



West Virginia Bureau for Public Health

**Harm Reduction Program (HRP)
Guidelines and Certification Procedures**

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Kentucky Harm Reduction and
Harm Reduction Program (HRHRP)
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TABLE OF CONTENTS

INTRODUCTION	5
CHAPTER 1. LAYING THE GROUNDWORK FOR PROGRAM IMPLEMENTATION.....	6
1.1 Assessing the Community’s Need for HRPs	7
1.2 Assessing the Community’s Readiness for HRPs.....	7
1.3 Building Community Support for HRPs.....	7
1.4 An Opportunity for Collaboration	8
1.5 Waste Management for Syringe Disposal.....	9
CHAPTER 2. REACHING POTENTIAL HRP PARTICIPANTS.....	9
2.1 Street Outreach.....	9
2.2 Emergency Departments	10
2.3 Pharmacies and Pharmacists	10
CHAPTER 3. OPERATING PRINCIPLES OF HRPS.....	10
3.1 Program Registration	10
TABLE 1. Types of Information Potentially Collected at HRP Intake.....	12
3.2 Syringe Transaction Models.....	13
3.3 Worker and Volunteer Safety	15
3.4 Health and Social Services: Provision and Linkage	16
3.5 Strategies to Increase Access to Services.....	17
3.6 Specific Health and Social Services	17
3.7 Provision or Linkage	19
CHAPTER 4. SERVICE DELIVERY MODELS	20

4.1 Fixed Site	20
4.2 Collaboration or Satellite Structure.....	21
4.3 Mobile/Street Based Programs.....	22
4.4 Delivery Models	23
4.5 Using Multiple Program Models	24
CHAPTER 5. MONITORING HRP PROGRAMS	24
5.1 Process Monitoring	25
5.2 Outcome Monitoring.....	26
5.3 Program Quality Improvement	27
TABLE 2. Basic and Advanced Training Topics for HRP Staff	28
CHAPTER 6. CERTIFICATION OF HARM REDUCTION PROGRAMS	29
1. PURPOSE	29
2. SCOPE.....	29
3. DEFINITIONS.....	29
4. HRP CERTIFICATION PROCESS.	30
APPENDIX A	37
Appendix A. SAMPLE MONITORING AND EVALUATION PROCESSES.....	38

Guidelines for Implementing Harm Reduction Programs

INTRODUCTION

Harm Reduction Programs (HRPs) are comprehensive programs designed to provide safe disposal of needles for injection drug users (IDUs), testing for blood borne viral infections for those at greater risk of infection due to injection drug use, supply clean needles to lessen the possibility of infection from shared needles, and to help IDUs find treatment and social services with which they may not otherwise be familiar. HRPs can also provide resources and education to the family members and friends of IDUs.

HRPs are designed to reduce the likelihood of transmission of blood borne diseases by providing sterile injection equipment to IDUs and reducing the potential of sharing syringes among this population. IDUs account for approximately 8 percent of new HIV infections in the United States¹ and over one half (68.2 percent) of newly reported acute hepatitis C virus (HCV) infections are IDU related.² Currently, there are no commercially available vaccines for HIV and HCV.

Scientific evidence indicates one of the most effective strategies for combating HIV infections among IDUs is ensuring access to sterile syringes by IDUs who cannot or will not stop injecting drugs. The Institute of Medicine of the Academy of Sciences has said: “For injection clients who cannot or will not stop injecting drugs, the once-only use of sterile needles and syringes remains the safest, most effective approach for limiting HIV transmission”.³

Therefore, the public health benefits of HRPs arise from (1) removing potentially infectious syringes from the community, (2) providing IDUs with sterile syringes and other clean injection equipment, and (3) distributing condoms. Several studies have found that HRPs reduce HIV incidence among IDUs. Most studies of injection-related HIV and HCV risks have found HRPs to be associated with a lower likelihood of syringe sharing or reductions in syringe sharing.⁴ Ecological studies have found that locales with HRPs tend to have lower HIV seroprevalence among IDUs, and one study reported that closing a HRP resulted in increased prevalence of HIV risk behaviors among IDUs. Other public health benefits of HRPs include the linkage of IDUs to critical services and programs and promoting integrative care among drug treatment programs, HIV/AIDS prevention and treatment services, HCV prevention and treatment programs and social and behavioral health services. The

¹ <http://www.cdc.gov/hiv/risk/idu.html>

² <http://www.cdc.gov/hepatitis/statistics/2014surveillance/commentary.htm#hepatitisC>

³ Preventing HIV Transmission: The role of sterile needles and bleach *N Engl J Med* 1997; 336:1035-1036 April 3, 1997 DOI: 10.1056/NEJM199704033361425

⁴ Greater Drug Injecting Risk for HIV, HBV, and HCV Infection in a City Where Syringe Exchange and Pharmacy Syringe Distribution are Illegal Alan Neaigus, Mingfang Zhao, V. Anna Gyarmathy, Linda Cisek, Samuel R. Friedman, Robert C. Baxter

evidence for the public health benefits of HRP is strong and consistent over time. HRP's have successfully operated in the United States since the late 1980s.

Syringe access saves lives and is cost effective. The CDC has stated a public health goal of 100% coverage, with all injections performed with a sterile syringe, noting that the one-time use of sterile syringes remains the most effective way to limit HIV transmission associated with injection drug use. HRP's reduce the spread of infection and address the personal and public health risks of injection drug use in a cost-effective, comprehensive fashion. The lifetime cost of medical care for a single new HIV infection is roughly \$385,200.⁵ The lifetime cost of treating someone with HCV is estimated between \$88,000 and 182,000.⁶ The average cost of a syringe is \$0.97, and the cost to prevent one HIV or one HCV infection via HRP is estimated between \$4,000 and \$12,000.⁷

HRPs are comprehensive service programs based on the harm reduction concept that include appropriate linkage and referral to substance abuse prevention and treatment services, behavioral health, blood borne pathogen prevention and treatment and other support services. Harm reduction is a set of practical strategies and ideas aimed at reducing the harm to the individual and society associated with drug use. Harm reduction incorporates a spectrum of strategies from safer use to meeting clients "where they are," addressing conditions of use along with the use itself.

CHAPTER 1. LAYING THE GROUNDWORK FOR PROGRAM IMPLEMENTATION

This chapter discusses the various factors that HRP entities will need to consider as they plan and implement HRP's in their jurisdictions, including the importance and necessity of assessing the community's need and readiness for HRP's, ways of working with law enforcement and strategies for building strong community relationships. General principles of community inclusion and creating programs and policies that are culturally and linguistically appropriate and reflect the makeup of the community should be incorporated. Any provider seeking the development of a HRP if not a local health department, the written approval from the local health department whose service area includes the location of the proposed HRP. A written statement from the county commission for the county in which the HRP is to be located that the county has not prohibited the operation of a harm reduction program by ordinance is also required.

All HRP's should be designed in a manner that will enable entities to effectively serve culturally diverse communities. Specifically, all program components, materials and marketing messages should reflect the history and culture of the target population and be linguistically-appropriate.

⁵ Harm Reduction Coalition, "Syringe Access,"

<http://www.harmreduction.org/article.php?list=type&type=49> (accessed October 21, 2010)

⁶ <http://www.medpagetoday.com/gastroenterology/hepatitis/44357>

⁷ Centers for Disease Control and Prevention, "Syringe Exchange Programs," 2005, http://www.cdc.gov/IDU/facts/AED_IDU_SYR.pdf (accessed November 17, 2010)

Additionally, providers should have a culturally competent workforce, including a diverse management team, have organizational policies that support the delivery of culturally competent services and care and a process for identifying if cultural competency goals have been met.

1.1 Assessing the Community’s Need for HRP

The first step in considering whether to implement a HRP is to determine whether the need exists in the HRP entity’s jurisdiction. Entities and community partners may identify IDUs as a target population by using community needs assessments of key epidemiological factors including HIV and/or HCV prevalence and demographics of risk groups and select the HRP as an appropriate intervention.

After the needs assessment is complete, HRP entities may work with community planning partners and other partners to (1) identify ways to tailor services based on the specific needs of special risk subgroups of IDUs in the community, (2) select the types of syringe distribution and service delivery models most appropriate given resources and context and (3) identify potential locations for HRPs. HRP entities may need to educate community partners about IDU-related epidemiological data and the importance of HRPs as an intervention to further address the shared goal of reducing the incidence of blood borne pathogens in the community.

1.2 Assessing the Community’s Readiness for HRP

Once the provider has determined that a HRP is needed to address the HIV/HCV prevention needs of IDUs, the next step is to assess whether the community is “ready for” or receptive to a HRP. Gaining community approval of a HRP is also a very important step. Community support is necessary before a HRP can be implemented. The following sections outline ways to build community support.

1.3 Building Community Support for HRP

Providing sterile syringes to IDUs has been shown to reduce sharing of syringes. Like other important public health interventions, in order to successfully implement HRPs, there must be an enabling environment consisting of support from key stakeholders such as selected public officials, other government agencies, the general public and consumers. Building community support for HRPs is an integral part of successful HRP implementation. A careful and systematic process can help build community support for HRPs, including assembling the facts and intervention options, assessing stakeholder knowledge and attitudes, and developing an action plan. HRPs operate best in a supportive community environment. Staff, volunteers and HRP participants should be involved in community engagement programs. Several strategies have proven effective across a broad range of programs and locations, including: (1) building relationships with community leaders, officials,

opinion leaders, law enforcement, public health officials, religious leaders and groups, and businesses most affected by HRP site location; (2) educating the community about drug use, HRPs, and safe syringe disposal; (3) framing messages about HRPs to emphasize the community benefits, including reduced HIV and HCV infection rates, proper syringe disposal, and cost-effectiveness; (4) understanding and addressing the concerns of resistant stakeholders in the community; (5) recruiting staff and volunteers who represent the community where the site is located; and (6) involving IDUs in the HRP planning process so their voices and concerns are heard. As described below, several steps can be taken to successfully implement HRPs.

(a) Assemble the Facts and Intervention Options

Start by assessing the characteristics of the local IDU epidemic and identifying current modes of syringe access. HRPs take many forms, and depending on the spatial distribution of IDUs, the accessibility of other health care facilities, and other relevant factors, more than one approach may be worth considering. Having identified potential HRP models, providers will also need to consult with their legal counsel and other stakeholders to discuss the viability of each prospective HRP option for the specific jurisdictions.

(b) Assess Stakeholder Knowledge and Attitudes

Identify key stakeholders and assess their knowledge of and attitudes toward HRPs. A HRP may fail if it is framed negatively or communities resist it. Police, prosecutors, and public defenders are encouraged to be engaged in the HRP development from the outset to help ensure the program's success.

1.4 An Opportunity for Collaboration

Providers that desire to operate a HRP should contact local law enforcement leadership prior to approaching city or county units of government, if possible. Harm reduction should be explained in a three part application to include: reducing harm to the community, reducing harm to addicted persons and officer safety. The array of services offered immediately, as well as those planned for the future, should be fully explained.

The goals of the program should be clearly outlined as well as the expectations of clients. Data concerning the increase and dangers of viral hepatitis and HIV often spread by IDUs, the goals and benefits of a HRP and the success of existing programs in other states should be discussed. Details such as location, mobile or stationary, and expectations of clients and staff may benefit from law enforcement input.

1.5 Waste Management for Syringe Disposal

As part of building community partnerships, it is useful to engage city, county or state waste management boards and their leadership, meet with them to introduce the program, and outline waste management plans. Collaborating with waste management staff is a good way to discuss how to expand syringe disposal through hazardous waste disposal programs already in place or through stand-alone syringe disposal kiosks. Hospitals or physician offices may provide in-kind support of the HRP through an agreement to provide disposal services of used syringes for the HRP. Because the primary goal of the HRP is to protect IDUs and the public from dirty needles and syringes, an HRP must have a waste management plan in effect from its outset.

CHAPTER 2. REACHING POTENTIAL HRP PARTICIPANTS

After the HRP entity has developed collaborative relationships and earned community support, it must next consider how the HRP will reach potential participants. There are many options and what works best in one community may not work in another. Street outreach, referrals from emergency department staff or pharmacists may also be effective.

2.1 Street Outreach

To reach potential program participants, HRP staff needs to have the IDU community's support and trust. Contacting IDUs initially may require time and patience but will help build a good foundation for the outreach effort. When HRP staff first approach potential HRP participants, they should introduce themselves and indicate the program for which they work. Initially, HRP staff should be sensitive to any cues the potential participant provides to indicate she/he is not interested in talking at that moment. They can simply let people know what services are provided and when they are offered. It is important for HRP staff to develop a comfortable relationship with IDUs while also keeping outreach and service delivery as priorities. Maintaining potential HRP participants' confidentiality is of the utmost importance, especially when program staff have group discussions and personal information might be overheard. As they build a relationship with participants, HRP staff can discuss safer injection methods and health matters with them in a way that does not seem threatening. Furthermore, culturally competent outreach practices consider the distinct needs of IDU subpopulations and also help build support for the program within the community.

Another good resource for conducting street outreach is utilizing peers as they have access to social networks of IDUs. Since they are a part of the IDU community, they may be able to gain peoples' trust faster than non-peer workers. In addition, peers often know the best locations for outreach efforts, can foresee potential challenges to getting IDUs into the program, and can help HRP staff assess situations and offer solutions.

When a program engages in street outreach, it is important to consider the safety of outreach teams; culturally appropriate personnel and attire; culturally relevant educational materials and supplies; training and materials for safe syringe disposal; HRP staff training in overdose prevention, recognition, and response; and procedures for documentation of outreach activities, including any adverse incidents.

2.2 Emergency Departments

For some IDUs seeking health care services for detoxification, wound infections, abscesses and overdose, emergency departments may serve as access points to identify and recruit IDUs for HRPs. Emergency departments can refer IDUs to HRPs for not only sterile syringes, but also for wound care and overdose prevention education, HIV and STD screening and referral to substance abuse treatment services. HRPs can provide information about the partnering medical facility and refer IDUs for medical care. Other potential partnership strategies may include having a medical practitioner embedded within a fixed site or mobile-based HRP and have HRP staff navigate IDUs to appropriate medical care.

2.3 Pharmacies and Pharmacists

Pharmacies and pharmacists can be a good resource and a strong ally for HRP modalities. As health care providers who generally work with large and highly diverse populations, pharmacists may be willing to speak directly with their colleagues about HRPs. Pharmacists have daily contact with the public and can be a valuable resource for referring IDUs to the HRP directly or through the IDU's family members with whom the pharmacist may have contact.

CHAPTER 3. OPERATING PRINCIPLES OF HRPS

Several elements should be considered in developing local operating principles for HRPs. Among these, registration, transaction model, delivery model and worker/volunteer safety are of primary concern.

3.1 Program Registration

Any HRP entity planning to implement a HRP will need to decide if it will institute a formal registration process for participants. In many HRPs, the formal establishment of a relationship between IDUs and the HRP begins with intake or enrollment. It should be noted that HRPs often do not have established enrollment or program registration procedures. However, the enrollment experience can be important in gaining the participant's trust and setting the tone for future interactions. In order to accommodate participant needs and encourage enrollment, initial intake

procedures should be kept to a minimum. However, HRP staff may need to use a longer intake process for referral to additional services, such as medical care or social services.

Collecting information may decrease participants' anonymity, which may reduce the likelihood that participants will access services. Asking participants to provide government-issued identification (ID) at enrollment may also deter people from using the HRP as some may not have ID cards.

By registering participants, the HRP can collect statistical data that staff can use to monitor the program. The purpose of program evaluation is to ensure that the program is operating in conformity to its design, reaching its specific target population and achieving anticipated implementation goals. Future monitoring activities can then be linked to the same participant through a unique participant code.

Table 1 presents the types of information that might be collected at intake/enrollment. This list offers a range of ideas and is not an intake template.

TABLE 1. Types of Information Potentially Collected at HRP Intake

Information	Purpose
Initials	As an alternative to participants' names
Birth year	To describe the service population
ZIP code or area of current residence	To describe the program's reach and identify geographic areas where there are gaps
Sex or gender	To describe the service population
Sexual Orientation	To describe the service population
Race/ethnicity	To describe the service population
Preferred Language	To tailor program services to participants' needs
Injection frequency	To estimate syringe needs for needs based negotiation models
Drug preferences	To evaluate program services and tailor them to participants' needs
Medical Home	To identify access point for medical care for program planning and referrals
Access to Other Services	To identify needed medical, substance abuse, and mental health services for program planning, referrals, and quality improvement
Social Determinants of Health	To identify homelessness, unemployment, and other social factors for program planning and referrals, to include access to health insurance where applicable

3.2 Syringe Transaction Models

The goal of HRP is to provide as close to 100 percent syringe coverage as possible, which means a sterile syringe for every injection of every IDU in a jurisdiction. HRP typically use one of three types of syringe transaction models: needs based negotiated model, strict one-for-one exchange and one-for-one plus exchange. Although there is little published research on the comparative efficacy of the three model types, subject matter experts agree that all three types are in common usage and that each has a set of strengths and limitations. Programs will need to consider available resources and public expectations when selecting the type of syringe transaction model to implement.

(a) Needs Based Negotiation

In the needs based negotiation model, the program does not set a limit on the syringes a participant can receive regardless of the number of returned syringes. Although HRP using this model generally encourage participants to return used syringes, participants can still receive sterile syringes even if they do not. The number of syringes distributed is negotiated based on the participant's need, the frequency of injection and the length of time until she/he can next access the HRP. Some HRP place an upper limit on the number of syringes distributed under this model (e.g., 100 or 500-syringe limit), but they do not place a limit on how often a participant can access services.

(b) Strict One-for-One Exchange

Strict one-for-one exchange programs provide HRP participants with the exact same number of sterile syringes that the participant brings in for disposal. For example, if the participant disposes of 14 used syringes at the HRP, then she/he receives 14 new, sterile syringes in return. With this model, participants cannot get sterile syringes if they do not bring in any used syringes for disposal. However, some HRP that employ strict one-for-one exchange models issue one or more syringes at the outset of client participation when participants enroll in the program to lessen the risk of syringe sharing. For example, the HRP might provide 10 sterile syringes the first time someone comes to the HRP even if the participant has no used syringes for disposal.

In cases where participants do not want to receive as many syringes as they returned during a single transaction, the HRP using the one-for-one exchange model can issue a voucher (similar to an "IOU"). For example, someone may return 300 syringes but only wants 10 syringes at that time. The HRP can give the participant a voucher for the other 290 syringes that she/he can redeem at another time. Vouchers are also useful when HRP do not have enough supplies to complete the exchange or when there are limits on the number of syringes a participant can get during a single transaction. HRP should consider recording the voucher

on-site in case participants lose their vouchers, but recording this information would affect anonymity unless HRP use a unique participant code.

(c) One-for-One Plus Exchange

One-for-one plus exchange programs modify the basic concept of the strict one-for-one exchange programs by providing a predetermined number of extra syringes beyond one for one. For example, these programs often provide 10 extra syringes regardless of the number of disposed syringes brought in, and even if no syringes were returned for disposal they could receive 10 new syringes. Other such programs allow two-for-one exchange models up to a certain limit. For example, if a participant disposes of eight syringes, she/he receives 16 sterile syringes. A voucher system can also be used with one-for-one plus exchange models.

(d) Strengths and Limitations of Each Syringe Transaction Model

Prior research has shown that the needs based negotiated distribution model is best at achieving the goal of reaching as close to 100 percent coverage as possible, followed by the one-for-one plus exchange model and then the strict one-for-one exchange model. The main drawback of the strict one-for-one exchange model is that people who have no used syringes to dispose of are unable to receive any sterile syringes. People could have many legitimate reasons for not returning their used syringes. For example, their syringes may have been confiscated by law enforcement, stolen by peers or taken by family members. For reasons of public safety or fear of law enforcement action, IDUs may choose to safely dispose of syringes at the time of injection as opposed to carrying them around until the next time they access a HRP. If IDUs are not provided sterile syringes at a HRP because they did not have any used syringes to dispose of, they may use unsterile syringes from their associates, which defeats the purpose of HRPs.

Another potential drawback of a strict one-for-one exchange model may be a lack of uniformity in its implementation by staff. Staff members may relax the strict one-for-one exchange rule to further encourage safer injection, which can create a scenario in which participants favor certain staff members who appear to be willing to bend the rules. The legitimacy of the program can be called into question by participants and/or the community if there are inconsistencies in applying the rules. Thus, the one-for-one plus exchange model provides staff a built-in alternative to denying syringes without returns.

Although the needs based negotiated model is better at increasing syringe coverage, programs may have other reasons for using a one-for-one plus exchange model. In some communities, it is more politically palatable to assure everyone that the program is exchanging needles as opposed to distributing them. The one-for-one plus exchange model may also be better than the needs based negotiated model at encouraging IDUs to access the HRP more often, which may increase opportunities for them to dispose of used syringes and the chances they will use

other services, including HIV/HCV testing and drug treatment referrals. Lastly, the needs based negotiated model may require spending more money on syringes, which depends on budgets and funding agencies. HRP's should consider working with their local partners to develop the best funding models for their community.

3.3 Worker and Volunteer Safety

(a) Safe Syringe Disposal

HRP entities must ensure proper disposal of syringes collected through their HRP's. Proper disposal of used syringes is critical to protecting individual health and public safety. Safe disposal procedures help prevent accidental needle stick injuries among staff, law enforcement, volunteers, participants and the public. Infectious diseases can be transmitted during an accidental needle stick; therefore, the experience can be very stressful for the people involved. Furthermore, making disposal resources available to IDUs helps reduce the amount of syringes and other injection equipment inappropriately discarded, helping to protect the HRP from public scrutiny.

HRP's must document policies and procedures governing disposal of syringes and other medical waste and supervise disposal to ensure that staff and volunteers are adhering to the rules as outlined by the program's policies and protocol.

The following suggestions may help guide safe disposal procedures:

- Develop or expand partnerships with waste management companies to obtain and dispose of medical waste.
- Do not require that returned syringes be counted by hand. Estimates can be made by observation or by weighing the returned syringe containers to determine the number of syringes disposed of for monitoring purposes.
- If the HRP uses a mobile unit, close sharps containers when the vehicle is moving in case the vehicle stops short or there is an accident. Similar strategies should be used when conducting street outreach.
- Provide individual disposal containers to clients (i.e. syringe and needle collection boxes, laundry detergent bottles, etc.)

(b) Prevention of Occupational Blood Borne Pathogen Transmission among HRP Staff

As is the case for other health care workers, HRP staff can be at risk for acquiring HIV/HCV from needle stick injuries and cuts during syringe exchange and disposal. To prevent the occupational transmission of blood borne pathogens. HRP staff should assume that blood

and other bodily fluids from HRP participants are potentially infectious, therefore requiring infection control precautions at all times including:

- routine use of barriers (e.g., gloves, goggles, closed-toe and heel shoes) when anticipating contact with blood;
- immediate washing of hands and other skin surfaces after contact with blood or body fluids; and
- careful handling and disposal of sharp instruments during and after use.

Although prevention of occupational blood borne transmission is the most important strategy, HRPs should have plans in place for post-exposure management of staff. CDC has issued guidelines for management of health care worker exposure to blood borne pathogens and recommendations for post-exposure prophylaxis (PEP). The PEP guidelines provide considerations in determining whether health care workers should receive PEP and in choosing the type of PEP regimen. Issues such as delayed exposure reporting, pregnancy in the exposed person, resistance of the source virus to antiviral agents and toxicity of PEP regimens are also discussed in the guidance. Occupational exposures should be considered urgent medical concerns. HRPs should demonstrate continued due diligence to reduce the risk of occupational HIV transmission by:

- at least annually training all staff in infection control procedures and the importance of reporting occupational exposure;
- promoting and monitoring the availability and use of safety devices to prevent sharps injuries, and developing a post-exposure management plan; and
- implementation of a PEP policy for HRP health care workers.

3.4 Health and Social Services: Provision and Linkage

IDUs participating in HRPs may need services to prevent HIV and HCV infection and to address other health and basic human needs. The CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) programs have developed a strategy called "Program Collaboration and Service Integration (PCSI)" to help health departments improve health outcomes, efficiency and cost-effectiveness. PCSI is a mechanism for organizing and blending interrelated health issues, activities and prevention strategies to facilitate a comprehensive delivery of services. HRPs can use PCSI to structure health delivery to populations of IDUs and specifically address the challenges associated with integrating services at a HRP location or through linkage to community service providers. The CDC's White Paper on PCSI (2009) can be found at:

www.cdc.gov/nchhstp/programintegration/docs/207181-c_nchhstp_pcsi-whitepaper-508c.pdf

3.5 Strategies to Increase Access to Services

HRPs can enhance their success by employing the following strategies:

- Establish collaborative relationships with referral agencies.
- Make referrals, when possible, to social service agencies that aim to reduce drug use and its consequences.
- Address barriers to accessing services (e.g., financial, transportation, child care, bench warrants).
- Have designated staff call ahead and provide transportation to referral sites (i.e. assisted referrals).

HRP entities can work with community agencies to ensure that HRP participants are able to access services. Specific strategies include the following:

- Develop protocols for referrals to relevant medical, behavioral health, substance abuse treatment and social services.
- Identify points of contact within each referral agency that can facilitate HRP participant access to needed services.
- Work with HRPs to train other agencies about HRPs.
- Address barriers to care at community programs, including stigmatization of clients as a requirement for receiving services.
- Support flexible community programs that are inclusive of clients.
- Involve state hepatitis/HIV/sexually transmitted disease (STD) coordinators (see <http://www.dhhr.wv.gov/oeps/std-hiv-hep/Pages/default.aspx>).

Using a combination of motivational interviewing and incentives has shown promise in increasing enrollment of referred participants in drug abuse treatment.

3.6 Specific Health and Social Services

HRPs play an important role in providing information and counseling to IDUs that allow them to reduce the consequences associated with drug use and to increase their general well-being. HRP staff can benefit from training on providing accurate information and using evidence-based approaches to counseling.

(a) Education and Counseling

Educational materials need to be accurate, up to date and matched to the population served in terms of cultural relevance, language and reading level. Specific content areas to be covered can include:

- HRP services, location and hours;
- local health centers and clinics locations and hours;
- safer injection practices and vein care;
- safer sex practices;
- identification and treatment of soft-tissue infections;
- HIV, HBV, HCV, and STD prevention and treatment associated with unsafe drug injection and sexual practices;
- drug abuse treatment options;
- overdose prevention and response; and
- accidental needlestick response.

(b) Social Services

HRPs can help participants meet basic needs and increase engagement by providing information and referral on an array of services that are appropriate for the population. Potential services include:

- referrals for uninsured clients;
- food and clothing distribution;
- hygiene supplies (e.g., feminine products, soap);
- child care;
- telephone, mail, and computer access;
- vocational assistance;
- legal aid;
- housing; and
- treatment services.

(c) Medical Care

IDUs have the same preventive and basic medical care needs as the general population. However, they also are at higher risk for specific health problems, such as blood borne infections and wounds. HRPs serve as a good opportunity for IDUs to meet and build a relationship that will encourage participation in routine services provided by the HRP entity, such as:

- HIV, HBV, HCV, tuberculosis (TB) and STD screening;
- linkage to and retention in care for IDUs living with HIV and/or HCV;
- primary medical care;
- pregnancy testing and prenatal care;
- vaccinations (hepatitis A/B, influenza, pneumonia);
- TB prophylaxis; and
- wound care.

IDUs using HRP services have a high prevalence of psychiatric disorders, such as major depression and antisocial personality disorder. HRP staff may benefit from training on recognizing the signs and symptoms of common psychiatric disorders and suicide prevention so that appropriate referrals can be made.

(d) Drug Abuse Treatment

The HRP may partner with local community treatment providers to combine services in one location. Each community will have different needs and resources. Therefore, consideration should be given to the best way to achieve all the goals of the HRP. At a minimum, resources and referrals to treatment services in the community should be provided to HRP participants.

(e) Overdose Prevention

The “Access to Opioid Antagonists Act” W.Va. Code §§16-46-1 allows a person or agency to receive a prescription for naloxone and administer it. Overdose is a major cause of mortality among clients and HRPs can address overdose prevention and response with both staff and participants. Naloxone is a drug used to counter the effects of opiate overdose. Making naloxone available is a recommended evidence-based strategy that reduces opioid overdose fatalities. Key overdose prevention strategies include:

- providing comprehensive training on overdose prevention, recognition and response for all HRP staff and volunteers, including rescue breathing and the use of naloxone;
- developing protocols for responding to overdoses on-site;
- educating program participants about overdose prevention and response; and
- educating the IDU’s family members and friends as well as the community at large how to recognize and respond to overdoses.

3.7 Provision or Linkage

Based on multiple factors, including location, financial constraints, availability of community resources and participant preference, HRPs will need to decide whether to co-locate services or provide linkages to community resources. Research and HRP experience suggest that co-location

of services has advantages in both acceptability and effectiveness for HRP participants because IDUs have relatively low rates of utilization of community services. Consequently, the HRP may be the participant's only or most trusted point of contact with service agencies. Moreover, partnering with agencies that can provide services on-site increases utilization rates.

Using community linkages to provide services also has advantages, because these collaborations can help organizations broaden their mission, develop more comprehensive strategies, ensure that participants receive high-quality services, minimize duplication of services and maximize the utilization of available resources.

CHAPTER 4. SERVICE DELIVERY MODELS

Various service delivery models can be used to make syringes available. HRPs may find that the best approach is to use a single model exclusively or to combine models to expand the program's reach. When choosing a service delivery model, HRPs will find the results from the needs assessment process helpful. Model selection should be driven by numerous factors such as available resources and budget, the organizational infrastructure, local political concerns, availability of staff and volunteers, and the local drug subculture and geographic context. Staffing needs may vary depending on service modality as well as participant volume. For solely distributing and disposing of syringes in low volume programs, adequate coverage can be achieved with as few as two people. However, a minimum of four workers would be preferable for high volume programs. Job tasks include the following:

- syringe distribution;
- syringe collection;
- tracking of basic demographics; and
- referrals to services.

Staffing needs increase as more services are added to accompany syringe distribution and collection. The following sections briefly outline the inherent strengths and potential limitations of different HRP models, including fixed site, mobile/street based, and delivery.

4.1 Fixed Site

Fixed-site models include hospital/clinic-based settings, integrated syringe access services, and collaboration or satellite structures. Typically in fixed-site models, the HRP is located in a building or specific location, such as a local health department, a storefront, office, or other space with street-level access. Fixed sites work best in health jurisdictions where IDUs are clustered in a somewhat centrally located area.

The strengths of fixed-site models include the following:

- It is easier for other social service agencies to refer their clients to the HRP because there is a set location with predictable hours.
- Other services can be integrated with HRP activities, including HIV, HBV, and HCV testing; STD testing; TB screening and prophylaxis; food provision; clinical treatment; abscess and wound care; and overdose prevention.
- Having a permanent site makes it easier to tailor the space to the needs and preferences of the participants.
- Computer-based systems (e.g. electronically tracking inventory of syringes) can more easily be supported in a set indoor location.
- HRP services can be provided in a private setting.
- The location provides shelter from weather and street-based activities.
- On-site storage space may be available to house materials.

The potential limitations of fixed-site models include the following:

- A fixed-site may be more costly to maintain because of higher overhead and upkeep.
- Clients may be reluctant to go to the site because of concerns about stigma.
- It can be challenging to stay abreast of and adapt to changes in the drug scene (e.g., if the HRP's location is no longer close to where IDUs congregate).
- The community may not support the site's location.
- Participants must come to the site, which can be a barrier if IDUs are spread apart geographically and they do not have transportation.

4.2 Collaboration or Satellite Structure

In the collaboration or satellite structure model, existing HRPs provide harm reduction services at partner social service agencies in fixed sites in the community (e.g., homeless shelters). It requires that the HRP provide capacity-building training for the partner agency. This approach works best in health jurisdictions where HRPs are supported and there is a need to increase access through multiple modalities. The strengths of collaboration or satellite structures include the following:

- Access to services may be enhanced through additional locations and expanded operating hours.
- The existing participant base of IDUs can help advertise the availability of Harm Reductions with their peers.
- The parent program has experience managing public relations, which may help increase community support for Harm Reductions.

Additional operational and human resource costs may be offset because the parent organization already has the requisite systems and expertise, an established training program and sufficient staff

to implement the additional services. It may expand the program's reach by attracting new groups of IDUs.

The potential limitations of collaboration or satellite structures include the following:

- It may be challenging to keep track of inventory if specific systems for doing so are not in place.
- The parent organization and satellite site may have different policies or procedures, which can lead to inconsistencies or discord.

4.3 Mobile/Street Based Programs

Mobile/street-based programs are conducted on foot, by bicycle or by vehicle (e.g., van, bus or recreational vehicle). This method is also referred to as an outreach program. Many mobile HRPs stop at specified locations and times. Although this model is often combined with a fixed-site program, it may also operate independently. This model is well suited to communities where IDUs do not congregate in centralized locations or where participants have limited transportation options. Note that jurisdictional approval for all areas of operation and stops for a mobile unit is required.

The cost for mobile sites can vary based on the style of outreach implemented and the transportation needs. For example, some mobile sites involve setting up a cart with supplies on a street corner, whereas others use recreational vehicles. Aside from the cost of a vehicle, other costs must be considered, including automobile insurance, parking, maintenance and gasoline. Training should emphasize security and safety. To ensure staff safety, it is also important to collaborate with law enforcement and other community stakeholders about the program.

The strengths of mobile/street-based sites include the following:

- The program may encounter less resistance from the local community because it will not attract congregations of IDU clients;
- Mobile sites offer heightened flexibility and the advantage of being closer to a street drug market, increasing accessibility for IDUs who are unable to come to a fixed site;
- The program can adapt to changes in the drug scene or neighborhood and can relocate to places where IDUs congregate;
- The existing participant base of IDUs can help promote the time and place of services to their peers;
- The informal and easily accessible location may help put participants at ease.
- Groups of IDUs who may be less likely to visit a HRP can still get sterile syringes and dispose of used ones safely;

- Peers may feel empowered by conducting a public health service in their community.

The potential limitations of mobile/street-based sites include the following:

- It is less anonymous, because people can see who is using the services in the community;
- Staff needs to have a valid driver's license if a motor vehicle is involved;
- Services can be interrupted if the vehicle needs to be repaired;
- It can be harder to provide additional services that require a physical location;
- The work conditions can be stressful for staff because of inclement weather or concerns about safety;
- Supplies need to be stored elsewhere and transported to the sites;
- Participants may be reluctant to come to the HRP in inclement weather;
- It can be costly to maintain because of expenses related to vehicle maintenance and insurance.

4.4 Delivery Models

The delivery model involves the delivery of injection supplies to a prearranged site, such as a house, apartment, hotel, or other prearranged location. Service delivery can take place on a regular schedule or by appointment. It is a direct means of observing the more private aspects of participants' living situations, and services can be developed and tailored to meet those needs. Medical and nutritional services, overdose prevention, directly observed therapy and safer injection education, for example, can all occur in the privacy of a person's home. It is important for the HRP to deliver only in its jurisdiction as approved by its governing board and county and city officials for that specific delivery site.

It may be best if site managers and landlords of the facilities are informed that unspecified social services are coming to the location. Promotion can occur by HRP staff and through the facility's management, as well as through IDU networks. Delivery is an excellent option in rural jurisdictions, where there are often large geographical areas to cover and privacy is of utmost importance. Delivery may be combined with mobile or fixed sites. Enhanced training for staff and volunteers on safety and confidentiality of participants' needs is necessary.

The strengths of delivery models include the following:

- This form of syringe access is more discreet and consequently reduces negative reactions from the neighboring community, which is rarely aware of the program activity;
- Since participants do not have to transport used injection equipment, it reduces needle stick risk and potential involvement with law enforcement;

- It can be easier to begin a delivery program than other program models due to the reduced need for a physical space;
- Information sharing about injection practices, health, and other issues can occur more privately;
- Participants' safety is enhanced if they do not need to leave their home;
- It increases access to IDUs who may be less likely or unable to attend a fixed site;
- HRP staff has more opportunities to interact with family and peer networks.

The limitations of delivery models include the following:

- It requires the HRP to have and use transportation to provide services;
- It can be challenging to sustain because of staff burnout;
- It can be potentially time consuming, depending on the geographic dispersion of participants;
- It may take time to overcome potential privacy concerns and build a foundation of trust;
- Worker and volunteer safety is a concern;
- It can be expensive to maintain and insure vehicles.

4.5 Using Multiple Program Models

Incorporating multiple models may be the most effective way for programs to expand syringe coverage and reach the greatest number and diversity of IDUs within a given health jurisdiction. Combining models—for example, a fixed site with a mobile van increase the likelihood that diverse populations have access to syringes. Also, using multiple program models is more flexible and can direct resources to the most affected areas, allowing programs to respond to changes in patterns among local IDUs. Using a multiple-model approach can require significant resources and demand more effort from staff. This can make them less sustainable. However, multiple program models can be a valuable, comprehensive approach when they are well executed and have sufficient resources.

CHAPTER 5. MONITORING HRP PROGRAMS

The main goal of monitoring local HRPs is to assess whether a program is operating in conformity to its design, reaching its specific target population and achieving anticipated implementation goals. HRP entities are strongly encouraged to require HRPs to continually conduct process monitoring and periodically conduct outcome monitoring.

5.1 Process Monitoring

The overarching goal of process monitoring is to document whether the program is being implemented as intended. The process outcomes to be monitored depend on the type of service delivery model selected and the type and number of additional services provided. In general, it is recommended that programs minimize the data collection burden associated with monitoring so they do not interfere with IDUs participation or HRP operations.

Process monitoring serves a number of important and valuable functions for HRPs:

- assesses which services are being used and how often they are used;
- facilitates accounting practices;
- allows HRPs to report back to regulators, funders, and others (such as their communities) about program reach; and
- maintains or increases program support.

Three minimum essential data elements are recommended for every syringe transaction occurring at HRPs, without regard to the type of service delivery model:

- number of participant contacts (i.e., duplicated participant counts);
- number of syringes distributed; and
- estimated number of syringes returned for disposal (refer to Section 3.3 for safe syringe disposal strategies).

In addition to these core data elements, additional data can be used to monitor process outcomes depending on the type of service delivery model and types of services provided. Appendix A lists additional process indicators that programs may wish to monitor, depending on the service delivery model and types of services that are provided in addition to syringe exchange.

Most programs use service logs to obtain data on the number of syringes provided per transaction and the estimated number of syringes returned. In these programs, HRP staff writes the site name and the date at the top of the log daily and record transaction data as participants' access services. Then staff enters the data into a software program on a daily or weekly basis. Using a handheld electronic device programmed for data input is preferable if the program can afford it because it eliminates the need for entering data from paper forms.

Process monitoring does not require sophisticated statistical methods. Descriptive statistics are usually sufficient to answer process monitoring questions, such as comparing actual program outputs (e.g., number of HIV tests conducted) with target outputs (e.g., projected number of HIV tests conducted).

5.2 Outcome Monitoring

Quantitative assessments should occur periodically with HRP participants for outcome monitoring. Outcome monitoring provides important information for improving program efficiency, quality and effectiveness. In general, outcome monitoring methods should aim to minimize participant burden, not disrupt normal program activities and only collect information that is critical for understanding process outcomes. Utilizing a variety of data types and sources, together with program specific outcome monitoring activities, enhances the assessment of the HRP. For example, data that provide information on HIV/ HCV incidence rates, crime statistics, incarceration rates, and arrest rates may provide system-level indicators for the impact of the program on outcomes related to the overarching goals of the HRP. Quantitative assessments conducted with HRP participants should occur, at a minimum annually or every other year and include a representative sample of participants. Choosing participants randomly is preferable but may not be feasible in all locations or for all syringe modalities. Participants may be incentivized for providing their expertise to the HRP by participating in outcome monitoring surveys. Key domains for HRP outcome monitoring include:

- types of services used at the HRP;
- frequency and duration of HRP use, including estimation of numbers of syringes distributed in a given period;
- receptive and distributive syringe sharing;
- disposal practices;
- overdose risk and history;
- access and linkage to drug treatment and medical and social services (e.g., referrals and linkage to medical homes, behavioral health services and homes and substance abuse treatment facilities);
- participant satisfaction with program elements, such as hours, locations and staff interactions;
- client characteristics (e.g. demographics, injection drug use history, medical history, and substance abuse treatment history);
- drug use preferences (e.g. types of drugs used, including hormones or steroids) and practices (e.g. with whom and how often participants use drugs);
- estimates of number of IDUs reached through outreach; and
- changes in drug use, injection and treatment as a result of HRP participation.

An individual trained in epidemiological and statistical methods and familiar with the literature on factors associated with HIV, HCV, and overdose risk and HRPs should analyze the data. HRP staff should be involved in interpreting the results. See Appendix A for process monitoring indicators.

5.3 Program Quality Improvement

Program quality improvement relies on the systematic collection and use of process monitoring and periodic outcome monitoring to determine if and how well program objectives are being met and to reassess program goals. If goals are not being met, program quality improvement can help HRPs decide if and how to change services to better meet the needs of the target population. Based on program goals, working with a research partner can be an appropriate method for assessing program quality.

Quality improvement may include perspectives from community stakeholders, HRP participants, and others with important perspectives regarding the usefulness and effectiveness of the HRP. For instance, programs can use methods such as key informant interviews and focus groups to assess participant satisfaction with program elements, such as hours, locations and staff interactions; learn how HRP participants use program services; or understand how new services might be received.

Using unobtrusive approaches, programs can observe HRP transactions systematically to identify opportunities to provide more education, counseling, or other services or simply time them to determine barriers to providing other activities. Many quality improvement ideas can also be discussed through a participant or community advisory board if the HRP has one.

5.4 Building Capacity of HRP Staff

Building capacity of staff increases individual skill level and overall service quality and productivity. In addition to improving service delivery, training staff on the program's philosophy and mission helps ensure that participants feel welcome at the HRP and are comfortable accessing services.

HRPs may have staff or volunteers who can provide training on a regular or ad hoc basis. Other times in-house training is not available on important topics. In such cases, training and technical assistance can be obtained through other mechanisms. A number of organizations and institutions provide training and technical assistance to HRPs. Additionally, staff and volunteers can attend conferences and off-site trainings that can be good opportunities to interact with other providers and gain relevant experience and insight. It is recommended that all staff and volunteers complete a basic training curriculum that encompasses the core topics shown in Table 2. In addition to the core training program, programs should prioritize ongoing staff development by offering advanced training on topics such as those shown in Table 2.

TABLE 2. Basic and Advanced Training Topics for HRP Staff

Basic Training Topics	Advanced Training Topics
<ul style="list-style-type: none">• Standard operating procedures• Referral to medical, substance abuse treatment, behavioral health, other service agencies• Cultural sensitivity• Overview of neighborhood concerns• Outreach strategies• HIV and viral hepatitis transmission and prevention• Overdose prevention• Syringe safety/disposal• Plan for accidental needle sticks• Legal and law enforcement climate	<ul style="list-style-type: none">• Polysubstance use• Conflict resolution and de-escalation• Specialized interviewing techniques (e.g. motivational interviewing)• Principles of case management• Abscess and cellulitis treatment and prevention• Domestic violence issues• Co-occurring behavioral health and substance use disorders

CHAPTER 6. CERTIFICATION OF HARM REDUCTION PROGRAMS

1. PURPOSE

This procedure establishes the mechanism for certifying Harm Reduction Programs (herein referred to as HRP) to reduce drug related harm while enhancing individual, family, and community wellness, primarily through the provision of appropriate and competent services to injection drug users.

2. SCOPE

This procedure is applicable to any entity, public or private, (referred to in this document as “HRP entity”) operating or intending to operate a Harm Reduction program in the State of West Virginia.

3. DEFINITIONS

The following definitions used herein shall have the meaning:

- 3.1. “AIDS” means acquired immune deficiency syndrome.
- 3.2. “Administrator” means a person having the authority and responsibility for the operation of the HRP and serves as the contact for communication with the harm reduction program with the Bureau.
- 3.3. “Applicant” means the entity applying for authorization under this rule series, and includes the individual who signs the application for certification of the HRP.
- 3.4. “Bloodborne pathogens” means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus, hepatitis C virus and human immunodeficiency virus (HIV).
- 3.5. “Bureau” means the West Virginia Bureau for Public Health.
- 3.6. “Certification” means Bureau authorization of a HRP to operate for up to 2 years.
- 3.7. “Core services” means the primary activities an entity undertakes in order to serve its clients.
- 3.8. “Fixed site” means a building or single location, not a mobile site, where harm reduction services are provided on a regular basis.
- 3.9. “Harm Reduction Program” or “HRP” means a program that provides services intended to lessen the adverse consequences of drug use and protect the public health.
- 3.10. “HIV” means the etiologic virus of AIDS or human immunodeficiency virus.
- 3.11. “Injection drug user” means a person who uses a syringe to self-administer drugs.
- 3.12. “Local health Department” means a health department operated by a local board of health created, established and maintained pursuant to *W.Va. Code* §§ 16-2-1 *et seq.*

- 3.13. “Local Law Enforcement Official” means the individual designated by the sheriff or police chief in the jurisdiction in which the HRP operates who has authority to receive communications from state and local public health agencies.
- 3.14. “Location” means a site within the jurisdiction of a local health department. A location can be a fixed or mobile site.
- 3.15. “Mobile site” means a location where harm reduction is conducted using a vehicle such as a van, or by foot in a location that is not a fixed indoor setting.
- 3.16. “Needlestick Injury” means a penetrating wound from a needle that may result in exposure to blood.
- 3.17. “Needlestick Injury Protocol” means policies and procedures to prevent needlestick injury to HRP staff, including volunteers, and to HRP participants, and that outline both immediate and subsequent remedial and prophylactic actions to take in the event of a needlestick injury.
- 3.18. “Needs Statement” means a document that provides the rationale for the request for certification in the location specified and uses data and other objective sources to document the need. Examples include statistics on HIV infection and/or viral hepatitis among injection drug users in the applicant’s service area, the presence of injection drug users in the location, and the presence or absence of other Harm Reduction services in the applicant’s service area.
- 3.19. “Participant” means a person who uses harm reduction services, a client of the HRP.
- 3.20. “Participant Confidentiality Protocols” means written protocols that strictly limit the disclosure of participant identification information.
- 3.21. “Program” means a HRP.
- 3.22. “Protocols” mean written guidelines that define the limits and extent of practice of the staff of a HRP.
- 3.23. “Service Area” means the territorial jurisdiction of the local board of health.
- 3.24. “Sharps Waste” means used needles, syringes and lancets.
- 3.25. “Site” means the location(s) where harm reduction services are offered to participants.
- 3.26. “Staff” means anyone who provides harm reduction services on behalf of a program.
- 3.27. “Syringe” means both the needle and syringe used to inject fluids into the body.
- 3.28. “Viral hepatitis” means any of the forms of hepatitis caused by a virus, including hepatitis B (HBV) virus and hepatitis C virus (HCV).

4. HRP CERTIFICATION PROCESS.

- 4.1. An applicant desiring state certification of an HRP must file an application for certification with the Bureau, through its website or by mail on a form approved by the commissioner.
- 4.2. Each application must contain the following information:
 - 4.2.a. The name of the applicant, the name under which it will be providing harm reduction services, and the date the application is submitted.

- 4.2.b. The full name, title, email address and telephone number of the individual designated by the applicant as the administrator of the HRP.
- 4.2.c. A description of the applicant organization's mission and core services, including a list of services the applicant currently provides to injection drug users. Services may be offered directly or by referral. These are:
 - 4.2.c.1. Drug abuse treatment services;
 - 4.2.c.2. HIV or Hepatitis screening;
 - 4.2.c.3. Hepatitis A and Hepatitis B vaccination;
 - 4.2.c.4. Screening for sexually transmitted infections;
 - 4.2.c.5. Referrals to behavioral health services; and
 - 4.2.c.6. Services related to provision of education and materials for the reduction of sexual risk behaviors, including, but not limited to, the distribution of condoms.
- 4.2.d. A needs statement that includes information about the scope of the problem and population the program would serve, concerns of law enforcement, statistics on HIV infection and /or viral hepatitis among injection drug users, the presence of injection drug users in the location, and the presence or absence of other Harm reduction services in the proposed location.
- 4.2.e. A description of the proposed harm reduction services, the anticipated number of participants to be served each year and the estimated number of syringes to be dispensed and collected each year. HRP services include:
 - 4.2.e.1. Providing needles and harm reduction services for all of its participants;
 - 4.2.e.2. Providing HIV and viral hepatitis prevention education services for all of its participants; and
 - 4.2.e.3. Providing for the safe recovery and disposal of used syringes and sharps waste from all of its participants.
- 4.2.f. A description of the service delivery mode(s) to be employed, whether fixed or mobile site, including:
 - 4.2.f.1. The number of locations at which harm reduction services will be provided; and
 - 4.2.f.2. A description of the location(s) where harm reduction services will be provided that includes the full address (street number, street name, city and zip code) and county of the fixed or mobile site location(s).
- 4.2.g. A description of additional services that will accompany harm reduction, such as overdose prevention supplies and education.
- 4.2.h. The HRP hours of operation in the location(s) and staffing. The description of hours of operation must include the specific days the HRP is open, opening and closing times, and frequency of harm reduction services. The description of staffing must include number of staff, titles of positions and descriptions of duties.
- 4.2.i. A copy of the following plans that guide the HRP's operations:

- 4.2.i.1. A syringe dispensing plan as described in subdivision 8.1.a;
- 4.2.i.2. A syringe collection and disposal plan as described in subdivision 8.1.b.;
- 4.2.i.3. A service delivery plan as described in subdivision 8.1.c.;
- 4.2.i.4. A staff training plan as described in subdivision 8.1.d.;
- 4.2.i.5. A data collection and program evaluation plan as described in subdivision 8.1.e.;
- and
- 4.2.i.6. A community relations plan as described in subdivision 8.1.f.
- 4.2.j. A budget for the program which includes at a minimum projected income and costs for personnel, outside services, and operating expenses, including but not limited to rent, utilities, equipment, materials including syringes and disposal containers, transportation, insurance, training, meetings, syringe disposal services, and indirect costs.
- 4.2.k. A signed statement attesting to:
 - 4.2.k.1. The applicant's compliance with state laws, rules, and local ordinances;
 - 4.2.k.2. The capacity of the applicant to begin harm reduction services within 90 days of certification; and
 - 4.2.k.3. The involvement of the local health department and program participants in HRP design, implementation and evaluation.
- 4.3. The Bureau shall issue a final decision to certify or not to certify within 30 business days after the close of the 30-day public comment period. The certification is valid for no more than two years, subject to renewal.
- 4.4. In considering whether to approve or disapprove an application, the Commissioner shall consider the applicants ability to:
 - 4.4.a. Provide an injection drug user with information and the means to protect himself or herself, his or her partner, and his or her family from exposure to blood-borne disease through access to education, sterile injection equipment, voluntary testing for blood-borne diseases, and counseling;
 - 4.4.b. Provide referrals to facilitate entry into drug abuse treatment, including opioid substitution therapy;
 - 4.4.c. Encourage usage of medical care and health services as well as social welfare and health promotion;
 - 4.4.d. Provide safety protocols and classes for the proper handling and disposal of injection materials;
 - 4.4.e. Plan and implement the clean syringe exchange program with the clear objective of reducing the transmission of blood-borne diseases within a specific geographic area; and
 - 4.4.f. Develop a timeline for the proposed program and for the development of policies and procedures.

5. RENEWAL OF HRP CERTIFICATION.

- 5.1. A certification is valid for no more than two years and may be renewed by the Bureau by request.
- 5.2. At least 30 days prior to the end of the two-year certification period, the HRP administrator may communicate to the Bureau by mail or email to request renewal of certification for an additional two years.
- 5.3. The Bureau will consult with the applicant and local law enforcement leadership regarding reauthorization requests. The Bureau has 30 business days to review and respond to the applicant's request for renewal of the certification.

6. DENIAL OF CERTIFICATION RENEWAL OR REVOCATION OF HRP CERTIFICATION.

A HRP's certification will be revoked and an application for renewal of certification may be denied by the Bureau if the applicant or the HRP violates the provisions of this procedure.

7. PROCESS TO REQUEST REVIEW FOLLOWING DENIAL OR REVOCATION.

- 7.1. Any person aggrieved by the Bureau's decision to deny, revoke or refuse to renew a certification, or by the Bureau's deemed denial resulting from the Bureau's failure to respond to the applicant's request for renewal within 30 business days, may request a hearing.
- 7.2. A request for a hearing must be made in writing within 30 days of the date that the Bureau's notification of denial or revocation is issued, or after the date of the Bureau's deemed denial, if applicable.
- 7.3. The request for hearing must be made in writing to the address found on the Bureau website and must clearly state the reasons for the request.

8. OPERATIONAL REQUIREMENTS FOR CERTIFIED HRPs.

- 8.1. A certified HRP must include program participant input into the program design, implementation and evaluation. Program design, implementation, and evaluation must be guided by the following plans:
 - 8.1.a. A syringe dispensing plan that:
 - 8.1.a.1. Is designed to provide new, sterile syringes to meet the needs of participants in accordance with the recommendations made by the U.S. Public Health Service, published by the Centers for Disease Control and Prevention, to support the use of a new, sterile syringe for each injection; and
 - 8.1.a.2. Tracks the number of syringes dispensed.
 - 8.1.b. A syringe collection and sharps waste disposal plan that:
 - 8.1.b.1. Is designed to maximize return of used syringes without increasing risk of needlestick injury to staff or program participants;

- 8.1.b.2. Tracks number of syringes returned in a manner that eliminates direct handling of sharps waste and does not interfere with service provision;
- 8.1.b.3. Includes a needlestick injury protocol and a plan for ensuring staff and participant familiarity with the protocol;
- 8.1.b.4. Includes sharps waste disposal education that ensures staff and participants are familiar with state law regulating proper disposal of home-generated sharps waste; and
- 8.1.b.5. Includes a plan and budget for sharps waste disposal, or an explanation if no cost is associated with sharps waste disposal.
- 8.1.c. A service delivery plan that includes:
 - 8.1.c.1. Needles and harm reduction services for all of its participants;
 - 8.1.c.2. HIV and viral hepatitis prevention education services for all of its participants;
 - 8.1.c.3. The safe recovery and disposal of used syringes and sharps waste from all of its participants;
 - 8.1.c.4. HIV or hepatitis screening;
 - 8.1.c.5. Participant confidentiality protocol.
 - 8.1.c.6. Screening for sexually transmitted infections;
 - 8.1.c.7. Education and supplies for safer sex practices; and
 - 8.1.c.8. Participant confidentiality protocol.
- 8.1.d. A staff training plan that includes:
 - 8.1.d.1. Mandatory staff training on the following topics:
 - 8.1.d.1.A. Orientation to the applicant's services and eligibility requirements for the program;
 - 8.1.d.1.B. Overview of harm reduction philosophy and the harm reduction model used by the program;
 - 8.1.d.1.C. The applicant's approved policies and procedures that cover harm reduction transactions, handling disposal of infectious waste, and needlestick prevention management;
 - 8.1.d.1.D. Procedures that ensure secure storage, handling and disposal of syringes in accordance with State law and rules;
 - 8.1.d.1.E. Procedures for making referrals, including primary care, detox and drug treatment, HIV counseling and testing, prenatal care, tuberculosis and Hepatitis A, B and C screening and treatment, screening and treatment for sexually transmitted infections, and other HIV support and social services;
 - 8.1.d.1.F. Hierarchy of risks associated with sexual and drug-using behaviors and risk reduction practices for those behaviors;

- 8.1.d.1.G. Education and demonstration of safer injection practices, including techniques for disinfecting injection equipment, rotation of injection sites and the use of alcohol pads to disinfect injection sites; and
- 8.1.d.1.H. Cultural diversity including sensitivity to race/ethnicity, age, gender and gender identity, sexual orientation, literacy, socio-economic status and employment status.
- 8.1.d.2. Training logs and attendance sheets for all trainings provided to HRP staff. The training log must include the name of the training and trainer, date, location and agenda/topics covered. The attendance sheet must record the names of all staff who received the training, date and agenda/topics. A copy of the attendance sheet or a certificate of completion must be maintained in the personnel/training record for each HRP staff member.
- 8.1.e. A data collection and program evaluation plan that:
 - 8.1.e.1. Incorporates evaluation data into program design;
 - 8.1.e.2. Uses the Bureau designated data reporting method to collect the data elements which includes:
 - 8.1.e.2.A. The total number of persons served;
 - 8.1.e.2.B. The total number of syringes and needles dispensed, collected and disposed of; and
 - 8.1.e.2.C. The total numbers and types of referrals made to drug treatment and other services.
- 8.1.f. A community relations plan that:
 - 8.1.f.1. Records adverse incidents and positive interactions between local law enforcement and HRP staff, volunteers or participants in their role as program participants;
 - 8.1.f.2. Document concerns and positive feedback expressed by program participants, community members, neighborhood associations and/or local law enforcement officials; and
 - 8.1.f.3. Documents steps the program has taken to address any reasonable concerns.

9. COMPLIANCE WITH STATE LAW, REGULATIONS AND LOCAL ORDINANCES.

The program and its staff shall operate and furnish services in compliance with all applicable state laws, rules and local ordinances.

10. REPORTING REQUIREMENTS FOR CERTIFIED HRPs.

10.1. HRPs certified pursuant to this procedure must return a report to the Bureau, postmarked or delivered by email by the anniversary date of certification each and every year of the program's operation under the Bureau's certification. The report must include:

10.1.a. The data elements listed in subparagraph 8.1.e.2. and

10.1.b. A report on the events recorded under the community relations plan are in subdivision 8.1.f.

APPENDIX A
SAMPLE MONITORING AND EVALUATION PROCESSES
HRP Process Monitoring Indicators

HRP entities may wish to incorporate the following process and program monitoring indicators.

Minimum required process monitoring indicators for all HRP models:

- Number of clients/participants
- Number of syringes distributed
- Number of syringes returned/disposed

Recommended list of process monitoring indicators for each HRP model:

- ***Fixed Site*** (e.g. hospital/clinic based settings, integrated syringe access services, collaboration or satellite structure)
 - Number of hours open per week for harm reduction
 - Number of HIV tests provided
 - Number of positive HIV tests
 - Number of HCV tests provided
 - Number of tests positive for HCV
 - Number of referrals for HCV testing
 - Number of referrals for HIV testing
 - Number of referrals for substance abuse treatment and other clinical services such as STD testing and treatment
 - Number of each type of service directly provided or referral provided
 - Client demographics: age, gender, race/ethnicity
- ***Mobile/Street Based***
 - Number of hours open per week for harm reduction
 - Number of HIV tests provided
 - Number of positive HIV tests
 - Number of referrals for HIV testing
 - Number of HCV tests provided
 - Number of tests positive for HCV
 - Number of referrals for HCV testing
 - Number of referrals for substance abuse treatment and other clinical services such as STD testing and treatment
 - Number of each type of service directly provided or referral provided
 - Client demographics: age, gender, race/ethnicity
- ***Delivery Model***

- Number of delivery sites
- Number of persons served per delivery site
- Number of referrals for HIV testing
- Number of referrals for HCV testing
- Number of referrals for substance abuse treatment

- **Multiple Programs**
 - Number of hours open per week for harm reduction
 - Number of HIV tests provided
 - Number of positive HIV tests
 - Number of referrals for HIV testing
 - Number of HCV tests provided
 - Number of tests positive for HCV
 - Number of referrals for HCV testing
 - Number of referrals for substance abuse treatment and other clinical services such as STD testing and treatment
 - Number of each type of service directly provided or referrals provided
 - Client demographics: age, gender, race/ethnicity

Other process monitoring indicators

- Number of participants
- Number of new clients
- Client demographics:
 - Age
 - Gender
 - Race/ethnicity
 - ZIP code of residence
 - Behavioral characteristics

- Number of syringes distributed
- Number of syringes collected/disposed
- Number of syringes each participant is exchanging
- Number of visits per client per month
- Number of hours open for harm reduction per week
- Number of delivery sites
- Number of persons served per delivery site
- Number of each type of service directly provided or referral provided
- Number of referrals made to HIV services
- Number of HIV tests provided
- Number of positive HIV tests
- Number of HCV tests provided

- Number of tests positive for HCV Number of referrals for HCV testing
- Number of referrals for substance abuse treatment and other clinical services such as
- Number of STD test and treatment
- Number of condoms distributed
- Number of flu vaccines provided
- Number of hepatitis A vaccination doses
- Number of hepatitis B vaccination doses
- Number of adverse events
- Number of community-based syringe-disposal kiosks