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December 7, 2017

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket Number FDA-2017-N-5093, Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration; Proposed Rule (Vol. 82, No. 42506) September 8, 2017.

To the Dockets Management Staff:

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 respond to the Food and Drug Administration's (FDA) request for information on regulatory flexibilities and efficiencies.

The regulatory burden faced by hospitals is substantial and unsustainable. While some regulation is clearly necessary to ensure safe and accountable care to patients, close to 24,000 pages of hospital-related federal regulations were published in 2016 alone. Providers are constantly challenged to interpret and implement new or revised regulations while maintaining their core mission to provide high-quality patient care.

In fact, the AHA on Oct. 26 released a new [analysis](#) showing that hospitals, health systems and post-acute care providers spend nearly \$39 billion a year solely on administrative activities related to regulatory compliance. In addition, the analysis found that an average-sized hospital dedicates 59 full-time equivalents (FTEs) to regulatory compliance; one-quarter of those employees are physicians, nurses and other health professionals who would otherwise be caring for patients. The study found that an average-sized community hospital spends \$7.6 million annually to comply with federal regulations, this equates to \$1,200 every time a patient is admitted. Reducing the administrative burden will enable providers to focus more on patient care, and redeploy resources to improve care, improve health and reduce costs.



We very much appreciate the steps the Administration has taken already to reduce administrative burden; for example, the FDA's recent decision not to finalize guidance on the oversight of laboratory-developed tests in order to allow for further public discussion and to give Congress the opportunity to develop a legislative solution. Such willingness to tackle regulatory burden and complexity could save billions of dollars annually and allow providers to spend more time on patients, not paperwork.

Below we describe actions that FDA could take immediately to reduce the regulatory burden on hospitals, health systems and the patients we serve with regard to the compounding of drug products. The steps we recommend also would lead to enhanced access to safe and high-quality compounded drug products. However, while reducing regulatory burden on hospitals and health systems is critical, recent ransomware attacks have highlighted the vulnerability of medical devices and hospital information systems to cyberattack and the need for greater oversight of medical device manufacturers with respect to the security of their products. In particular, we believe that more oversight is needed as it relates to updating and patching devices as new threats emerge, as well as efforts to improve transparency and dissemination of key information regarding device software during cyberattacks.

MAINTAINING TIMELY PATIENT ACCESS TO SAFE AND HIGH-QUALITY COMPOUNDED DRUGS

In April 2016, the FDA issued draft guidance for hospital and health system compounding of drugs that included an exception to its "prescription requirements." This provision was intended to allow hospital pharmacies to compound and distribute a limited amount of drug products prior to the receipt of a patient-specific prescription, as long as the compounded products were used only within the hospital's facilities for its own patients. Yet, this exception included an arbitrary and unworkable provision that would limit the distribution of these compounded products only to those health care facilities *that are located within a one-mile radius of the hospital's compounding pharmacy*. **The AHA continues to urge the Administration to eliminate the "one-mile" limitation and replace it with an alternative approach that would support the existing hospital and health system care delivery model, and rather support widely-vetted, evidence-based limits on anticipatory compounding in hospitals and health systems to ensure safe, high-quality patient care.**

The AHA is concerned that the one-mile radius limitation is not workable for many hospitals and health systems that have centralized their sterile compounding activities in a single location and distribute compounded products to their other system facilities located more than one mile away. As noted in our July 15, 2016 [comment letter](#), we believe that this limitation would be counterproductive, reduce timely access to care and potentially have a negative impact on patient safety and quality of care. Allowing hospitals and health systems to distribute needed amounts of non patient-specific compounded products to their health care facilities without consideration of this arbitrary boundary is especially important when there are national shortages of critical and widely used drugs, such as the current shortage of small-volume parenteral solutions.

Instead of the one-mile radius limitation, the AHA recommends that the FDA allow hospitals and health systems to use the beyond-use date (BUD)¹ timeframes contained in United States Pharmacopoeia (USP) Chapter 797 Pharmaceutical Compounding—Sterile Preparations and USP Chapter 800 Hazardous Drugs—Handling in Healthcare Settings.²

We believe that limiting the distribution of non-patient-specific sterile compounded drugs in hospitals and health systems based on these BUDs addresses the FDA's concerns regarding the risk and quality associated with compounded products. The AHA's [comment letter](#) includes further discussion of this alternative approach and its rationale.

NEED FOR INCREASED OVERSIGHT OF CYBERSECURITY OF MEDICAL DEVICES

Hospital and health system leaders recognize that data held by health care organizations is highly sensitive, as well as valuable, and are taking cybersecurity challenges extremely seriously. The vast majority of hospitals already are taking many important security steps to safeguard data while they continue to enhance their data protection capabilities (details on the steps hospitals are taking can be found at www.aha.org/cybersecurity).

However, the recent global ransomware attack underscores the cybersecurity risks hospitals and health systems face and the importance of strong cybersecurity protections. More than 200,000 computers in more than 150 countries were infected with the WannaCry ransomware worm, which locked down systems and demanded a ransom payment to have them restored. While this attack was waged against all sectors, the health sector drew attention from the media and federal officials because of the critical nature of the services we provide and the widespread impact of the attack on the United Kingdom's National Health Service. There are reports that WannaCry hit some American hospitals and health systems – and medical devices with embedded, outdated software likely were the vector.

Thus, this recent ransomware attack highlighted the extent to which medical devices are vulnerable and can create high-risk areas for the security of hospitals' overall information systems. **The FDA must provide greater oversight of medical device manufacturers with respect to the security of their products. Manufacturers must be held accountable to proactively minimize risk and continue updating and patching devices as new intelligence and threats emerge.** They share responsibility for safeguarding confidentiality of patient data, maintaining data integrity and assuring the continued availability of the device itself. While the FDA has released both pre- and post-market guidance to device manufacturers on how to secure systems, the device manufacturers have yet to resolve concerns, particularly for the large number of legacy devices still in use.

¹ A BUD is the date or time after which administration of a compounded sterile product must not be initiated.

² USP Chapter 797 describes the procedures and requirements for compounding sterile preparations in order to ensure conditions and practices that prevent harm to patients from: microbial, chemical, or physical contamination; excessive bacterial endotoxins; variations in product strength; or poor quality ingredients. Further, it requires that all personnel involved in sterile compounding undergo specific training and testing. USP Chapter 800 describes the standards for the handling and administration of hazardous drugs, including consideration of patient safety, worker safety, and environmental protection.

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Moreover, AHA members report that many manufacturers were slow to provide needed information about their products during the WannaCry attack. This includes information on the software components embedded in devices, the existence of vulnerabilities and the availability of patches. Furthermore, the mitigating steps recommended by manufacturers – such as taking a device off-line, putting it behind a firewall or further segmenting the network – had significant, and sometimes expensive, operational or patient care impacts. **We recommend that the FDA proactively set clear measurable expectations for manufacturers before incidents and play a more active role during cybersecurity attacks. This active role could include, for example, issuing guidance to manufacturers outlining the expectations for supporting their customers to secure their products.**

Again, we thank you for your consideration of our comments. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, director of policy, at rschulman@aha.org or (202) 626-2273.

Sincerely,

/s/

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