Lessons Learned: Regulations and Payment for Laboratories

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

CLIA Laboratory Requirements and the FDA

Laboratories must obtain a certificate that corresponds to the level of testing and level of complexity of the tests being offered.

- Certificate of Waiver Labs
  - Can only perform tests approved by the FDA that are:
    - For home use
    - Waived (meaning there is little risk of inaccuracy or patient harm)
- Certificate of Compliance or Accreditation Labs can be:
  - Moderate Complexity
    - Perform tests determined to be of moderate complexity by the FDA
  - High Complexity
    - Perform tests determined to be of high complexity by the FDA **OR** in-house developed tests (Lab Developed Tests)

CLIA Responses to the Public Health Emergency

- Remote review of pathology slides/data
- Expedited review of CLIA applications
- Testing authorization as soon as CLIA application is filed
- Use of alternate collection devices and expired reagents
- Contiguous site flexibilities
- Allowance of university non-CLIA COVID testing
- CARES Act mandate requiring COVID test reporting

CLIA Lessons Learned from COVID/MoPox

- The PHE emphasized the need and importance to ensure lab quality and patient safety
- CMS lacks authority to waive CLIA requirements
- Cooperative relationships between the FDA, CDC and CMS are vital
- Clear communication to stakeholders especially nontraditional labs like schools, workplace labs is critical.
- CLIA regulations allowed for rapid expansion of temporary testing sites to increase testing availability and safety
- There are no CLIA regulations that require routine reporting to any state, local or tribal authority.

CLIA Requirements during a Public Health Emergency

- The primary role of CLIA is to ensure safe and accurate testing.
- During a Public Health Emergency (PHE), CLIA serves to provide ongoing oversight to ensure lab quality, safety and reliability.
- During the PHE, CMS expanded testing capacity by working with non-traditional labs, including research and veterinary labs, while maintaining regulatory requirements related to lab quality.

CLIA Requirements and 1135 Public Health Emergency Waiver Authority

CLIA cannot waive the CLIA regulations to facilitate testing during a Public Health Emergency (PHE)

- The authority for CMS to waive program requirements stems from Section 1135 of the Social Security Act.
- This section is only applicable to specified programs authorized by the Social Security Act.
- CLIA does not fall into one of these categories of programs.

Medicare

- Clinical diagnostic testing covered, subject to usual requirements
- “General” screening (absent known exposure) not covered
- Exempt from cost sharing under Original Medicare
  - Medicare Advantage plans can require cost sharing
- National payment rates for new clinical diagnostic laboratory tests (CDLTs) set during an annual process
  - Until that time, rates are locally determined by Medicare Administrative Contractors (MACs)

Commercial

- Commercial individual and small group plans (including QHPs) must cover 10 Essential Health Benefits (EHBs), including laboratory services
  - Coverage details may vary by state and plan
- Otherwise, testing covered at plan's discretion
- Cost-sharing also at plan's discretion

Medicaid/CHIP

- In Medicaid
  - Covered under mandatory lab and x-ray services benefit

- In the Children's Health Insurance Program (CHIP)
  - Can be covered under the optional laboratory and x-ray services benefit.

- Option, but not requirement, to impose cost-sharing

- Certain flexibilities (e.g., location of test administration and physician's order) available to states under HHS PHE declaration