Pharmacy Health Information Technology Collaborative

<u>**Via Electronic Submission to:**</u> **https://www.regulations.gov**

July 7, 2022

Dockets Management Staff
Food and Drug Administration
U.S. Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

> **Re: Docket No. FDA-2021-D-1158 for "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."**

Dear Sir/Madam:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (PHIT), we are pleased to submit comments for Docket No. FDA-2021-D-1158 – *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions; Draft Guidance for Industry and Food and Drug Administration Staff.*

PHIT has been involved with the federal agencies, including the Office of the National Coordinator (ONC) and the Centers for Medicare & Medicaid Services (CMS), developing the national health information technology (HIT) framework since 2010.

Pharmacists provide essential services patients and are part of team-based care models. Additionally, pharmacists are users of medical devices, telehealth and health IT, and in particular, e-prescribing (eRx), electronic medical record (EMR)/electronic health record (EHR) systems, and those utilizing certified EHR technology (CEHRT). PHIT supports the use of these systems, which are important to pharmacists in working with other health care providers to provide needed medications and transmit patient information related to overall patient care, transitions of care, immunization, medication lists, medication allergies, allergy reactions, patient problem lists, smoking status, and other social determinants of health (SDOH). Pharmacists also use health IT for reporting to public health agencies, including immunization reporting; clinical decision support services/knowledge artifacts; and drug formulary checking.

Comments

PHIT supports the general principles for medical device cybersecurity outlined in the draft guidance. As users of medical devices, cybersecurity is of the utmost concern to pharmacists for patient safety, especially in light of increasing cyberattacks and breaches on the health care industry and health systems. Health care data breaches hit an all-time high in

2021.[1] "More than 100 breaches have been reported to the federal government" since January 1, 2022.[2] Experts believe that 2022 could be worse than last year for health care organizations, as "attackers are going after two primary objectives: disruption and data."[3]

To further ensure medical devices are secure and effective, PHIT strongly recommends at the premarket stage that these devices and their application program interfaces (APIs) be certified according to CEHRT certification standards and follow the certification criteria in the 2015 Health IT Certification Criteria Cures Update Edition as part of the secure product development framework (SPDF). The draft guidance does not discuss this aspect. As medical devices commonly include third-party software, it is critical that they be certified according to CEHRT standards to achieve secure interoperability.

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The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. PHIT's membership is composed of the key national pharmacy associations involved in health IT, the National Council for Prescription Drug Programs, and 13 associate members encompassing e-prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacists' services.

As the leading authority in pharmacy health information technology, PHIT's vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-centered care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, PHIT identifies and voices the health IT needs of pharmacists; promotes awareness of functionality and pharmacists' use of health IT; provides resources, guidance, and support for the adoption and implementation of standards-driven health IT; and guides health IT standards development to address pharmacists' needs. For additional information, visit www.pharmacyhit.org.

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On behalf of PHIT, thank you again for the opportunity to comment on Docket No. FDA-2021-D-1158 – *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions; Draft Guidance for Industry and Food and Drug Administration Staff.*

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[1] Health Landi, "Healthcare data breaches hit an all-time high in 2021, impacting 45M people." February 1, 2022. https://www.fiercehealthcare.com/health-tech/healthcare-data-breaches-hit-all-time-high-2021-impacting-45m-people.
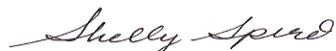[2] Ron Southwick, "The 10 biggest cyberattacks in healthcare in 1st quarter of 2022." April 4, 2022. https://www.chiefhealthcareexecutive.com/view/the-10-biggest-healthcare-cybersecurity-attacks-in-the-1st-quarter-of-2022.
[3] Ron Southwick, "Cyberattacks in healthcare surged last year, and 2022 could be even worse." January 24, 2022. https://www.chiefhealthcareexecutive.com/view/cyberattacks-in-healthcare-surged-last-year-and-2022-could-be-even-worse.

For more information, contact Shelly Spiro, executive director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,

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