Child and Adolescent Health Center (CAHC)
Clinical Laboratory Requirements and Best Practice Considerations
Content Relevant to: CAHC and SWP Models

CAHC MPR #16 The health center shall conform to the regulations determined by the Department of Health and Human Services for laboratory standards.

SWP MPR #2 The SWP shall provide clinical nursing services full time during the school year. Clinical services shall include individual health services that fall within the current, recognized scope of registered nurse (RN) practice in Michigan.*

SWP MPR #9 The SWP shall have a licensed physician as a medical director who supervises the medical services provided and who approves clinical policies, procedures, protocols, and standing orders.

*The guidance material provided in this document is indicative of the CAHC program recommendations and requirements for **policy and procedure content, and is not an actual policy and procedure** (P&P). The CAHC program does not intend to dictate P&Ps except in the case of state or federal law and legislative boilerplate requirements for the prohibition of abortion counseling, services and referral and prescription and distribution of family planning drugs and devices on school property.*

P&Ps work best when they meet local needs and circumstances. The development of all policies and procedures should, however, be done within the context of laws and best practices. Use this guidance document, applicable law, Minimum Program Requirements (MPRs), center and client needs, and your own sponsoring agency's policies and procedures to develop or modify materials to address and accommodate your individual health center and fiduciary requirements. Content of a P&P pertaining to a specific MPR(s), as in this guidance, may also pertain to other MPRs.

Child and Adolescent Health Centers (CAHCs) and School Wellness Programs (SWPs) follow the required Clinical Laboratory Improvement Amendments (CLIA) guidelines and CAHC program laboratory requirements. The fiduciary must maintain compliance with all CLIA laboratory standards throughout the agency, including the CAHC and/or SWP. The CAHC program highlights eight components to assess fiduciary compliance with Centers for Medicare & Medicaid Services (CMS) established laboratory standards and program requirements.

*The SWP model has an optional laboratory requirement that is determined by the fiduciary. The SWP nurse provider would function under standing orders from the medical director. The SWP model would comply with all applicable laws, regulations, and standards of care identical to the full and alternative CAHC clinical models.

Program Requirements:

- Laboratory policies and procedures (P&Ps)
- Lab manual present
- Current CLIA license or certificate of waiver specific to each site and posted
- All required testing and follow-up documentation
- Evidence of annual competency testing and proficiency testing, as appropriate
- Equipment is in working order and calibrated to industry standard
- Method of identifying equipment in use at health center is accessible to health center staff

Laboratory Policy and Procedure (P&P)

Laboratory P&P Program Requirements:

- Lab Director identified with role and responsibilities (e.g., site visit annually, test procedures [including follow up on abnormal labs] reviewed/signed annually)
- CLIA license or waiver (if applicable) renewal and amendment processes
- List point-of-care (POC) waived tests performed on-site and reference lab testing specimen(s) collected
- Manufacturer inserts for POC tests and send-out tests are located on-site and/or in laboratory manual for staff
- Process for training personnel responsible for all lab procedures and annual competency testing (e.g., who completes and who oversees)
- Process for training/review of OSHA safety standards pertinent to lab (e.g., use of PPE, eyewash, sharps/medical waste, possible occupational exposure/laboratory emergencies)
- General expectations for the lab environment (see below “Laboratory Space/Environment”)
- Use of standing orders for RNs or MAs, as needed
- Lab equipment calibration and maintenance process (e.g., who performs it and when
- Method of identifying equipment in use on-site and is accessible to staff
- Testing procedure process for POC and send out specimens (e.g., client identification, pretest counseling, collection procedures, manufacturer/reference lab instructions followed (MPR #1, MPR #2, CLIA)
- Pre- and post-testing result interpretation, result reporting to the client, Primary Care Provider and/or parent guardian (where appropriate), tracking and follow-up for laboratory tests, communicable disease reporting, and referral tracking and documentation as appropriate for client status and needs (MPR #1, MPR#2)

Laboratory P&P Best Practice Considerations:

- Testing procedure send out test pick up/transportation, required documentation
- Outlined quality control measures (e.g., test and/or instrument control processes, corrective action process for failures in standard practices, periodic lab inspection/ who and how often)
- Record retention (e.g., client/specimen logs, test requisitions and results, quality control documents, length of time for retention)

Laboratory Space/Environment

The lab space/environment should meet clinical laboratory standards to ensure quality service provision and is a required component of laboratory policies and procedures (as listed above). At CAHC and SWP (when applicable) site reviews, a site reviewer will determine if policy and practice are aligned, as well as evaluate the following laboratory service criteria.

Laboratory Space/Environment Program Requirements:

- Current CLIA certification or waiver posted (site-specific or specific site information proof available)
- Space is clean and provides confidentiality for the client
- Designated “clean” and “dirty” areas
- Specimen and control storage according to manufacturer inserts
- Monitoring testing and storage areas for temperature and humidity per testing materials with documentation kept on site
- Hand washing facility or antiseptic hand washing solutions
- Materials on-site to include appropriate PPE, eyewash stand/equivalent, sharps container(s) properly placed, spill kit, other medical waste disposal as needed
- Secured storage cabinets/other to ensure safety and confidentiality
- Space is free of “non-lab” materials (e.g., food/eating, food stored in specimen refrigerator)

Laboratory Space/Environment Best Practice Considerations:

- Identified cleaning process (when, who, what materials used)
- Posted safety/emergency procedure information for staff and clients

Lab Manual

CLIA requires a laboratory to have the manufacture package insert on-site and instructions for all point-of-care (POC) tests performed. Maintaining a lab manual can be useful to store lab resources, logs, and other documents. Review the following program requirements and best practice considerations for a lab manual.

Lab Manual Program Requirements:

- POC test manufacturer inserts
- Safety Data Sheet (SDS) for lab materials
- CAHC and/or SWP standing orders specific to lab testing
- Laboratory policy and procedure (i.e., send out tests)

Lab Manual Best Practice Considerations:

- Copy of the current CLIA waiver and previous expired copies
- Equipment manufacturer product information
- Laboratory Director name and any documentation by lab director needed for retention
- Lab training resources and materials
- Quality control logs with response to controls outside of expected range
- Documentation of corrective action taken on any discrepancies or problems with a test procedure
- Annual competency testing and proficiency testing documentation, as appropriate
- Equipment calibration/maintenance documentation, documentation of site inspections
- Waste management and occupational exposure/laboratory emergencies policy and procedure

Laboratory Testing Documentation

Laboratory testing documentation examples include all personnel competency/training logs, lab test quality control measures, completed testing and results, equipment maintenance and cleaning. All laboratory testing documentation may be kept in the Lab Manual, as desired.

Laboratory Testing Documentation Program Requirements:

- Annual competency evaluation for all testing personnel, signed and reviewed by the lab director/technical advisor or designee, with any corrective action taken documented
- Evidence/documentation that equipment is calibrated
- Records maintained onsite for minimum of two (2) years or per fiduciary if longer

- All required Quality Control (QC) testing documentation
    - Test lot #
    - Test expiration date
    - Date of QC
    - Control numbers for QC tests
    - QC results and any action required for results out of range
- All required patient test results
    - Patient identifier
    - Test lot #
    - Test expiration date
    - Date of QC
    - Test results documented with appropriate measurement units
    - Tester initials
    - Invalid results recorded and retested

Testing Documentation Best Practice Considerations:

- Test problem resolutions (i.e., invalid controls)
- Test results documented (“NEG”, “POS”, “INV“ vs. “+” or “-”)
- Check and label expiration dates on kits and reagents and/or on lab documents
- Complaint investigation/communication logs

Resources

CDC CLIA Waived Tests Page and Resources

Self-Assessment Checklist

Ready? Set? Test! Booklet

Ready? Set? Test! Tips and Reminders

References

American College of Physicians CLIA and Your Laboratory

CDC CLIA Page

MDHHS CLIA Page

CMS CLIA Lab Director Responsibilities

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