Attachment 1

Frequently Asked Questions (FAQs) for Blood Glucose Monitoring Systems (BGMS) - CMS

Q1: Can I use a BGMS to test only diabetic patients?

BGMS are indicated only for monitoring known diabetic patients, while other point-of care glucose testing devices are indicated for broader use (e.g., for screening or diagnosing diabetes mellitus). Laboratories must refer to product labeling when determining the indications for their glucose measurement device. Facilities may still choose to use the BGMS in populations that are not specifically indicated in the product label (i.e. off-label use). However, when laboratories use any FDA-cleared or approved tests off-label, the CLIA categorization of that device defaults to high complexity, and the laboratory must meet the CLIA requirements for high complexity testing.

Q2: If I establish the performance specifications for my meter for off-label uses, is it still waived?

No. When a laboratory uses a device off-label, the device defaults to high complexity, and the laboratory must meet the CLIA requirements for high complexity testing. They must establish the performance specifications (i.e. accuracy, precision, analytical sensitivity, analytical specificity including interfering substances, reportable range of test results, reference intervals and any other performance characteristic required for test performance) for use in their patient population, and they must meet the personnel and all other applicable requirements for high complexity testing.

Laboratories wishing to meet high complexity requirements so that they can continue to use BGMS in populations not specifically indicated in the product label, may obtain further information regarding performance specifications via two resources

1. The CLIA Interpretive Guidelines (IG) at 42 CFR 493.1253, and,
2. In CLIA Brochure Number Two (2), 'Verification of Performance Specifications', on the CMS/CLIA web site at:

   http://www.cms.gov/Regulations-andGuidance/Legislation/CLIA/index.html?redirect=/clia/.

Q3: During a laboratory survey, it is discovered that my facility is using glucose meters off-label. What will happen?

When a facility uses a device off-label, the device defaults to high complexity, and the facility must meet the CLIA requirements for high complexity testing. The facility will be issued a written statement of deficiencies for non-compliance with the applicable CLIA regulatory requirements.

Q4: What will happen if my facility is issued a written statement of deficiencies (CMS Form-2567)?

The facility will be given an opportunity to submit a plan of correction to come into compliance with CLIA, according to CLIA standard operating procedures. Laboratories receiving only standard-level citations will generally have a reasonable timeframe (up to 12 months) to obtain certification of compliance or accreditation for high complexity testing requirements, or switch to a BGMS appropriate to their certificate and patient population. Laboratories receiving the more serious condition-level citations will have a much shorter timeframe as appropriate.

Q5: What requirements need to be met to allow my facility to use these meters off-label?

The laboratory must meet the applicable CLIA requirements for high complexity testing. They must establish the performance specifications for use in their patient population, perform quality control (QC), enroll and participate in proficiency testing (PT), meet the personnel qualifications and other applicable requirements for high complexity testing.

Q6: What educational requirements need to be met for personnel performing high complexity testing?

The CLIA personnel qualification requirements for high complexity testing can be found in Subpart M of the CLIA regulations and are further discussed in the CLIA IGs, http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/apcsubm.pdf.

Laboratories performing high complexity testing are required to have a qualified laboratory director, technical supervior(s), clinical consultant, general supervisor and testing personnel. The specific requirements for high-complexity testing personnel are located at 42 CFR §493.1489.

In summation the high complexity testing personnel must:

- Have a current license in states in which licenses are required,
- Have one of the following:
    - an M.D., D.O., or D.P.M.,
    - an earned doctoral, master's or bachelor's degree in a chemical, physical, biological science, or
    - an earned associate degree in a laboratory science or medical laboratory technology from an accredited institution or have education **and** training equivalent to that specified in 42 CFR 193.1487(b)(2)(i)

The training requirements for associate's degree holders can include a requirement that the individual has at least 3 months experience with the BGMS. In those instances, if the individual is new or lacks the 3 months experience, the probationary period may count towards meeting the 3 months experience as long as training is provided and competency is evaluated during the probationary period. The training and competency evaluations should be documented.

Q7: What are my options for meeting CLIA compliance if my facility continues to use BGMS to test glucose in patient populations not indicated by the manufacturer?

The facility may:

- Continue using their BGMS as waived tests as long as they follow the manufacturer's instructions.
- Obtain a Certificate of Compliance (CoC) or Certificate of Accreditation (CoA), establish the performance specifications and meet the additional regulatory requirements for high complexity testing to continue using a BGM on patient populations not indicated by the manufacturer.
- Identify a point-of-care glucose testing device that the manufacturer's instructions support using with the desired patient population limitation, or
- Refer the glucose testing to another CLIA-certified or -accredited laboratory (e.g. central hospital laboratory) that meets the requirements to perform such testing.