Requirements of the Clinical Laboratory Improvement Amendments

HealthKeepers, Inc.’s Anthem HealthKeepers Medicare-Medicaid Plan (MMP) is a Commonwealth Coordinated Care plan. HealthKeepers, Inc. works to keep Anthem HealthKeepers MMP providers informed of health plan and industry developments that impact your practice. The following overview of requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) is provided for your information and reference.

What are the Clinical Laboratory Improvement Amendments of 1988 (CLIA)?
CLIA was instituted to regulate all laboratories that examine human specimens to provide information to assess, diagnose, prevent, or treat any disease or impairment. The purpose of the CLIA Program is to ensure laboratories testing specimens in interstate commerce consistently provide accurate procedures and services. As a result of CLIA, any laboratory soliciting or accepting specimens in interstate commerce for laboratory testing is required to hold a valid certificate or letter of exemption from certification issued by the Secretary of the Department of Health and Human Services.

What does this mean to you?
Laboratories, including physician office laboratories (POLs), must meet applicable federal requirements and have a CLIA certificate in order to receive reimbursement from federal programs. CLIA also lists requirements for laboratories performing only certain tests to be eligible for a certificate of waiver or a certificate for physician-performed microscopy procedures. Since 1992, carriers have been instructed to deny clinical laboratory services billed by independent laboratories that do not meet the CLIA requirements. POLs were excluded from the 1992 instruction but are included in the 1997 instruction.

NOTE: The CLIA number or waiver must be included on each CMS-1500 claim form for laboratory services by any laboratory performing tests covered by CLIA. Claims submitted without the required CLIA number or waiver will not be denied in full, but each claim line associated with a laboratory service requiring a CLIA number will be denied if it is not provided.

What if I need assistance?
If you have questions about CLIA and the mandated requirements, please call our Anthem HealthKeepers MMP Customer Care team at 1-855-817-5788, Monday through Friday, 8 a.m. to 8 p.m., Eastern time.