**REQUIREMENTS**

**FOR AUTHORIZATION, IMPLEMENTATION AND REPORTING FOR COMPREHENSIVE HARM REDUCTION PROGRAMS IN VIRGINIA**

**July 1, 2020**

This document describes the process for agencies seeking Virginia Department of Health (VDH) authorization to establish Comprehensive Harm Reduction (CHR) programs, including syringe services, in Virginia; minimum requirements for the operation of such programs; and reporting elements and deadlines as set forth in the [Code of Virginia Section 32.1-45.4](https://law.lis.virginia.gov/vacode/title32.1/chapter2/section32.1-45.4/). It also describes best practices for CHR programs and additional programmatic and reporting requirements for those agencies seeking CHR funding support from the Virginia Department of Health.

**Definition**

CHR programs are defined as organizations or local health departments that provide, at a minimum, harm reduction education and counseling, distribute sterile syringes/needles, offer disposal of used syringes/needles, provide education and linkage for naloxone (Narcan) or similar Food and Drug Administration (FDA) approved medications for opioid overdose reversals, and offer referrals and linkages to mental health and substance use disorder treatment.

**CHR Sites**

CHR sites must be operated by an organization or local health department that promotes scientifically proven methods of mitigating the health risks associated with drug use and other high-risk behaviors. Examples of organizations may include business entities including but not limited to small businesses, non-profits, and Limited Liability Corporations (LLC). VDH will not authorize individuals to operate CHR sites. Individuals interested in providing CHR services may team with an established business entity or form an organization or business of their own. More information on starting a business in Virginia can be found here: [http://www.bos.virginia.gov/starting.shtml](http://www.bos.virginia.gov/starting.shtml%20).

CHR sites will be categorized as VDH-funded sites or sites not funded by VDH. Sites funded by VDH will have additional implementation, data collection and reporting requirements than unfunded sites.

A Memorandum of Agreement will be established between VDH and the CHR site and funded sites must register as a vendor in [eVA](https://www.eva.virginia.gov/index.html)- Virginia’s eProcurement Marketplace.

**CHR Program Objectives:**

CHR programs in Virginia seek to:

1. Reduce the spread of human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and other blood-borne diseases;
2. Reduce the transmission of blood-borne diseases through needle stick injuries to law-enforcement and other emergency personnel, as well as the general public;
3. Provide information regarding and referral to substance use treatment services to individuals who use drugs;
4. Facilitate the safe return and disposal of hypodermic needles and syringes
5. Reduce overdoses and resulting deaths in the Commonwealth; and
6. Improve the overall health of people who use drugs in Virginia.

**CHR Services**

ALL CHR programs must provide the following services, either directly or through a documented referral process, with a verification feedback mechanism:

Table 1

|  |  |  |  |
| --- | --- | --- | --- |
| Service  | All Applicants Must\* Provide Directly  | All Applicants Must Provide Directly or Through Referral | VDH Funded CHR Sites Must Provide Directly or Through Referral |
| Provision of sterile needles and syringes and other injection supplies  | x |  |  |
| Substance use disorder educational materials  | x |  |  |
| Educational materials regarding overdose prevention  | x |  |  |
| Educational materials regarding the prevention of HIV, hepatitis and other blood-borne diseases  | x |  |  |
| A listing of the available substance use disorder and mental health treatment facilities in the jurisdictions you serve. | **x** |  |  |
| Safe return and disposal of used syringes/needles | **x** |  |  |
| Verification that syringes/needles/injection supplies came from a CHR site | **x** |  |  |
| Overdose prevention kits that include naloxone  |  | **x** |  |
| Substance use disorder treatment consultations  |  | **x** |  |
| Mental health services consultations |  | **x** |  |
| Referral and linkage to social services  |  |  | **x** |
| Referral and linkage to HIV testing  |  |  | **x** |
| Referral and linkage to hepatitis B (HBV) testing  |  |  | **x** |
| Referral and linkage to hepatitis C (HCV) testing  |  |  | **x** |
| Referral and linkage to tuberculous (TB) testing  |  |  | **x** |
| Referral and linkage to sexually transmitted disease (STD) testing  |  |  | **x** |
| Referral and linkage to hepatitis A and HBV vaccination  |  |  | **x** |
| Referral and linkage to HIV pre-exposure prophylaxis (PrEP)  |  |  | **x** |
| Referral and linkage to HIV post-exposure prophylaxis (PEP)  |  |  | **x** |
| Referral and linkage to health insurance enrollment assistance  |  |  | **x** |
| Referral; and linkage to medical care and treatment for HIV, HBV, HCV, TB, STDs, and common complications of injecting  |  |  | **x** |
| Condom distribution |  |  | **x** |

\*When “must” and “shall” are used in this document, this is a mandatory requirement. Failure to comply could mean losing authorization to perform CHR in Virginia. When “should”, “may”, and “could” are used, these are recommendations as best practices for CHR, but are not mandatory.

1. **Application and Authorization Process**

The application and approval process for entities seeking authorization to operate a CHR program:

1. The application for all sites must include a security plan that specifies:
	1. Location (physical address for fixed sites, general locations for mobile sites) and hours of operation of all service delivery sites;
	2. Description of how entity will securely store, collect, dispose of and transport hypodermic needles and syringes;
	3. Mechanism (e.g., signage, participant handout) used to inform participants that substances are not to be used or exchanged at CHR sites, including the parking and exterior areas of the site;
	4. How the entity will adequately staff service delivery; and
	5. What mechanism will the CHR program use to identify personnel authorized to purchase, transport, distribute, and collect hypodermic needles and syringes. Issuance of a personnel identification card with agency name, phone number and address, “Comprehensive Harm Reduction Program Personnel,” and individual’s name and personnel records documenting card distribution will suffice for this purpose.
	6. Entity’s personnel policies and training plan that includes but is not limited to:
		1. Education on HIV/HBV/HCV transmission, prevention, counseling and testing such as [Virginia HIV AIDS Resource and Consultation Centers’ Facts and Fundamentals](http://vharcc.com/trainingcalendar.html) or equivalent courses is recommended for ALL site and required for VDH funded sites;
		2. Infection control and exposure management compliant with
			1. [Occupational Safety and Health Administration (OSHA)’s Bloodborne Pathogens Standard (29 CFR 1910.1030)](https://www.osha.gov/SLTC/bloodbornepathogens/otherresources.html)
			2. [Centers for Disease Control and Prevention’s (CDC) Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care](https://www.cdc.gov/hai/settings/outpatient/outpatient-settings.html);
		3. Entity’s procedures for preventing and managing personnel’s or participants’ inadvertent exposure to blood in a manner that may transmit infection (e.g., via needle stick injury) in compliance with [current CDC recommendations](https://stacks.cdc.gov/view/cdc/20711);
	7. CHR sites should educate local law enforcement in jurisdictions they operate in on harm reduction as a public health strategy and the sites method of participant verification prior to opening or soon after. This can be done in person or by mail/email. Including a sample program ID may also be helpful so it is recognizable if your participants have to present it to an officer.
2. The application must demonstrate the level of operational readiness by providing the following from each locality in which it proposes to provide services:
	1. Letters of agreement from agencies that will accept referrals of participants in need of services required in the CHR Standards listed above that state the agency will accept referrals from your program with the exception of the Department of Social Services and health insurance enrollment agencies;
	2. Description of how applicants will develop, implement, document, and maintain a process for community engagement that may include a community advisory board; and
	3. Applicants may provide additional documentation supporting their application that may include support letters from local health departments, law enforcement, local government officials, coalitions, businesses, parent groups, drug courts, educational institutions, religious organizations, and other stakeholders.
3. The application must demonstrate programmatic administrative capacity by including the following:
	1. Budget and funding source(s) that may be used for harm reduction services (including purchase of hypodermic syringes and needles. Federal and state funds may not be used at this time for syringes/needles/cookers or any equipment used to prepare or administer illegal drugs;
	2. Description of related health and/or behavioral health services currently provided by the applicant, if any, and number of years these services have been provided;
	3. Description of experience collecting and reporting data; and
	4. Description of current practices used to protect confidentiality of clients, records, data and [signed verification of receipt and assurance](http://www.vdh.virginia.gov/content/uploads/sites/10/2017/05/Verification-of-Receipt-and-Assurance-of-Key-Requirements-for-Non-DDP-Personnel.pdf) of [VDH Division of Disease Prevention (DDP) Security and Confidentiality Policies and Procedures](http://www.vdh.virginia.gov/content/uploads/sites/10/2017/05/Final-DDP-Security-and-Confidentiality-Policies-and-Procedures-1.pdf).

Additional Application Procedures for Sites Seeking VDH Funding:

1. Application for VDH funding must include a time-phased work plan for sites funded by VDH with process measures that describe how the CHR program will meet CHR objectives. The plan must specify timing and frequency of CHR counseling and required services. Sites not applying for VDH funding are encouraged to, but not required to submit work plans; and
2. Organizational chart that includes positions that will provide CHR services are required for VDH funded sites, non-funded sites should submit contact information for key staff members (phone and email address).
3. **Application Review**
4. VDH has established a Harm Reduction Review Team comprised of subject matter experts, epidemiologists, VDH leadership, and at least one person with lived injection drug use experience. This team will receive and review applications at a minimum on a quarterly basis;
5. VDH staff will perform a pre-operational site visit to applicants approved by the Harm Reduction Review Team. This visit will provide an opportunity to validate application information, perform any additional assessment needed, and offer technical assistance to ensure successful implementation;
	1. If the site visit findings are favorable, the Health Commissioner will issue an authorization letter that will allow the entity to provide CHR services. These steps should be completed within 45 days of VDH’s receipt of the entity’s application;
	2. VDH will then establish a memorandum of agreement (MOA) with the applicant to document that it is an affiliated organization with which VDH contracts. The applicant may begin providing CHR services after all parties sign the MOA; and
	3. VDH will repeat a site visit within 45 days of the start of services to ensure programs are operating under the established standards and protocols. Regular site visits (at least every six months), announced or unannounced, will be performed throughout the period during which the program is operating.
6. **Programmatic Requirements**

**Requirement 1:** CHR programs are required to provide appropriate disposal of used hypodermic needles and syringes.

1. Programs should collect and dispose of used needles and syringes in accordance with federal, state, and local laws and regulations and provide safe disposal containers (sharps containers, heavy plastic containers such as those used for laundry detergent), and proper instruction on the use and lawful disposal of these containers. Programs are responsible for ensuring that they research and abide by these requirements;
2. Programs will use clearly labeled, rigid, puncture-resistant containers specifically designed for sharps disposal when collecting needles and syringes from participants;
3. Programs must provide written proof (e.g., contract, purchase order) of an agreement with the entity that serves as their disposal service for these items before providing services (before or at the time of the pre-operational site visit); and
4. VDH funded programs must track and report on the number of syringes returned for disposal.

**Requirement 2**: CHR programs must provide at no cost to the participant, new and sterile hypodermic needles and syringes in quantities sufficient to ensure, to the best of their abilities, that needles, syringes and other injection supplies are not shared or reused.

1. Programs should not impose restrictions such as a 1:1 exchange without VDH approval. However, programs can establish a maximum number of syringes distributed per visit based on supply limitations;
2. Programs must obtain and distribute single-use, medical-grade, sterile hypodermic needles and syringes appropriate for substances injected by their participants;
3. Programs must provide quantities sufficient to ensure that needles, syringes, and other injection supplies are not shared or reused; and
4. All programs must track and report on the number of syringes/needles distributed to participants.

**Requirement 3**: CHR sites must provide reasonable and adequate security to their program site, program equipment and supplies and program personnel.

1. In keeping with VDH’s mission to protect the health of all Virginians,
	1. Within six months of initiating CHR, all program staff must provide evidence that they have received the complete Hepatitis B (HBV) vaccination series or declined vaccination. Test counselors who do not want to receive the HBV vaccine may sign a waiver declaring that they have been offered vaccination and declined (Attachment 1). Vaccination records or waiver of vaccination must be kept in the tester’s personnel or volunteer file.
	2. CHR site staff must complete a DDP Security and Confidentiality Agreement (Attachment 2);
	3. Sites must comply with OSHA, Americans with Disabilities Act;
	4. Program staff must receive universal precautions trainings. VDH can provide assistance in obtaining this training;
	5. Program staff should receive blood-borne pathogen education. VDH can provide assistance in obtaining this training;
	6. Participant records must be keep locked in a secure area, with three-levels of protection (locked file cabinet, in a locked room in a locked building or office);
	7. Programs must submit a security plan to VDH;
	8. Programs must offer local law enforcement the opportunity to review their security plan; and
	9. Street and mobile outreach and staffing of fixed sites should include at least two program personnel. Home visits, counseling sessions, and other meetings requiring confidentiality and privacy do not require two individuals. Programs should provide precautions that these visits be conducted in the safest way possible and describe these precautions in their safety plan.

**Requirement 4:** CHR sites must provide educational materials concerning (a) substance use disorder prevention, (b) overdose prevention, (c) the prevention of transmission of HIV, viral hepatitis, and other blood-borne diseases, (d) available mental health treatment options, including referrals for mental health treatment, and (e) available substance use disorder treatment options, which shall include options for medication assisted treatment of substance use disorder, including referrals for treatment to participants.

1. Educational materials that inform participants about prevention and treatment of HIV, HCV and other blood-borne pathogens
2. Materials must reinforce harm reduction counseling described above and include information about where and how participants can access substance use disorder treatment;
3. Materials distributed pertaining to the above topics must be from trusted scientific sources and contain the most current scientific knowledge. Trusted sources would include the CDC, Substance Abuse and Mental Health Services Administration, National Institute of Drug Abuse, VDH and other state health departments, the Harm Reduction Coalition and peer-reviewed journals, among others; and
4. VDH funded CHR sites wishing to produce their own harm reduction educational materials should adhere to copyright laws and submit finished materials to the VDH/DDP Materials Review Board before printing and distribution. More information on materials review can be found at: <https://www.vdh.virginia.gov/disease-prevention/resources/>.

**Requirement 5:** CHR sites must provide their participants access to overdose prevention kitsthat contain naloxone or other opioid antagonist approved by the U.S. Food and Drug Administration for opioid overdose reversal. Access can be by direct distribution to participants or by referring participants to a community partner that provides naloxone or another FDA approved opioid antagonist.

**Requirement 6:** CHR sites must provide individual CHR counseling*,* including individual consultations regarding appropriate mental health or substance use disorder treatment. VDH can connect sites to training programs that include how to counsel participants.

Individual harm reduction counseling that addresses actions and behavioral changes that reduce or eliminate use of drugs, injuries caused by drugs (e.g., overdose, tissue damage), and transmission of infections via sex and injection drug use.

**Requirement 7:** People age 18 and older, who are at risk for harm or injury due to using and/or injecting substances may enroll in CHR services, without regard to income or insurance status

At the first visit, CHR program personnel must, at a minimum, collect the following information: a name, and the age, gender, and zip code of residence of the participant.

1. CHR sites must provide participants a means of verification, such as an identification card, that a hypodermic needle or syringe or other injection supplies were obtained from the CHR program,;
2. ID cards should have the name of the CHR site and a phone number to reach a staff member who can provide verifications.
3. CHR sites should assess the frequency, volume and type of substances injected in order to meet the supply and harm reduction needs of participants; an
4. The program will provide CHR counseling and required services as specified in its approved application. The program will maintain documentation that demonstrates counseling and services are provided as required. VDH will review documentation during subsequent site visits.

**Requirement 8**: CHR programs must be able to verify that a hypodermic needle, syringe, or other injection supplies were obtained from their program. Supplies do not have to be individually labeled. Sites may choose to label bags supplies come in or include a business card with supplies. At minimum sites should be able to document supply manufacturers/brand names, are distributed by their CHR program.

**Requirement 9:** CHR programs must be able to verify which personnel the program authorizes to purchase, transport, distribute, and collect hypodermic needles and syringes.

Programs must develop a documentation process that shows an individual is a program staff (including volunteers) such as an identification card. The documentation should list the duties that staff member can perform.

**Requirement 10:** All VDH funded site must distribute condoms to participants. Unfunded sites may also distribute condoms. Condom and lubricants are available free of charge if sites register for VDH’s condom distribution program. If you would like to participate, please contact **Beth Marschak** at elizabeth.marschak@vdh.virginia.gov or (804) 864-8008.

1. **Data Reporting Requirements:**

By July 1 each year for the preceding calendar year, CHR sites must collect and report the following data to VDH:

1. the number of individuals served by the program;
2. the number of needles, hypodermic syringes, and other injection supplies distributed by the program;
3. the number of overdose prevention kits distributed by the program; and
4. the number and type of referrals to mental health or substance use disorder treatment services provided to individuals served by the program, including the number of individuals referred to programs that provide naloxone or other opioid antagonists approved by the FDA.

Frequency and amount of data depends on the type of site, VDH funded or VDH non-unfunded. All sites performing HIV and HCV testing will report testing/referral and linkage data in their CHR report, as well as in accordance to their HIV/HCV testing contract.

VDH funded sites will enter program data monthly and submit a narrative report on a quarterly basis. Unfunded sites are encouraged to enter data on a monthly basis to enhance the information available supporting the impact of CHR services, but are required to report on the mandatory variables listed in Table 1 on an annual basis.

Funded sites are required to use VDH’s data entry system. Unfunded site are strongly encouraged to use the same system. VDH will offer training and assistance to those who use this system.

Sites funded by VDH will be required to enter data on a monthly basis and submit a written progress report quarterly.

Additional information including application forms are available at [www.vdh.virginia.gov/diease-prevention/CHR](http://www.vdh.virginia.gov/diease-prevention/CHR)

**Attachment 1:**

Agency Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Waiver of Hepatitis B Vaccination

 I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me. I have read the above information and I agree to comply with this policy. If I have any questions or concerns I will address them with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (supervisor name)

Print Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sign Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Attachment 2:**

**Division of Disease Prevention (DDP) Security and Confidentiality Policies and Procedures Verification of Receipt and Assurance of Key Requirements for Non-DDP Personnel**

**(External contractors, service providers and data recipients)**

Division of Disease Prevention (DDP) Security and Confidentiality Policies and Procedures Verification of Receipt and Assurance of Key Requirements for Non-DDP Personnel (External contractors, service providers and data recipients). If you handle, use, enter, or analyze DDP’s confidential paper or electronic records or data, you must follow these requirements:

 • Always protect and maintain security of state property you use (such as paper and electronic records, computers, flash drives, cell phones).

 • Do not connect personal storage devices (such as non-state issued cameras, phones, MP3 players, flash drives) to state IT equipment/computers.

• Obtain DDP approval before removing or transporting confidential information from agreed upon locations/offices.

• Transport confidential information in a locked briefcase or similar secure container.

• Use an approved IronKey™ flash drive if you must transport confidential electronic data. o Ensure data is encrypted or flash drive is stored under lock and key when not in use, o Keep flash drive in a separate location from your computer, and o Delete all data immediately after use.

• Store all confidential information in specified, locked filing locations.

• Return all confidential information to locked file locations at end of workday.

• Do not store confidential DDP information on the hard drive of your computer.

• Collect, share, and transport the minimum confidential information necessary to conduct your work.

• Whenever possible, code information to avoid use of disease specific or client identifying information. • Immediately report any known or suspected confidentiality breach to your immediate supervisor, DDP contract monitor and the DDP director.

• No confidential information should be transmitted via email.

• Send mail in manner that does not allow confidential contents to be revealed.

• Faxes containing confidential information must only be sent to, or received at secure locations.

• Do not disclose confidential information over the telephone without first confirming the recipient is allowed access to the information.

• Make every effort to ensure that confidential data is removed from PCs prior to surplus.

• Avoid photography or video in office locations that involve DDP confidential data, unless it is absolutely necessary for business purposes and approved by your supervisor(s).

• If you are a recipient of data from DDP, you will ensure that all data stewardship activities are handled according to the signed Data Request and Data Recipient Agreement forms. Your signature below indicates that:

• You have read the Security and Confidentiality Policies and Procedures in its entirety, You have read and understand these key requirements, and

• You have discussed any content you do not understand with your supervisor.

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

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_

Supervisor’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If employed external to DDP, identify your employer or affiliation:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*This document summarizes key attributes of the Security and Confidentiality Policies and Procedures. It is not inclusive of all Security and Confidentiality Policies and Procedures requirements.*