American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-D-1445-0065: Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use Draft Guidance for Industry and Food and Drug Administration Staff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 clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, 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American Hospital Association (AHA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) draft guidance on blood glucose monitoring test systems (BGMS) for prescription point-of-care (POC) use.

We commend FDA's work to provide clear, practical guidance around BGMS for POC use. America's hospitals are committed to providing patients with safe, high-quality health care, and BGMS play an important role in providing this care. Blood glucose testing remains one of the most commonly performed initial diagnostic screening tests in the acute and post-acute care settings, and ensuring safe and effective use of these devices is essential. Providers at the patient's bedside often rely on the quick and effective results of BGM readings to make important health care decisions for their patients. While laboratory tests may be more precise, the importance of having information quickly often outweighs the additional precision to be gained by sending a sample to the laboratory. The provisions of the agency's draft guidance appropriately improve the safety and efficacy of POC BGMS, while simultaneously recognizing the vital role these devices play in hospitals and health systems. If finalized, this guidance would provide automatic Clinical Laboratory Improvement Act (CLIA) waiver status to BGMS for POC use, eliminating the previous requirements under "high complexity" testing and, ultimately, benefiting the patients for whom we care.

In addition, in light of continued efforts to reduce regulatory burden for hospitals, health systems and their care teams, we would be remiss not to identify the potential for

additional regulatory relief within the FDA's jurisdiction, specifically around disinfectant products. In its draft guidance, the agency states that disinfectant products for BGMS should be effective against HIV, Hepatitis B and Hepatitis C. We agree with the agency's reasoning regarding disinfectant effectiveness; however, permitting each manufacturer to select the disinfectant product best suited for their respective device can create burden and risks for hospitals. Allowing device manufacturers to dictate the appropriate disinfectant can lead to confusion for hospital personnel responsible for cleaning the devices; early device corrosion and degradation without warranty coverage; and overstocking of disinfectants for each device. To help eliminate these occurrences, we urge FDA to consider compiling a finite list of universally acceptable disinfectant products that would apply to all medical devices or classes of device. In doing so, the agency would set forth a list of approved disinfectants, requiring device manufacturers to ensure that their products can be cleaned and sterilized properly using one of the pre-approved disinfectants on the list. This commonsense approach will limit waste and confusion and decrease the potential for hospital staff to apply the improper disinfectant to a specific device.

Thank you for allowing us to share our comments. Please contact me if you have questions or feel free to have a member of your team contact Mark Howell, senior associate director of policy, at mhowell@aha.org or (202) 626-2274.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development