Physician Office Laboratory

Nonwaived Laboratory Implementation and Operations Guidance

1. **FEASIBILITY:** Conduct a comprehensive feasibility study to ensure that your proposed nonwaived laboratory is a viable opportunity for your Practice. Consider the following:
    a. Reimbursement of proposed test utilization by private and public payers
    b. Operational Expenses: personnel, instrumentation & service, reagents & supplies, equipment, laboratory information system & interfaces, regulatory fees, billing and facility allocation, build-out
    c. Outside Services: hazardous waste disposal, consultant

2. **REGULATIONS:**
    a. Review the following applicable regulations
        i. CLIA, http://wwwn.cdc.gov/clia/Regulatory/default.aspx
        ii. State, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf
        iii. Accreditation, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf
    b. Determine the highest complexity of the tests you will perform in your laboratory, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
    c. Contact your State CLIA Office
        i. Does your State require licensure?
        ii. Does your State have additional regulations beyond CLIA?
        iii. Are there any pre-inspections?
        iv. Is the test categorization the same as CLIA?
    d. Evaluate Certificate options of Compliance and Accreditation and determine what will best meet the needs of your Practice, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCLIACertificate.pdf
    e. If you choose to be accredited, what additional regulations will your lab have to follow?

3. **PERSONNEL:** Identify qualified personnel for the required roles for your laboratory complexity
    a. Laboratory Director, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/brochure7.pdf
        i. Identify committed laboratory director
        ii. Does the laboratory director meet the qualifications based on the lab complexity?
        iii. Have you arranged for training, if needed?
        iv. Current CME Courses for Laboratory Directors of Moderate Complexity Laboratories, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CME_Courses_for_Laboratory_Directors_of_Moderate_Complexity_Laboratories.html
            1. University of Iowa: On-line laboratory director course
            2. COLA: Symposium for Clinical Laboratories
            3. COLA Lab University: On-line laboratory director course
            4. AMA/AAFP Equivalency
    b. Clinical Consultant
    c. Technical Consultant
    d. Technical Supervisor (high complexity)
    e. General Supervisor (high complexity)
    f. Testing Personnel

4. **TEST MENU:** Select appropriate test menu for Practice

5. **INSTRUMENTATION:** Choose instrumentation appropriate for utilization, space and budget

6. **CLIA CERTIFICATE:** Obtain or update CLIA certificate to compliance or accreditation
    a. Complete CMS-116 Form, https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf
    b. Identify as "Initial Application or "Change in Certificate Type"
    c. Indicate all testing to be performed and estimate annual utilization
    d. Have laboratory director sign upon completion
    e. Pay the "Certificate of Registration" invoice sent by your State CLIA Office

7. **LOCATION:**
    a. Identify laboratory location
    b. Complete laboratory build out and/or renovations

8. **PROFICIENCY TESTING:** Order proficiency testing
    a. Enroll in Proficiency Testing Program that will meet the needs of your entire test menu
    b. Review http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html for current CLIA-approved PT Programs
    c. Consider enrolling in proficiency testing for waived tests to enhance the quality program – this is often mandated by accreditation organizations
    d. Critically evaluate the proficiency testing program guidelines, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure8.pdf

9. **INFRASTRUCTURE:** Set up laboratory infrastructure
    a. Design flow from ordering to testing to resulting
    b. Create a compliant laboratory requisition (optional if electronic ordering is used)
    c. Read all manufacturing testing requirements
    d. Develop laboratory manuals
        i. SOP (customized policies and procedures for CLIA compliance)
        ii. Directory of Service (for multiple offices and draw sites)
        iii. Analytic Procedure Manual (test system procedures with verified reference ranges and reportable ranges)
        iv. Maintenance per test system
        v. Quality Control Review per test system
        vi. Quality Assessment
        vii. OSHA (should be Practice-wide OSHA Manual)
    e. Develop record keeping system
    f. Facility management
    g. Purchasing
    h. Personnel
    i. Proficiency testing

10. **INFORMATION TECHNOLOGY:** Install LIS including all instrument and system interfaces
    a. Set reasonable expectations for LIS installation with respect to systems interfaces
    b. Install LIS concurrently with instrumentation so interfaces can be tested and validated
    c. Validate all processes from ordering, interfacing, resulting, reporting and communications
    d. Continue with systems interfacing as needed

11. **PERSONNEL TRAINING:** Conduct training of Practice personnel on policies and procedures
    a. Construct thorough training plan or designate to technical consultant
        i. Testing Personnel
            1. Lab policies and procedures
            2. Instrumentation operation
            3. Manual kits
            4. Lab flow: ordering, testing, resulting
        ii. Phlebotomy Personnel
            1. Lab policies and procedures, as applicable
            2. Patient registration and order entry
            3. Medical necessity and Advanced Beneficiary Notices
            4. Specimen collection techniques
            5. Specimen processing, storage and transport
        iii. Billing Personnel
            1. Charges and claims
        iv. Providers/Clinical Personnel
            1. Ordering
            2. Receiving results
    b. Document all training
    c. Confirm competency via laboratory director review and sign-off

12. **METHOD VALIDATION:** Verify method performance specifications for each test system: accuracy, precision, reportable range, reference range, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6064bk.pdf
    a. Complete necessary experiments for each test system to verify acceptable method performance (testing personnel must complete; vendors may assist)
    b. Have laboratory director review, approve and sign all studies
    c. Perform actual patient testing on test systems for correlation data and go-live simulation

13. **BILLING & COLLECTIONS:** Set-up laboratory billing and collections
    a. Identify resources required to add lab billing
    b. Prepare and finalize plan for lab billing
    c. Customize Advanced Beneficiary Notice, https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html
    d. Review current Clinical Laboratory Fee Schedule, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/clinlab.html
    e. Review and implement medical necessity policies:
        i. National Coverage Determinations, https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/Downloads/manual201601_ICD10.pdf
        ii. Local Coverage Determinations, https://www.cms.gov/medicare-coverage-database/indexes/lcd-state-index.aspx?bc=AgAAAAAAAAAA
    f. Create additional Practice policies as needed

14. **GO-LIVE**
    a. Communicate go-live date with Practice staff, vendors, reference lab(s) and courier(s)

15. **OPERATIONS:** Maintain state-of-the art and financially sound laboratory services
    a. Perform competency assessment every 6 months initially and annually thereafter for each test system and trained testing personnel, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf
    b. Set up and maintain Quality Control Program with daily, weekly and monthly review
    c. Complete proficiency testing test events as received

d. Perform quality control verification for each new lot of QC materials received
e. Perform calibration verification on needed test systems every 6 months, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6065bk.pdf
f. Manage purchasing program by maintaining acceptable inventory and ordering at regular intervals

16. **QUALITY ASSESSMENT:** Assess quality on a regular basis for all laboratory systems, such as:
    a. Monthly: test systems (maintenance, calibration and quality control), proficiency testing, communications, utilization
    b. Annually: facility, safety, quality, patient test management

17. **COMMUNICATIONS:** Integrate laboratory services fully into the Practice via a laboratory committee
    a. Form Laboratory Committee with representation from Practice, e.g.
        i. Laboratory Director
        ii. Laboratory Supervisor/Manager
        iii. Technical Consultant
        iv. Practice Administrator
    b. Set agenda to include
        i. Utilization and financials review
        ii. Quality issues
        iii. Regulatory updates
        iv. Growth opportunities

18. **REGULATIONS:**
    a. Stay abreast of regulatory updates
        i. CLIA
        ii. Accrediting organization
        iii. OSHA
        iv. CMS
        v. State Agency
    b. Participate in biennial surveys by CLIA/accrediting agency and correct any deficiencies within required timeframe
        i. Be prepared at all times! Notice is generally no more than 2-4 weeks.
        ii. Ensure appropriate staff is available on survey date
        iii. Laboratory director does not have to be present, but it is advisable
        iv. Organize all manuals and records for easy access for the surveyor
        v. Actively engage in survey process
    c. Notify CMS via State Agency (and accrediting agency if applicable) of changes with ownership, address, personnel and test menu

19. **FINANCIALS:** Complete laboratory financials on a monthly basis
    a. Analyze variances of expected reimbursement and budgeted expenses
    b. Ensure accurate pricing of reagents and supplies as quoted and negotiate minimum pricing increases

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