American Hospital Association

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May 2, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1601
Rockville, MD 20852

RE: Docket No. FDA-2013-D-1445: Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use; Draft Guidance for Industry and Food and Drug Administration Staff.

Dear Sir/Madam:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) draft guidance on blood glucose monitoring test systems (BGMS) for prescription point-of-care (POC) use.

Blood glucose testing is one of the most commonly performed tests in acute care hospitals and is critical to managing diabetes in hospitalized patients. **We support FDA's efforts to improve the safety and efficacy of POC BGMS used for hospitalized patients. However, we are concerned that, as written, the draft guidance would have serious unintended consequences for patients and hospitals, including placing patients at unnecessary risk. As a result, the AHA urges FDA to delay issuing final guidance until it consults with stakeholders to consider alternatives that do not have the unintended consequences of inappropriately limiting proper use of glucose meters in hospitals and in other health care settings.**

Historically, FDA has not distinguished between requirements for prescription blood glucose meters used by medical professionals in hospitals or other health care settings and meters used for "over-the-counter" (OTC) self-monitoring by lay users (e.g. diabetics). FDA reports that most blood glucose meters that it has approved, even those intended for use in health care facilities, were submitted to FDA with claims for OTC "home use," and thus evaluated only for this purpose. Under the Clinical Laboratory Improvement Amendments (CLIA), tests, including meters, that are approved by FDA for OTC "home use" are automatically categorized as "waived tests," which are then subject to the lowest level of CLIA regulatory requirements. This waiver allows hospitals to use these meters for convenient, rapid and real-time bedside testing.

However, FDA has reported that in recent years, concerns have been raised about the risk associated with glucose meters that are used on multiple patients in hospitals. Concerns also have been raised about the accuracy of glucose testing in hospitalized patients who may have physiological and pathological factors that could interfere with glucose measurements. Therefore, on January 7, FDA issued two draft guidance documents that set out significantly different requirements for: (1) prescription BGMS operated by health care professionals in medical facilities and (2) self-monitoring blood glucose (SMBG) systems used by lay users OTC. Specifically, FDA would require different accuracy and study requirements for each environment that reflect the intended use of the devices.

The AHA supports the development and availability of medical devices that are safe and effective for use in all types of hospitalized patients. We agree with FDA that the additional steps that it has included in its guidance, such as validated cleaning and disinfection procedures, are needed to protect patients against the transmission of blood-borne pathogens when blood glucose meters are used on multiple patients in a hospital setting. However, we believe that the draft guidance inadvertently calls into question the regulatory status of blood glucose meters *currently in use* by hospitals, when the guidance is actually intended to apply only to new and improved blood glucose meters that are *yet to be developed*.

Specifically, we are concerned that the guidance essentially deems hospital blood glucose testing an "off label" use, which effectively nullifies the automatic CLIA waiver status that OTC blood glucose meters currently in use have been granted in hospital settings. Therefore, these meters would be subject to the highest level of regulation under CLIA as "high complexity" testing, which could be detrimental to patient care for reasons outlined below. The specific statements in the guidance that we are concerned about include, in the BGMS guidance, "Use of glucose monitoring devices in professional healthcare settings when they were cleared [only] for lay use puts patients at increased risk." In addition, the guidance also recommends manufacturers include on their BGMS labels the statement that, "critically ill patients should not be tested with a glucose meter because results may be inaccurate." Further, the SMBG guidance would require prominent placement of the following warning on OTC devices: "This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician's offices, or long-term care facilities because it has not been determined to be safe and effective for use in these settings, including for routine assisted testing or as part of glycemic control procedures."

Subjecting BGMS to stringent "high complexity" testing requirements under CLIA is not necessary for the continued safe use of blood glucose meters in health care settings when the core intended use of the product (e.g. monitoring glucose to manage diabetes) is the same in both the OTC home and professional environment. In addition, many hospitals would be unable to meet the much more resource-intensive requirements of "high complexity" testing, such as the stricter testing personnel qualifications, the laboratory director qualifications and requirements and the competency assessment requirements. For instance, most nurses would not meet the education and training requirements to perform high complexity testing. This type of testing requires a trained laboratory professional. This would make it far more difficult to perform rapid glucose screening at the bedside in hospital intensive care units, operating rooms and emergency departments. Therefore, hospitals would have no choice but to use the only current alternative to

bedside blood glucose monitoring – central laboratory testing of blood. While there are well-known limitations to using blood glucose meters, the alternative of central lab testing is a poor substitute and would be dangerous because it would delay appropriate interventions for controlling glucose levels in hospitalized patients. Specifically, it is time-consuming and does not allow blood glucose levels to be known in real time. These shortcomings are important because patients in hospitals have health issues that require timely diagnosis and treatment. Rapid changes in glucose levels in critically ill patients could make test results from laboratory tests obsolete by the time results are received. These delays could lead to poor treatment decisions that could seriously compromise patient safety and quality of care.

Further, FDA's draft guidance recommends that "critically ill" hospitalized patients should not be tested with a blood glucose meter. However, the agency neither cites evidence to support this conclusion, nor defines which patient populations would fall under that category. While we agree that blood glucose meters should not be utilized for inpatients requiring tight glycemic control, we are concerned that the broad assertions FDA makes in its draft guidance against the use of blood glucose meters for "critically ill" hospitalized patients is sowing confusion in hospitals and in state and federal agencies that have authority over hospitals.

Our concerns are not just theoretical. For example, on January 13, the New York State Department of Health issued a letter to hospital laboratory directors citing FDA's draft guidance and stating that laboratories that use glucose meters in populations in which its use had not been approved would be engaging in off-label use and would be required to meet the CLIA requirements of high complexity testing. In addition, the Veterans Health Administration issued a memo in January warning providers that devices categorized under CLIA as waived, would lose their waived status if they were used off-label.

The AHA also is concerned about claims made by the device industry that the standards FDA proposes for the accuracy of BGMS devices for use in hospitals are unrealistic and disregard the international standards of ISO 15197 and Clinical Laboratory Standards Institute (CLSI) Point of Care Testing (POCT) 12, which were recently updated by the international community of diabetes stakeholders. We are told that FDA participated in these most recent ISO efforts, but has, nonetheless, decided to go beyond these standards without providing additional clinical justification for the different standard. **The AHA urges FDA to harmonize its standards with the international standards, rather than impose new requirements that could result in reduced options for hospitals and patients and stifle innovation in medical technology.**

Given all these concerns, the AHA urges FDA to delay issuing final guidance until it convenes a workshop with clinicians, hospitals, the device industry and other stakeholders to discuss key issues that have been raised and to consider alternative approaches to regulation that do not have the unintended consequences of limiting the appropriate use of blood glucose meters in hospitals and in other health care settings. Furthermore, the AHA recommends that FDA immediately issue a statement clarifying that its draft guidance should not be used by state or federal regulatory agencies as a tool to enforce new restrictions and requirements on the use of blood glucose meters in hospitals or in other health care settings.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Linda E. Fishman
Senior Vice President, Public Policy Analysis and Development