestation that the SEP has, at all times, been operating and will continue to operate during the extension period in a manner consistent with I.C. 16-41-7.5-6.
- The written approval of the request for extension of the public health emergency declaration by the executive body of the county or the legislative body of the municipality that adopted the initial declaration by the LHO.

#### **IV. Contact Information**

Should you have any questions during the reapplication process please contact:

Erika Chapman, HIV Surveillance, Service Integration, and Harm Reduction Coordinator at 317-234-3122 or [echapman@isdh.in.gov](mailto:echapman@isdh.in.gov) .

Your question(s) will then be responded to or routed for response.

## V. Letter Template

*(Applicant Letterhead)*

Date

Dr. Jerome Adams, MD, MPH  
Indiana State Health Commissioner  
2 North Meridian Street  
Indianapolis, Indiana 46204

Dear Dr. Adams,

*(Insert County or Municipality)* would like to formally request an extension of the public health emergency declared on *(insert original approval date)* for a period of *(one year or less)* based upon the continued epidemic of *(HIV, HCV, or both)*. During our initial application period our *(HIV, HCV, or both)* numbers were and are currently *(insert most recent HIV, HCV, or both numbers)*. As documented below and in the attached attestations, it has been determined that the public health of *(insert county or municipality)* can be improved by the continuation of the syringe exchange program.

Attached to this letter are the following required documents as described in the renewal guidance:

- Written statement from the local health officer,
- A copy of the most recent quarterly report,
- An attestation that the syringe exchange program has and will continue to operate according to the law,
- Written request for an extension by *(the executive body of the county or the legislative body of the municipality)* that adopted the initial declaration by the local health officer.

*(Insert name and contact information of individual responsible for medical oversight)* will act as medical oversight for the *(insert name of qualified entity)* during the requested renewal period.

*(Insert paragraph highlighting the strengths and positive outcomes of note during the previous approval period. These can include: number of participants transitioned into substance abuse treatment and/or medical care, new or strengthened community partnerships, etc.)*

***(Insert paragraph highlighting the challenges encountered by the syringe exchange program in the previous approval period. These can include: challenges developing trust within the community and/or among potential participants, etc.)***

The primary goals of the ***(insert county name)*** syringe exchange program in the requested renewal period are as follows ***(Please outline each goal using specific, measurable, attainable, relevant, and time relevant (SMART) language. You may use as few or as many goals and objectives as are appropriate. ),***

***Goal 1:***

***Objective 1-***

***Objective 2-***

***Objective 3 –***

***Goal 2:***

***Objective 1-***

***Objective 2-***

***Objective 3 –***

***Goal 3:***

***Objective 1-***

***Objective 2-***

***Objective 3 –***

The ***(insert county or municipality)*** syringe exchange would like to request technical assistance with ***(insert needs)***.

Should you have any outstanding questions please contact ***(name and contact information of primary contact)***. Thank you, Dr. Adams, for your time and consideration of our syringe exchange program application.

Sincerely,

***(Insert name and title)***