NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Commissioner

JOHANNE E. MORNE, M.S.
Executive Deputy Commissioner

June 11, 2024

DHDTC DAL#: 24-03
Upcoming Changes from the Centers for Medicare and Medicaid Services regarding Clinical Laboratory Testing Personnel

Dear Chief Executive Officer and Administrators:

This correspondence is to provide additional direction to hospitals and Diagnostic and Treatment Centers regarding changes forthcoming for clinical laboratory personnel requirements.

On December 28, 2023, the federal Centers for Medicare and Medicaid Services (CMS) issued a Final Rule regarding Fees, Histocompatibility, Personnel and Alternative Sanctions. This Final Rule focuses specifically on the changes for who can perform clinical laboratory testing. The New York Clinical Laboratory Evaluation Program (CLEP) has been granted a CLIA Exemption, pursuant to Subpart E of Title 42, Part 493 of the Code of Federal Regulations, and must maintain requirements that are at least as stringent as the federal rules governing clinical laboratories.

The federal Final Rule for Personnel will take effect on December 28, 2024. The changes include the allowance for nurses to perform clinical laboratory testing. Prior to this Final Rule and in accordance with a CMS memo issued April 1, 2016, individuals with a baccalaureate or associate degree in nursing were authorized to perform testing of any complexity; where complexity in federal regulations is defined as waived, moderate, or high. Upon implementation of this Final Rule, a nursing degree will continue to qualify nurses to perform waived and moderate complexity testing. However, a nursing degree alone will not be sufficient to qualify a nurse to perform high complexity testing. Rather, the nurse must demonstrate completion of 60 semester hours from an accredited institution that includes 6 hours of chemistry, 6 hours of biology and 12 hours of a combination of chemistry, biology and/or medical laboratory technology and a total of three months of training in high complexity testing for each category in which testing will be performed.

This change may impact testing performed by nurses at point-of-care in medical facilities. Point-of-care testing includes both waived and non-waived testing and it cannot be assumed that a test is waived simply because it is performed at patient bedside. The federal Food and Drug Administration assigns the complexity of testing for each testing device they assess. The complexity for a test for the same analyte may be assigned differently for a different manufacturer. Best practice is to perform a search for the test device in use at your facility, based on manufacturer and device name, to determine the complexity. Links to the FDA database is provided below.

CMS has explained that nurses authorized to perform high complexity testing prior to December 28, 2024 will be allowed to continue such testing so long as they maintain continuous employment in their position. Note that CLEP does not maintain a listing of point-of-care testing personnel. It will be the facility's responsibility to document the status of their staff to demonstrate compliance with this provision. This will be reviewed during the next CLEP on-site inspection of your facility.

Search FDA Database for Approved Test Devices

Thank you for your partnership. Please forward any questions regarding this guidance to clep@health.ny.gov.

Sincerely,

Beverly Rauch
Director, Clinical Laboratory Evaluation Program
Acting Director, Blood Resources Program
Deputy Director, Division of Laboratory Quality Certification

Stephanie Shulman, DrPH, MS
Director, Division of Hospitals and Diagnostic & Treatment Centers