Overview of Health Care Service Requirements

For New Jersey Harm Reduction Centers

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This guidance was written and prepared for the New Jersey Department of Health to outline requirements across several categories of health services domains for harm reduction center consideration. The breadth of services offered will be contingent upon each harm reduction center's setting, model, staffing, resources (including funding), licensing (in some cases), and participants' needs.

Overview

The New Jersey Harm Reduction Centers (HRCs) are authorized to operate by the New Jersey Department of Health (NJ DOH). An HRC must be registered with and approved by the NJ DOH.^{1 2 3 4} HRCs are not licensed facilities in NJ; however, offer services that fall under their authorization to operate. The licensure requirements relate to the HRC staff licenses not the facility itself in the context of the HRC.

HRCs wishing to expand their health care services may need assistance in determining when the level of clinical services they are providing crosses the threshold of requiring a primary care clinic license (regulated by NJAC 8:43A). ^{5 6 7} NJAC 8:43A governs ambulatory care facilities which cover primary care, family planning, family practice, etc. The NJ Certificate of Need and Licensing (CN&L) may need to be consulted to determine if licensure is required.⁸

The NJ DOH has proposed the <u>Single Integrated Health Care License</u> which aims to consolidate licensing requirements, allowing facilities to offer a broader range of services under one streamlined license. The new license will replace the need for separate approvals for services like primary care, behavioral health, and substance use treatment. When available, this will give flexibility on the breadth and services that HRCs can offer if they opt for a Single Integrated Health Care License.

The information in this document is intended to provide guidance to HRCs in New Jersey related to offering health care services. It is hoped that this information inspires the HRCs to expand their health care services based on their participants' stated and anticipated needs. Each section corresponds to a specific domain of healthcare services including:

Harm Reduction Services

¹ NJ Legislature Harm Reduction Centers

² NJ Department of Health: Harm Reduction Center Registration Application

³ <u>Harm Reduction Services Adopted Special Repeals and New Rules and Concurrent Proposed Readoption of Specially Adopted Repeals and New Rules: N.J.A.C. 8:63</u>

⁴ Department of Health | HIV, STD, and TB Services | Harm Reduction Centers

⁵ N.J. Admin. Code Tit. 8, ch. 43A - MANUAL OF STANDARDS FOR LICENSING OF AMBULATORY CARE FACILITIES | State Regulations | US Law | LII / Legal Information Institute

⁶ New Jersey Administrative Code, Chapter 43A, Subchapter 13 - MEDICAL RECORDS | New Jersey Administrative Code | Justia

⁷ docx (NJ DOH)

⁸ Department of Health | Health Facilities | Certificate of Need and Facility Licensing

⁹ (6) New Jersey's Single Integrated Health Care License: A Game Changer for Providers and Patients

- Vaccines
- Point of Care Testing (POCT) Services
- Other Lab Testing Services
- Triage and Routine Services
- Medical Treatment Services
- Pap Smears and Pelvic Examinations
- Urgent and Emergency Services
- Mental Health, Substance Use, and Other Behavioral Health Services

Each domain of health care services includes guidance for the following common questions:

- What credentials are needed to provide this service? This outlines specific credentials and New Jersey requirements for each domain of service, including supervisory requirements.
- What space or equipment is needed? This outlines space considerations (e.g. storage, temperature, physical layout, privacy) and equipment (e.g. machines, medical equipment) necessary to conduct the services both comfortably and to be in compliance with any New Jersey specific regulations.
- Is a Medical Director required? A Medical Director is a physician responsible for overseeing the medical operations of a healthcare organization, such as a hospital, clinic, nursing home, insurance company, or pharmaceutical firm. Their primary role is to ensure that the facility or organization provides high-quality, efficient, and ethical medical care. This is specific to the requirement of having a credentialed Medical Director overseeing the provision of services, policies and procedures, and quality assurance activities to ensure proper care.
- What training is required? This outlines New Jersey specific requirements by service type and any supplemental training to improve the standard of practice to ensure quality care.
- Are there competency testing requirements? This outlines both requirements and examples of setting up competency testing internally to ensure quality standards.
- **Documentation & Additional Notes.** This section includes notes for documentation of services (e.g. physical notes and/or electronic documentation) and any other considerations for harm reduction centers to note as they implement services.

Harm Reduction Services

including the distribution of supplies and resources

Services include	Distribution of harm reduction supplies for overdose prevention (e.g. naloxone, drug checking test strips), safer drug use (e.g. sterile syringes, pipes), wound care prevention, and other wellness materials.
What credentials are needed to provide this service?	Both licensed and non-licensed staff may deliver harm reduction services. Wound care services may be provided by licensed personnel only. Wound care information, education, and supplies for distribution can be shared by non-licensed personnel. See wound care policy and procedure for additional details.
What space or equipment is needed?	The space and equipment needed is dependent on which specific harm reduction services are offered by the HRC. Space may be needed for privacy and confidentiality of participant interactions. Space may be needed for storage of harm reduction supplies. Harm Reduction Supplies: Overdose reversal supplies, including the purchase of naloxone kits (this may include syringes for the purpose of administering injectable naloxone only) Substance test kits, including fentanyl test strips and xylazine test strips Safer sex kits, including condoms, and hygiene/dignity kits Sharps disposal and medication disposal kits Wound care supplies, including saline and antiseptic ointments Medication lock boxes Sterile water and saline Ascorbic acid (vitamin C)

- Nicotine cessation therapies (over the counter products)
- Food (e.g., snacks, protein drinks, water)
- Supplies to promote sterile injection and reduce infectious disease transmission through injection drug use — excluding sterile needles, syringes, tourniquets, band-aids, alcohol wipes, sharps containers, cotton, cookers, sterile water, and other drug use equipment*
- Safer smoking kits to reduce infectious disease transmission
- Safer sniffing kits, including straws and scoop utensils
- FDA-approved home testing kits for viral hepatitis (i.e., HBV and HCV) and HIV
- Written educational materials on safer injection practices and HIV and viral hepatitis and prevention, testing, treatment, and care services
- Distribution mechanisms (e.g., bags for naloxone or safer sex kits, metal boxes/containers for holding naloxone) for harm reduction supplies, including stock as otherwise described and delineated on this list

Harm Reduction Services:

Education

- Risk reduction education for HIV and viral hepatitis
- Education on safer sex and safer injection practices
- Overdose prevention education
- Trauma-informed harm reduction education sessions
- Counseling and education on PrEP/PEP¹⁰

Equipment

- Prevention supplies such as syringes, needles, tourniquets, band-aids, alcohol wipes, sharps containers, cotton, cookers, antiseptic ointments, and hygiene/dignity kits
- Safe disposal of injection equipment
- Access to naloxone and fentanyl test strips and other drug checking equipment

Care – available at select sites with Harm Reduction Health Nurse (HRHN) capacity

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¹⁰ Harm Reduction I SAMHSA

Is a Medical Director required?	 Nurse/healthcare services Low-threshold medication for addiction treatment Referrals and linkages to substance use treatment, medical care, and social/mental health services A Medical Director is not required for the provision of harm reduction services.
What training is required?	Harm reduction centers would benefit from creating onboarding and continued education plans for their organization in addition to supporting external professional development opportunities. This may include but is not limited to: • Onboarding resources for newer team members on harm reduction strategies and supplies • Asynchronous learning through e-courses, webinars, and review of materials • Shadowing and practice during service delivery • Staff meeting presentations for continuing education • Staff should participate in Basecamp and other communication channels to build relationships with other HRC providers Training should be consistent with harm reduction services and supplies provided. Rules require all HRCs (regardless of funding) receive training from DHSTS on HRC database and from 8:63-3.5 Training, policies, and procedures (a) A harm reduction center shall: 1. Ensure that staff and volunteers receive training as required at N.J.S.A. 26:5C28.b(2), and maintain records of staff and volunteer training; 2. Establish appropriate administrative, technical, and physical controls and safeguards that protect the confidentiality, integrity, and availablity of individually identifiable information about consumers, in compliance with applicable provisions of the CDC HIV Data Security and Confidentiality Guidelines; 3. Establish procedures for compliance with the Bloodborne Pathogens Standard; and 4. Develop and maintain protocols for HIV post-exposure prophylaxis in accordance with guidelines of the Centers for Disease Control and Prevention available at https://www.cdc.gov/hiv/risk/pep/index.html.

The NJ DHSTS RFA for Harm Reduction Expansion also states, for funded agencies: "Additionally, HRC staff should be trained and remain up to date on current service models related to syringe access, harm reduction supplies, and harm reduction counseling, including the incorporation of trauma-informed practices into service delivery. Please see Appendix C for examples of implementation resources from nationally recognized entities on harm reduction. Existing harm reduction centers in New Jersey may also be referenced as service model examples" 11

Resources:

- Education & Training of NJ Healthcare Providers in HIV Care François-Xavier Bagnoud Center
- Online Learning Center | National Harm Reduction Coalition
- In The Works e-courses
- Grayken Center for Addiction TTA | Boston Medical Center
- Opioid Response Network
- New Jersey NEXT Distro

Are there competency testing requirements?

Competency testing for harm reduction staff should be done to assess drug checking techniques, overdose prevention training techniques (including administration of IM and IN naloxone, rescue breathing, and oxygen administration as applicable)

Resources:

- Evaluation of a Drug Checking Training Program for Frontline Harm Reduction Workers and Implications for Practice¹²
- Core Competencies for Harm Reduction Peer Workers New York State Department of Health AIDS Institute
- <u>Certified Peer Recovery Specialist Addiction Professionals Certification Board, Inc.</u>
- Peer Certifications | NJPN
- Certified Peer Recovery Specialist Certificate | Training | My Career NJ
- <u>Department of Health | Family Health Services | Colette Lamothe-Galette Community Health Worker Institute</u>
- Education & Careers | New Jersey CHW Hub

¹¹ REQUEST FOR APPLICATIONS (RFA)

¹² Teal, Wallace, Hore. Evaluation of a Drug Checking Training Program for Frontline Harm Reduction Workers and Implications for Practice.

	State New Jersey - National Community Health Worker Registry NCHW™ Registry
Documentation & Additional Notes	To support the hiring and retention of people with lived/living experience, managers at HRCs are encouraged to review resources specific to creating cultural practices that are supportive of this value.
	Resources: • Harm Reduction At Work: A Guide for Organizations Employing People Who Use Drugs

Vaccines	
Services include	Providing vaccines to prevent the likelihood of infection including but not limited to COVID-19, influenza ("flu"), hepatitis A, hepatitis B, human papillomavirus "HPV", and other infectious diseases for which there is a vaccination.
What credentials are needed to provide this service?	Who can administer vaccines? A certified medical assistant*, RN, LPN, pharmacist technician, pharmacist, MD/DO, APN (including NP), and PA may administer vaccines in NJ. ¹³
	*Medical assistants in New Jersey must have a certification to give injections, and can only do so under a physician's instructions. ¹⁴
	Who can order vaccines? Vaccines must be ordered (or prescribed) by a MD/DO, APN (including NP), or a PA. ¹⁵
	The provision of vaccines is covered under the individual staff licenses that are authorized to provide this service (see above).
What space or equipment is needed?	Dedicated refrigerator : is needed for vaccine storage and specimen storage (separate from food storage).
	Temperature Log: There are very specific storage and temperature monitoring requirements for vaccines. ¹⁶
Is a Medical Director required?	A Medical Director (MD/DO) is only required for the administration of VFC (Vaccines for Children) vaccines for children 18 years old and younger. ¹⁷

NJ Legislature: Bill A5752 to Expand Vaccine Authority
 Can Medical Assistants Give Injections Or Shots? | Campus.edu
 State Law and Standing Orders for Immunization Services
 Vaccine Storage and Handling Resources | Vaccines & Immunizations | CDC
 NJ Department of Health: Vaccine Guidance For Providers

	Otherwise, APN (including NP), MD/DO, and PA may administer vaccines under their own authority or delegated authority (PA). A supervising health care practitioner is a MD/DO, RN, APN, PA, or RPh for a certified medical assistant. ¹⁸
What training is required?	Training on vaccine administration is a standard part of training for nurses (RN, LPN), APN (including NP), PA, and MD/DO. In NJ, medical assistants must be certified to give injections. Pharmacy technicians must hold an active PTCB CPhT Certification and complete a PTCB-Recognized Immunization Administration Education/Training Program to administer vaccines in NJ. ¹⁹
Are there competency testing requirements?	It is recommended that competency testing be in place for each staff member who administers vaccines. Resources: • Education & Training of NJ Healthcare Providers in HIV Care – François-Xavier Bagnoud Center • Skills Checklist for Vaccine Administration • You Call The Shots Vaccine Trainings CDC • Vaccine Administration Resource Library CDC • Chapter 6: Vaccine Administration Pink Book CDC
Documentation & Additional Notes	Documentation required on administration of vaccines: the vaccine manufacturer; the lot number; the expiration date; the date the vaccine was given; the name, title, and signature of the person giving the vaccine; the Vaccine Information Sheet (VIS) utilized with the participant; the date the VIS was given to the participant; and the anatomical location and by which route (IM, IN, SC, ID, or PO) the vaccine was given. ²⁰

Administration of COVID-19 Vaccines by Certified Medical Assistants, Health Care Practitioners-in-Training, and Health Care Personnel
 Credentialing Guidelines and Requirements - Guidebook
 Technically Speaking: Recording Vaccinations – What is Required by Federal Law? | Children's Hospital of Philadelphia

Point of Care Testing (POCT) Services	
Services include	Rapid testing for HIV, hepatitis C, COVID-19, influenza, and syphilis, blood glucose monitoring, pregnancy tests, urinalysis dipstick (as applicable), and POC urine toxicology testing (as applicable).
What credentials are needed to provide this service?	Who can provide the services? A wide variety of individuals can perform POCT, including laboratory technicians, emergency first responders, radiologists, physicians, nurses, PAs, NPs, or other health care practitioners. They may even be done by an individual on themselves, sometimes called "self-tests" or "home tests."
	POCT is usually performed by non-laboratory trained individuals such as licensed practical nurses, registered nurses, nurse aides, physicians, residents, students, technical assistants, respiratory therapists, emergency technicians, and pharmacists among others. ²²
What space or equipment is needed?	 Rapid test cassette: The core component of the POCT, containing the antibodies or probes necessary to detect the specific pathogen antigen. Sample application area: Where the participant sample is added to the cassette. Lateral flow membrane: A strip within the cassette where the sample migrates, allowing for interaction with the immobilized antibodies or probes. Control line: A visual indicator to confirm proper POCT performance. Test line: The line that indicates the presence of the target pathogen antigen. Reader device (optional): Some POCT tests require a dedicated instrument to analyze the test cassette and provide a quantitative result.²³ POCT is defined as diagnostic instruments performing in vitro analysis for patients and the result can
	be obtained within a short period of time without any special staff to do the POCT or any number of

Point-of-Care Testing Overview
 Yenice S. Training and Competency Strategies for Point-of-Care Testing
 Wang C, Liu M, Wang Z, Li S, Deng Y, He N. Point-of-care diagnostics for infectious diseases: From methods to devices

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	other limitations in other testing methods, and POCT can even be done in the field, in a home, in a mobile unit, as well as in a brick and mortar site. ²⁴
	Very little physical space is needed for POCT. Most devices for POCT are highly portable.
What training is required?	A majority of the staff who perform POCT are not trained laboratory staff and may not be as knowledgeable about the processes involved in testing, such as patient preparation, sample collection, management of equipment and supplies, instrument calibration and maintenance, the performance of the test, quality control, interpretation of the results, and reporting/documentation of results in each patient's context. Therefore, staff performing POCT must have the proper training and experience to ensure test results are accurate and reliable. ²⁵
	Staff performing POCT must be trained on how to perform each POCT utilized. This training should be codified in policies and procedures for POCT at that entity. Training may be done by within-agency staff or by external trainers.
	To support the development of a competent workforce with the knowledge and skills necessary to provide culturally responsive and appropriate services, DHSTS has partnered with Jefferson Health and the Northeast/Caribbean AIDS Education and Training Center (NE/CA AETC) to create the HIV Training and Capacity Development (TACD) Program as part of the HIV Community Support and Development Initiative (HCSDI). The mission of the TACD Program is to develop and implement a comprehensive training program to support ending the HIV epidemic in New Jersey. ²⁶
Are there competency testing requirements?	It is recommended that competency testing be in place for each staff member who performs POCT. There are many official and professionally based standards and guidelines that define how POCT should be implemented, managed and the performance quality checked and maintained. Most
	professionally based guidelines follow a similar template and provide similar information which includes specific references to staff training and competency assessment. Organizations that have a central biomedical laboratory are to use these standards in POCT - specific requirements for quality and

Yanawut Manmana, Takuya Kubo, Koji Otsuka, Recent developments of point-of-care (POC) testing platform for biomolecules
 Yenice S. Training and Competency Strategies for Point-of-Care Testing
 Department of Health | HIV, STD, and TB Services | Education and Training

	competence based on ISO 22870:2016 (see below). This standard is intended to be used in conjunction with ISO 15189:2022 (see below) and applies when POCT is carried out in a hospital, clinic, or healthcare organization providing ambulatory care. ²⁷
	Resources: • ISO 22870:2016(en), Point-of-care testing (POCT) — Requirements for quality and competence • ISO 15189:2022 - ISO 15189 - Medical laboratories — Requirements for quality and competence • Education and Training (NJ DOH) • NJ TACD
Documentation & Additional Notes	Documentation on POCT should include the following: • the type of POCT performed; • the results of the POCT; • the date the POCT was performed; • the name, credentials, and signature of the person performing the POCT; • and how the results were communicated to the participant.

Yenice S. Training and Competency Strategies for Point-of-Care Testing

Other Lab Testing Services

Including phlebotomy and other specimen collection services

monitoring labs

What credentials are

needed to provide this

service?

Services include...

Who can provide the services? An MD/DO, APN (including NP), PA, RN, and LPN (may vary depending on company/facility policy & procedure) may perform phlebotomy in NJ.

Confirmatory testing for hepatitis C (unless a qualitative RNA POC test²⁸ is used), HIV, and syphilis, full

panel blood draw (comprehensive metabolic panel for liver and kidney function tests and electrolytes, complete blood count, etc.), gonorrhea and Chlamydia testing, other sexually transmitted infection testing, urine culture, confirmatory urine toxicology testing (as applicable), HIV and HCV treatment

A physician may direct a certified medical assistant to perform phlebotomy only where the following conditions are satisfied:

- The physician has determined and documented that the certified medical assistant has the
 qualifications set forth above, has attained a satisfactory level of comprehension and
 experience in the performance of venipuncture, and has completed training that demonstrates
 to the physician proficiency in the procedures to be performed which shall include at least:
 - Ten hours of training in venipuncture and skin puncture for the purpose of withdrawing blood; and,
 - Satisfactory performance of at least 10 venipunctures.
- The certified medical assistant shall wear a clearly visible identification badge indicating their name and credentials.²⁹

A Phlebotomy Technician or Phlebotomist may perform phlebotomy in NJ under the supervision of a physician or other healthcare practitioner.³⁰ To become a Certified Phlebotomy Technician (CPT) in NJ, individuals must complete coursework and pass a national certification exam.³¹ Requirements include:

• Age: You need to be at least 18 years old to qualify for a phlebotomy training course.

²⁸ Xpert® HCV Info

²⁹ New Jersey Administrative Code Medical Examiners

³⁰ NJ Phlebotomy Technician Certification | Training

³¹ NJ Phlebotomy Technician | Training

• Educational requirements: The state of New Jersey requires prospective phlebotomists to hold a high school diploma or a GED to qualify for a training course. If you are not 18 yet but have these qualifications, you can enroll in a course. However, you will have to wait until you meet the age requirements before you can start finding work in the field.³²

What space or equipment is needed?

Equipment: Supplies required to collect other samples (urine toxicology test, urine culture, gonorrhea/Chlamydia testing, etc.) are typically provided by the commercial laboratory with which the HRC has a relationship. If doing blood glucose testing and urinalysis testing, a glucometer, lancets, blood glucose test strips, and urine dipstick tests would be needed. For phlebotomy, at a minimum, the equipment required when drawing blood includes gloves, alcohol or iodine to cleanse the area, a tourniquet, blood tubes, a tube holder, needles, tape, and gauze.³³

For processing and storage of phlebotomy and other samples, a centrifuge and a refrigerator and freezer (separate from one used to store food) are required.

During specimen processing, it may be required to centrifuge the phlebotomy specimen. Centrifugation is required to obtain either serum or plasma specimens.³⁴ A centrifuge separates blood components quickly and accurately. Centrifuges spin samples of blood at high speeds, using centrifugal force to separate the various parts of the blood.³⁵

Urine samples should be refrigerated at a temperature between 35.6°F and 46.4°F (2°C to 8°C).36

Pap smear samples should be stored at room temperature. No refrigeration of samples is needed.³⁷

For viral swab testing, refrigeration is preferable to storage at room temperature. Specimens should be stored in a temperature-monitored refrigerator at a temperature between 35.6° F and 46.4° F (2° C to

³² Everything You Need to Know About Becoming a Phlebotomy Technician in NJ - NAPTP

³³ Learning Phlebotomy Equipment | Arizona College

³⁴ Specimen Preparation Procedures | Services for Health Care Professionals | Pathology and Lab Services | Main Line Health

³⁵ The Ultimate Guide to Blood Centrifuges: Everything You Need to Know

³⁶ <u>Urine Specimens | Labcorp</u>

³⁷ 192005: Gynecologic Pap Test, Liquid-based Preparation | Labcorp

	8°C). If transport to the laboratory will be delayed for longer than 72 hours, the specimen should be frozen at -94°F (-70°C) or below and shipped on dry ice. ³⁸ For gonorrhea and Chlamydia sample storage, store the sample at 35.6°F to 86°F (2°C to 30°C) (refrigerated temperature of 35.6°F and 46.4°F or 2°C to 8°C is preferred). ³⁹ Phlebotomy samples should typically be stored at a temperature between 35.6°F and 46.4°F (2°C to 8°C), which is considered the standard refrigerator temperature range to preserve the integrity of the samples. Key points about phlebotomy sample storage temperature: • Ideal range: 2-8°C (35.6°F - 46.4°F) • Storage method: Keep samples in a refrigerator • Important consideration: Avoid freezing the samples unless specifically instructed ⁴⁰
What training is required?	Phlebotomy training may be done within the course of training to be a medical provider (MD/DO, APN, PA) or nurse (RN, LPN). Certified medical assistants may have sufficient practical experience in phlebotomy or an individual may complete a phlebotomy technician or certified phlebotomy technician course. Resources: New Jersey Administrative Code: Chapter 35 State Board of Medical Examiners South Jersey AIDS Education & Training Center (AETC) Phlebotomy Technician Certification Training
	 Phlebotomy Technician Training Everything You Need to Know About Becoming a Phlebotomy Technician in NJ - NAPTP
Are there competency testing requirements?	It is recommended that competency testing be in place for each staff member who performs lab testing.

 ^{38 2024} CDC Infectious Diseases Laboratory Test Directory, Version 30.0
 39 Chlamydia trachomatis and Neisseria gonorrhoeae, Nucleic Acid Amplification, Varies - Mayo Clinic Laboratories | Microbiology and Infectious Disease Catalog
 40 Recommended Storage Guidelines for Whole Blood Samples: Temperature, Light Exposure, and Duration of Storage

A phlebotomy competency assessment evaluates a phlebotomist's knowledge, skills, and abilities. It's performed regularly to ensure phlebotomists are competent in their role.

Assessment methods:

- Written exams: Test knowledge of phlebotomy procedures, safety protocols, and other topics
- Hands-on skills assessment: Evaluate a phlebotomist's ability to perform venipuncture
- **Direct observations**: Observe a phlebotomist performing routine patient tests
- **Review of test results**: Review test results, proficiency testing results, and quality control records

Assessment criteria:

- Technical skills, such as job knowledge, productivity, and work quality
- Behavioral skills, such as enthusiasm, cooperation, patient engagement, and attitude
- Organizational skills, such as work consistency, work relations, documentation, and dependability

Assessment process:

Assessors may provide corrective feedback and allow another chance to demonstrate competence Phlebotomists must demonstrate full competence before an assessor signs off on each task

Assessment frequency:

Phlebotomists may need to demonstrate competency at 6 months post training and yearly thereafter⁴¹ There are many official and professionally based standards and guidelines that define how POCT should be implemented, managed and the performance quality checked and maintained. Most professionally based guidelines follow a similar template and provide similar information which includes specific references to staff training and competency assessment. Organizations that have a central biomedical laboratory are to use these standards in POCT - specific requirements for quality and competence based on ISO 22870:2016 (see below). This standard is intended to be used in conjunction with ISO 15189:2022 (see below) and applies when POCT is carried out in a hospital, clinic, or healthcare organization providing ambulatory care.⁴²

Resources:

• Education & Training of NJ Healthcare Providers in HIV Care – François-Xavier Bagnoud Center

⁴¹ Phlebotomy Competency Assessment: Methods, Frequency, and Benefits

⁴² Yenice S. Training and Competency Strategies for Point-of-Care Testing

	 ISO 22870:2016(en), Point-of-care testing (POCT) — Requirements for quality and competence ISO 15189:2022 - ISO 15189 - Medical laboratories — Requirements for quality and competence
Documentation & Additional Notes	Best practices in phlebotomy involve the following factors: • planning ahead; • using an appropriate location; • quality control; Standards for quality care for patients and health workers, including • availability of appropriate supplies and personal protective equipment; • availability of post-exposure prophylaxis (PEP); • avoidance of contaminated phlebotomy equipment; • appropriate training in phlebotomy; • cooperation on the part of participants; • quality of laboratory sampling. 43 Keep in mind that someone who may be receiving phlebotomy services who has a history or current injection practice may be confident to share more about vein access; phlebotomists should use this opportunity to engage around vein care and promote education as needed.

⁴³ WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy

Triage and Routine Services	
Services include	The purpose of triage is to identify persons needing immediate care, identify individualized care needs, and prioritize liaising them with needed care. Triage services may include linkage to urgent care or emergency medical services, routine care including primary care, specialized medical services (cardiology, hepatology, infectious diseases, OB/GYN, etc.), dental services, wound care management services, social services agencies, care management, substance use disorder treatment facilities (opioid treatment program/OTP, outpatient programs, inpatient rehabilitation/residential services, acute withdrawal management services), mental health services, etc.
What credentials are needed to provide this service?	The level of provider or credentials needed for triage and routine services depend on the specific care or triage being provided. Some services may not require any credentialing; however, other services and/or triage may require specific knowledge (information, resources, skills) or credentials (MD/DO, APN, PA) • Assessment may be done by an RN, MD/DO, APN, PA • Diagnosis/treatment may be done by an MD/DO, APN, PA • An LPN, RN, or MA may be directed to provide aspects of treatment by an MD/DO, APN, or PA (e.g., wound care, injections, etc.) • A non-licensed staff member may share provide information and education to a participant and share observations they have made regarding the participant to a licensed staff member
What space or equipment is needed?	The space needed depends on the scope of services and triage offered and the volume of participants anticipated. See space/equipment needed for Medical Treatment Services . For triage, relationships with community-based organizations, federally qualified health centers (FQHCs), urgent care clinics, hospitals, substance use disorder treatment centers, dental clinics, reproductive health services providers, and mental health services providers are helpful.

^{44 &}lt;u>Triage Definition, Staffing & Tags - Video | Study.com</u>

Is a Medical Director required?	In NJ, it depends on the scope of services offered whether or not a Medical Director is required.
What training is required?	Depending on the nature of routine care provided, the training required would be determined. For example, if prenatal care were provided, this would necessitate having a medical provider whose scope of practice and training included prenatal care (FNP, CNM, family medicine physician, OB/GYN, but not an internal medicine physician).
	Resources: Education & Training of NJ Healthcare Providers in HIV Care — François-Xavier Bagnoud Center South Jersey AIDS Education & Training Center (AETC) HHS Office on Women's Health: Prenatal Care Guidance What Is Prenatal Care? Health Care During Pregnancy Wound Care & Medical Triage for People Who Use Drugs and the Programs That Serve Them NASTAD
Are there competency testing requirements?	Competency testing is necessary to ascertain that staff have the appropriate skills and training for the level of triage and/or routine services that are being provided. This may be ascertained by licensing, scope of practice and certification of staff members, continuing education credits, and/or an internal mechanism to assess competency.
Documentation & Additional Notes	Documentation should be done on any routine care provided and/or triage/referrals done. Ideally, a closed-loop referral process would occur to ensure that appropriate referrals actually are completed. ⁴⁵

⁴⁵ tcpi-san-pp-loop.pdf (CMS Transforming Clinical Practice Initiative: Closing the Loop)

Medical Treatment Services	
Services include	Medical treatment services may include reproductive health services (including routine and acute gynecological care, contraception provision, etc.), HIV treatment services, hepatitis C treatment services, STI treatment (and partner treatment) services, and gender affirming services (LGBTQIA+ services and gender affirming hormone provision).
	The HRC should be aware of any facility licensing that <i>may</i> be required for the provision and scope of services they plan to provide (e.g., a primary care clinic license governed by NJ Chapter 8:43A). ⁴⁶ 47 48
	See also the section entitled, "Mental Health, Substance Use, and Other Behavioral Health Services" for more information on the scope of services within these realms.
What credentials are needed to provide this service?	Who can provide these services? Only a licensed medical provider (MD/DO, APN, PA) can provide treatment services in NJ. A RN may provide services if directed to do so by a medical provider.
What space or equipment is needed?	The space needed depends on the scope of services offered and the volume of participants anticipated. If the scope of services is to include Pap smears, STI testing, and pelvic exams, then appropriate equipment would include an examination table with stirrups, disposable plastic speculums, and an examination light appropriate for doing pelvic and rectal exams. An appropriate space to preserve safety, privacy, and confidentiality would be necessary.
	In a low-threshold medical setting, essential equipment would prioritize basic medical assessment tools, medication administration supplies, wound care supplies, harm reduction items like clean

⁴⁶ N.J. Admin. Code Tit. 8, ch. 43A - MANUAL OF STANDARDS FOR LICENSING OF AMBULATORY CARE FACILITIES | State Regulations | US Law | LII / Legal Information Institute

47 New Jersey Administrative Code, Chapter 43A, Subchapter 13 - MEDICAL RECORDS | New Jersey Administrative Code | Justia docx (NJ DOH)

needles and syringes, and potentially portable devices for on-site testing, all with a focus on accessibility and minimal barriers to entry, including:

Basic Medical Assessment:

Vital signs monitoring: To measure blood pressure, heart rate, and temperature.

- Otoscope and ophthalmoscope: For basic ear and eye examinations.
- Stethoscope: To listen to heart and lung sounds.
- **Height and weight scale:** For basic anthropometric measurements.
- **Penlight:** For basic light source during examinations.

Medication Administration:

- Syringes and needles: Various sizes for injections.
- Alcohol swabs: For skin preparation before injections.
- **Medication vials and ampoules:** To store and administer medications.
- Sharps container: For safe disposal of used needles.

Wound Care:

- Sterile gloves: To maintain hygiene during wound care.
- Antiseptic solutions: For cleaning wounds.
- Gauze pads and bandages: To cover and protect wounds.
- See wound care policy and procedure for additional recommendations on wound care supplies.

Harm Reduction Supplies:

- Clean needles and syringes: For safe injection practices.
- Naloxone kits: To treat opioid overdose.
- Fentanyl test strips: To detect presence of fentanyl.
- **Xylazine test strips:** To detect the presence of xylazine.
- Syringe exchange containers (e.g., Sharps containers): For safe disposal of used needles.

Portable Diagnostic Tools (depending on setting):

- **Blood glucose meter (e.g., glucometer):** For checking blood sugar levels.
- Urine dipstick kit: For basic urinalysis.
- **Pulse oximeter:** To monitor oxygen saturation.
- Portable ECG machine: To record heart rhythm.

Other Considerations:

- Basic first aid supplies: Band-aids, antiseptic wipes, gauze pads.
- **Privacy screens:** To protect patient confidentiality.

	 Comfortable seating and/or examination tables: To promote patient comfort during consultations/examinations. Patient education materials: Brochures and pamphlets on relevant health topics.
Is a Medical Director required?	It does not appear that a medical director is required to provide medical treatment services in NJ. However, a medical director is responsible for the <i>quality</i> of medical care provided to patients.
	 Medical Director Responsibilities: A medical director is a physician who leads and coordinates medical care in a facility. They are responsible for ensuring that the medical services are provided appropriately and meet quality standards. They also help to coordinate medical care with other services to provide a continuum of care for the patient. They develop and maintain policies and procedures for the medical services. They also participate in planning and budgeting for the medical services.
What training is required?	Training for provision of medical treatment services would entail the medical provider (MD/DO, APN, PA) mastering the diagnostic, testing, and treatment options for the types of treatment services offered. This can be accomplished through continuing education requirements, certification programs, mentorships, or hand-on internships.
	Resources: • Education & Training of NJ Healthcare Providers in HIV Care – François-Xavier Bagnoud Center • South Jersey AIDS Education & Training Center (AETC) • NJ Department of Health HIV, STD, and TB Services Education and Training • Grayken Center for Addiction Training and Technical Assistance: Boston University • Free Continuing Education Opportunities HIV Nexus CDC • Department of Health HIV, STD, and TB Services • American Academy of HIV Medicine Credentialing • HealthHIV HIV Prevention Certified Provider™ Certification Program – HealthHIV

⁴⁹ Section 8:43A-7.3 - Medical director's responsibilities, N.J. Admin. Code § 8:43A-7.3 | Casetext Search + Citator

	Certification Resources for Health Care Professionals AIDS Education and Training Centers National Coordinating Resource Center (AETC NCRC)
Are there competency testing requirements?	Competency testing may include requiring certification for medical providers for a specific topic (HIV, HCV, STIs) or a specific number of continuing education credits per year on a specific topic. Resources: • See resources under Training above
Documentation & Additional Notes	Documentation when providing medical treatment services should, ideally, be in an electronic medical record that interfaces with a commercial laboratory, which allows for documentation that labs have been reviewed by the medical provider and results provided to the patient. When documenting medical treatment services, essential information includes: patient demographics, medical history, current symptoms, physical examination findings, diagnoses, treatment plan, medications, diagnostic test results, progress notes, any interventions performed, and a clear rationale for the chosen treatment, all while ensuring accuracy, completeness, relevance, and timeliness in the documentation. ⁵⁰

⁵⁰ Medical Records and Documentation Standards | Kaiser Permanente Washington

Urgent and Emergency Services

Services include...

Urgent and emergency services may include overdose response and monitoring (including naloxone administration, rescue breathing, placing in the recovery position, CPR, oxygen administration as applicable, activation of emergency medical services as applicable), overamping response, acute psychiatric or behavioral emergency response (including de-escalation, suicide screening, crisis intervention, etc.), wound care management and treatment, assessment, triage, and/or treatment for acute infections (abscess, cellulitis, pneumonia, acute HIV, acute hepatitis C, influenza, COVID-19, etc.), and triage to an urgent care center or emergency department.

Response to an emergency situation, including an overdose, can be done by both licensed and non-licensed, including non-clinical, personnel.

- For oxygen administration, standing orders for nursing and medical personnel, can specify oxygen administration for when a medical provider is not onsite. In emergency situations, oxygen administration can be done by nurses (RNs and LPNs) without a standing order.
- For other personnel (medical volunteers, first responders, etc.), they *may* obtain an Oxygen Administration certification, that is OSHA-compliant.
- The FDA distinguishes between medical and emergency oxygen. Oxygen standing orders for non-medical personnel typically involve pre-approved protocols that allow individuals, often first responders or workplace safety personnel or any personnel who may respond to an overdose, to administer oxygen without a direct physician order in specific, emergency situations. These

	orders often specify the conditions under which oxygen should be given and the equipment to be used, ensuring a quick and appropriate response in cases of respiratory distress. ^{51 52 53 54}
What credentials are needed to provide this service?	Depending on the specific concern of the participant, a licensed provider (MD/DO, ANP, PA) or RN could assess the patient. LPNs and MAs cannot assess patients. If a prescription is needed, an MD/DO, ANP, or PA would be required.
	Non-licensed and non-clinical personnel can respond to an overdose.
Are there waiver or licensing requirements?	The NJ DOH has proposed the Single Integrated Health Care License which aims to consolidate licensing requirements, allowing facilities to offer a broader range of services under one streamlined license. The new license will replace the need for separate approvals for services like primary care, behavioral health, and substance use treatment. ⁵⁵
What space or equipment is needed?	The space and equipment needed to provide urgent care and emergency services would be dependent on the breadth of services provided.

⁵¹ Open Resources for Nursing (Open RN); Ernstmeyer K, Christman E, editors. Nursing Fundamentals [Internet]. Eau Claire (WI): Chippewa Valley Technical College; 2021. Chapter 8 Oxygenation. Available from: https://www.ncbi.nlm.nih.gov/books/NBK591819/

⁵² Open Resources for Nurses, 2021

⁵³ Oxygen Administration – Vitali

⁵⁴ Starr LM. Emergency oxygen: What? Who? When? AAOHN J. 1994 Jan;42(1):15-7. PMID: 8147981.

⁵⁵ (6) New Jersey's Single Integrated Health Care License: A Game Changer for Providers and Patients

	(e.g., If wound care and provision of oral antibiotics were included, this would require significantly less resources, than assessing an individual for chest pain (where an electrocardiogram and other resources might be needed). Offering low acuity urgent care services and triaging individuals for emergent care is likely more feasible in the Harm Reduction Centers.
Is a Medical Director required?	Provision of urgent care services and/or emergency services on site would require a Medical Director.
What training is required?	The training needed would depend on the scope of services provided. If services required an assessment but no diagnosis, then an RN could provide those services. However, if a diagnosis is required, then an MD/DO, ANP, or PA would be required and training commensurate with their scope of practice and licensing. An LPN and MA cannot assess patients.
Are there competency testing requirements?	Competency testing is necessary to ascertain that staff have the appropriate skills and training for the level of urgent and/or emergency services that are being provided. This may be ascertained by licensing, scope of practice and certification of staff members, continuing education credits, and/or an internal mechanism to assess competency.
Documentation & Additional Notes	Documentation should be done regarding all urgent and emergency services provided, including refusal of services.

Mental Health, Substance Use, and Other Behavioral Health Services	
Services include	Mental health, substance use, and other behavioral health services may include peer support services, recovery support services, group counseling services, individual counseling services, navigation services, provision of low threshold medication for addiction treatment (medication for opioid use disorder/MOUD, medication for alcohol use disorder/MAUD, off label use of medication for stimulant use disorders, medication for tobacco use disorder), peer support groups on a variety of topics (safer injecting, safer sex, safer sniffing, safer smoking, safer booty bumping, etc.), and provision of medication for mental health conditions (via a psychiatrist or psychiatric nurse practitioner/PNP).
What credentials are needed to provide this service?	Mental health, substance use, and other behavioral health services must be provided by licensed and/or credentialed persons in NJ. This could include a MD/DO, ANP (including PNP), PA, LCSW (Licensed Clinical Social Worker), CADC (Certified Alcohol and Drug Counselor)* or LCADC (Licensed Clinical Alcohol and Drug Counselor. Clinical Alcohol and Drug Counselor. A CADC must work under the supervision of an LCADC or another New Jersey licensed clinical professional designated as a qualified clinical supervisor per 13:34C-6.2. A phlebotomist or staff member with phlebotomy skills (example, RN, LPN, or CMA) may be needed depending on the scope of services offered.
What space or equipment is needed?	The space and equipment needed depend on the scope of services provided. If groups are conducted, an adequately sized space would need to be provided. If individual counseling is provided, a private space would be needed to allow for confidentiality and privacy.

Microsoft Word - FAQs Regarding the LCADC CADC Process Revised 2012.doc

N.J. Admin. Code § 8:111-1.9 - Qualifications and responsibilities of the substance abuse counseling staff | State Regulations | US Law | LII / Legal Information Institute

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	If urinary toxicology testing or phlebotomy is needed, then a refrigerator for storage of samples and phlebotomy-related supplies would be required.
Is a Medical Director required?	A Medical Director is not required for all mental health services settings in NJ. Some SUD treatment centers do require a Medical Director. ^{59 60 61 62 63}
What training is required?	Training required would be dependent on the type of providers employed and the types of services offered.
	Most sites would benefit from crisis intervention training, suicide prevention training, and de-escalation training for all staff.
	Resources: Education & Training of NJ Healthcare Providers in HIV Care — François-Xavier Bagnoud Center Department of Human Services Trauma Informed Care (TIC) Trainings New Jersey Mental Health Screener Certification and Recertification Department of Health Division of Mental Health and Addiction Services New Jersey Disaster Response Crisis Counselor (NJDRCC) Certification
Are there competency testing requirements?	Competency testing should occur with all staff not licensed, certified or credentialed in mental health or substance use to assess competency in de-escalation techniques, suicide prevention assessment, and crisis intervention techniques.
	Resources:

Department of Health | Legal and Regulatory Compliance | Regulation of Mental Health and Substance Abuse Treatment Services

New Jersey Administrative Code

Designation of medical director, N.J. Admin. Code § 10:161B-7.2

Qualifications and responsibilities of the director of substance abuse counseling services N.J. Admin. Code § 8:111-1.8

Qualifications and responsibilities of the medical director, N.J. Admin. Code § 10:161B-1.4

	 Core Competencies in Suicide Risk Assessment and Management: Implications for Supervision De-escalation Training Skills Test
Documentation & Additional Notes	Documentation of all mental health, substance use, or other behavioral health services delivered either individually or in a group setting is imperative. Any de-escalation, crisis intervention, or suicide prevention interventions should be documented.