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SUBJECT Clinical Laboratory Improvement Amendments Requirements	BY  Vincent D. Gordon, Deputy Secretary Office of Medical Assistance Programs	

PURPOSE:

The purposes of this Medical Assistance (MA) Bulletin (bulletin) are to:

- Remind providers of laboratory services that their current Clinical Laboratory Improvement Amendments (CLIA) certificate for each testing site, i.e., provider service location, must be on file with the Office of Medical Assistance Programs (OMAP) in order to receive payment for laboratory services; and
- Inform providers that they must submit claims for CLIA waived tests using the QW informational modifier, when applicable, effective with dates of service on and after January 1, 2013.

SCOPE:

The requirement to maintain a current CLIA certification on file with OMAP is applicable to providers who render laboratory services to Medical Assistance (MA) beneficiaries, in both the Fee-for-Service (including ACCESS Plus) and the managed care delivery systems. MA enrolled providers of laboratory services who render services to MA beneficiaries under the managed care delivery system should address any laboratory service billing related questions to the applicable managed care organization.

BACKGROUND:

All laboratory testing sites, including physician’s offices, are required to have a CLIA certificate. The CLIA certificate and accompanying identification number identify those procedures that the laboratory is qualified to perform. (See 42 Code of Federal Regulations (CFR) §§ 493.1, 493.3 and 493.5 relating to Basis and Scope of Laboratory Requirements, Applicability of Laboratory Requirements and Categories of Laboratory Tests by Complexity). Only laboratories that have a CLIA certificate may receive payment for services provided to Medicaid beneficiaries. See 42 CFR § 493.1809. On September 5, 2008, MA Program

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
<http://www.dpw.state.pa.us/provider/healthcaremedicalassistance/index.htm>

regulations at Title 55 Pa.Code Chapter 1243 (relating to Outpatient Laboratory Services) were amended to include the Federal CLIA requirements.

MA Program regulations at 55 Pa.Code, § 1243.41 (relating to provider participation requirements) set forth that each laboratory submit a copy of its CLIA certificate, CLIA certificate number, a list of diagnostic procedures that the laboratory is CLIA certified to perform (by Healthcare Common Procedure Coding System procedure codes) and the fee currently charged to the general public for each of the diagnostic procedures.

On November 25, 1998, the Department of Public Welfare (Department) issued MA Bulletin 01-98-17, et al, titled "Clinical Laboratory Improvement Amendments (CLIA) Requirements" that reminded laboratories of the Department's requirement that a copy of the laboratory's CLIA certificate be submitted with the provider's MA Program enrollment packet and copies of renewal certificates be submitted prior to expiration of the CLIA certificate.

Hospital laboratories are to be Medicare certified or currently certified by the Pennsylvania Department of Health (DOH) as meeting the standards comparable to those of Medicare. All laboratories are to be licensed by the DOH, Bureau of Laboratories, and be Medicare certified under Title XVIII (42 U.S.C.A. §§ 1395-1395hhh), or certified as meeting standards comparable to Medicare. Out-of-state hospitals do not need to be licensed by DOH, but must be currently Medicare certified.

As set forth in 42 CFR §§ 493.2, 493.5, there are several different types of CLIA certifications. The types of certificates are set forth below:

Certificate of Waiver (CLIA Waived)

This certificate is issued to a laboratory that performs only waived tests.

Certificate of Provider Performed Microscopy Procedures (PPMP)

This certificate is issued to a laboratory in which a physician (MD or DO), midlevel practitioner or dentist performs no tests other than the microscopy procedures. This certificate permits the laboratory to also perform waived tests.

Certificate of Registration

This certificate is initially issued to a laboratory that applies for a certificate of compliance or accreditation. A registration certificate enables the entity to conduct moderate and/or high complexity laboratory testing until the entity is determined by Medicare survey and DOH licensure to be in compliance with the CLIA regulations. This certificate permits the laboratory to also perform waived tests. A registration certificate is temporary, and indicates only that the laboratory is registered with the Centers for Medicare & Medicaid Services (CMS) and does not indicate CMS approval or compliance with CLIA regulations. A registration certificate is valid until a survey takes place, or for two years, whichever is shorter. Registration certificates are not renewable but can be reissued if CMS determines compliance prior to the expiration date.

Certificate of Compliance

This certificate is issued to a laboratory after an inspection (survey) that finds the laboratory to be in compliance with all applicable CLIA requirements. This certificate permits the laboratory to perform moderate and/or high complexity testing, depending on the laboratory personnel qualifications and compliance with all other applicable CLIA requirements. This certificate permits the laboratory to also perform PPMP and CLIA waived tests.

Certificate of Accreditation

This certificate is issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. This certificate permits the laboratory to perform moderate and/or high complexity testing, depending on the laboratory personnel qualifications and compliance with all other applicable CLIA and organizational requirements. This certificate permits the laboratory to also perform PPMP and CLIA waived tests.

PROCEDURE:

In order to receive payment for laboratory services, MA providers must have a copy of their current CLIA certificate (applicable to the provider's service location) and as applicable, a copy of their DOH license in their MA Program enrollment file. Providers are to place their 13 digit MA identification number on the copy of their CLIA renewal certificate and submit it prior to the expiration date of the current CLIA certificate that is on file with the MA Program, so that there is no lapse in the effective dates of the CLIA certificates. Providers may submit their updated CLIA certificates to the MA Program as follows:

Via U.S. Mail:

Department of Public Welfare
Office of Medical Assistance Programs
Bureau of Fee-for-Service Programs
P.O. Box 8045
Harrisburg, PA 17105-8045
Attention: Provider Enrollment Unit

Via Facsimile:

Department of Public Welfare
Office of Medical Assistance Programs
Bureau of Fee for Service Programs – Provider Enrollment Unit
(717) 772-6765

Via Email:

RA-ProvApp@pa.gov

Providers are to ensure that they are submitting claims for laboratory services in compliance with their CLIA Certificate. The Department will deny laboratory claims when the provider's service location is not currently CLIA certified for the laboratory service billed, or when the dates of service of the laboratory test are not within the provider's CLIA certificate's begin and end dates (effective dates).

The Department added the QW informational modifier, when applicable, to laboratory procedure codes on the MA Program Fee Schedule that are listed with CMS as a CLIA waived test (see Attachment). Effective with dates of service on and after January 1, 2013, when submitting claims for CLIA waived tests, the QW modifier must be reflected with the applicable procedure code in order for the claims to process correctly.

Additional information related to CLIA including the "Categorization of Tests" may be obtained from the CMS web site at: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/10_Categorization_of_Tests.asp.

Providers of laboratory services that receive claim denials related to CLIA certification should contact OMAP's Provider Enrollment Unit to ensure that their current CLIA certificate for their applicable service location is on file with the MA Program. Providers are reminded that they are to submit original or initial invoices for laboratory services to the MA Program within 180 days of the date the service was rendered. Resubmission of a denied original claim or claim adjustment is to be received by the MA Program within 365 days of the date of service. This allows ample time for providers to submit their updated CLIA certificates to the MA Program in order to ensure appropriate payment.

Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) are required to submit their CLIA certificates to the MA Program even though they are paid an all-inclusive per encounter payment rate that includes laboratory tests provided at the time of a face-to-face visit.

NOTE: In 2007, the Department opened procedure codes 82271 defined as "Blood, occult, by peroxidase activity (e.g. guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (i.e. patient was provided 3 cards or single triple card for consecutive collection); other sources" and 82272 defined as "Blood, occult, by peroxidase activity (e.g., guaiac), qualitative, feces, 1-3 simultaneous determinations, performed for other than colorectal neoplasm screening" with the QW modifier. The Department identified that CMS no longer requires the QW informational modifier on claim submissions for these laboratory procedure codes. Effective with dates of service on and after January 1, 2013, providers are not to reflect the QW informational modifier on claim submissions to the MA Program for laboratory procedure codes 82271 and 82272.

ATTACHMENT:

[CLIA Waived Laboratory Tests](#)