

February 26, 2015

RE: Use of glucometers for
Blood Glucose Monitoring

At its most recent meeting the Louisiana State Board of Medical Examiners considered your inquiry as to whether or not Louisiana licensed nurses, who meet the requirements prescribed by the federal Clinical Laboratory Improvement Act Amendments of 1988 (“CLIA”)¹ for the performance of high complexity testing,² are required to possess a clinical laboratory (“CLP”) license issued by the Board in order to continue to use glucometers for blood glucose monitoring of critically ill patients being treated at your hospital.

As we understand, your question is the result of an announcement in November 2014 by the Centers for Medicare & Medicaid Services (“CMS”) and U.S. Food & Drug Administration (“FDA”)³ to state survey agency directors on *Directions for the Off-Label/Modified use of Waived Blood Glucose Monitoring Systems (“BGMS”)*. In that announcement, CMS pointed out that BGMS were originally cleared by the FDA as waived for home use. They were designed as consumer devices, intended for use in monitoring glucose levels in individual patients diagnosed with diabetes. Over time, the use of BGMS has expanded to include the use in healthcare facilities and in patient populations that the manufacturer’s studies and performance standards did not address (e.g., critically ill patients).

¹42 U.S.C. §263a.; 42 C.F.R. §§493.35–.39.

²42 C.F.R. §493.1489.

³CMS/FDA Ref. S&C:15-11-CLIA (Nov. 21, 2014); available at: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-11.PDF>

CMS noted that the use of BGMS on this patient population is considered to be “off-label” use and under CLIA automatically defaults to the category of high-complexity testing.⁴

Personnel. CLIA requires a nurse or other non-physician personnel who performs high-complexity testing to possess a doctoral, master’s or bachelor’s degree in chemical, physical or biological science, an associated degree in laboratory science or medical technology or equivalent training.⁵

Laboratory. In order to satisfy CLIA requirements the hospital’s laboratory must comply with high-complexity requirements for the off-label use of the BGMS, *e.g.*, obtain a CLIA Certificate of Compliance (CoC) or Certificate of Accreditation (CoA), establish performance specifications to address accuracy, precision, sensitivity, specificity, reportable range, and normal values of the BGMS; and comply with all other requirements specified by CLIA for high-complexity testing, including personnel qualifications.⁶

The significance of using BGMS that have not been evaluated or cleared for use in critically ill patients was described by the FDA as follows:

Patients in critical care settings can be more acutely ill and medically fragile, and are more likely to present physiological, pathological and pre-analytical factors that could interfere with glucose measurements, particularly in capillary blood samples, compared to other types of users. For critically ill patients, who by their very nature tend to be more seriously ill, any inaccuracies in the meters could lead to inappropriate treatment decisions that may put these patients at risk of serious injury or death. Use of these devices in the treatment of critically ill patients would be an off-label use and would result in facilities needing to validate such use, place appropriate controls on such use, and have such use meet CLIA’s requirements for performing high complexity tests to ensure the accurate and appropriate use of these devices.⁷

The Louisiana Clinical Laboratory Personnel Law (the “Law”) does not require licensure for “the performance of routine technical procedures under or eligible for a

⁴CMS provided the following guidance for meeting CLIA compliance:

1. continue using BMGS as waived tests as long as follow the manufacturer’s instructions;
2. obtain a certificate of compliance or certificate of accreditation, 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;
3. identify a point-of-care glucose testing device that the manufacturer’s instructions support using with the desired patient population limitation; or
4. refer the glucose testing to another CLIA-certified or accredited laboratory (*e.g.* central hospital laboratory) that meets the requirements to perform such testing. (See CMS Notification; Attachment 1, p. 3).

⁵CLIA requirements for non-physician/DPM high-complexity testing are set forth at 42 CFR 493.1489.

⁶(See: CMS Notification, p. 4, Attachment 1, p. 1).

⁷(See: CMS/FDA Notification, Attachment 2, p. 1).

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certificate of waiver” in accordance with regulations implementing CLIA.⁸ This exemption has reference to clinical laboratory test procedures “which do not require the exercise of independent judgment or responsibility” and are considered simple, noncomplex tests classified as “waived tests” by CLIA regulations, as distinct from tests of “moderate complexity” and tests of “high complexity.” Since the adoption of the Louisiana CLP Law over two decades ago⁹ the use of BMGS has been designated as a “waived test” by CLIA, Louisiana law and Board regulation.¹⁰

Nurses have utilized BMGS on critically ill, hospitalized patient populations for many years as waived testing. Therefore, because the unique circumstances relating to the reclassification of certain BGMS from “waved” to “high-complexity” testing, and provided that the nurse and hospital laboratory satisfy all CLIA requirements for high complexity testing, the Board will not require a clinical laboratory personnel license in this instance. Stated differently, provided the above-mentioned CLIA requirements are satisfied by the nurse and hospital laboratory, it will defer enforcement action against a nurse who uses BGMS off-label for critically ill patients in a hospital setting.

In closing, to this advice we append certain qualifications. First, this advice should not be perceived to mean or infer, by implication or otherwise, that the Board plans to withhold administrative or injunctive enforcement against a nurse or any other individual who performs high complexity testing outside of the scope of this opinion in the absence of CLP licensure. The reach of this opinion, that is, only address nurses duly qualified under CLIA, who perform BGMS on critically ill patients in a hospital that is supported by a laboratory that complies with all CLIA requirements to perform high complexity testing. The Board’s opinion is in large measure the result of the unique circumstance present in this one instance.

Second, given the potential for patient harm that may result from the use of BGMS that are not designed to accommodate a critically ill patient population, the Board questions the wisdom of not following an one of the other alternative courses suggested by CMS rather than continuing to rely on the off-label use of equipment *e.g.*, (i) using a BGMS that has been cleared by the manufacturer for critically-ill patients (at least 1 model has been approved); (ii) or drawing/submitting blood glucose specimens from patients whose clinical conditions do not meet those described in the intended use of the manufacturers’ instructions to a CLIA certified or accredited laboratory capable of doing the testing *e.g.*, presumably the hospital laboratory.¹¹

Finally, you should be aware that in an effort to expedite this reply the Board has not solicited the input of the Louisiana State Board of Nursing (“BON”) on this issue.

⁸La. Rev. Stat. §37:1313(C)(1), *referencing* 42 U.S.C. §263a.; 42 C.F.R. §§493.35–.39.

⁹La. R.S. §§37:1311-1329.

¹⁰42 C.F.R. §493.10; *see also* 42 C.F.R. §§ 493.15, 493.17. The Law, and the Board’s implementing regulations thereunder, set out an “illustrative list” of such routine or “waived” tests. La. Rev. Stat. §37:1313(C)(2); La. Admin. C. §§ 46:XLV.3503 (“Waived Test”), .3507(A)(8).

¹¹*See*: CMS/FDA Notification, p. 4 and Attachment 1, p. 3.

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Sincerely,

**LOUISIANA STATE BOARD
OF MEDICAL EXAMINERS**

A handwritten signature in cursive script, appearing to read "Rita L. Arceneaux".

Rita Arceneaux

Confidential Executive Assistant

C: LSBME Clinical Laboratory Advisory Comm.