



December 15, 2020

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

Re: Request for Feedback-Communicating Cybersecurity Vulnerabilities to Patients Discussion Paper

Dear Sir/Madam:

The Confidentiality Coalition appreciates the opportunity to submit comments on the Food and Drug Administration's (FDA) Patient Engagement Advisory Committee (PEAC) discussion paper on 'Communicating Cybersecurity Vulnerabilities to Patients: Considerations for a Framework.'

The Confidentiality Coalition is composed of a broad group of hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacies, pharmacy benefit managers, health information and research organizations, patient groups, and others founded to advance effective patient confidentiality protections. The Coalition's mission is to advocate policies and practices that safeguard the privacy of patients and healthcare consumers while, at the same time, enabling the essential flow of patient information that is critical to the timely and effective delivery of healthcare, improvements in quality and safety, and the development of new lifesaving and life-enhancing medical interventions.

As healthcare infrastructure continues to become more interconnected and data is shared with more applications, cybersecurity vulnerabilities will continue to be pressing issues for healthcare stakeholders. The COVID-19 health pandemic has highlighted the increased danger that cybersecurity vulnerabilities can create. One cybersecurity company has reported that its clients have seen over 1 million spam messages related to COVID-19 between March – September.¹ Given these complex challenges, we support efforts by the FDA to create a unified standard for communicating cybersecurity vulnerabilities to consumers so that they can easily understand the nature of the vulnerability and how it affects them. The FDA's proposed framework provides a clear and understandable model so that impacted entities can convey the nature of the vulnerability and steps they have already taken to protect consumer data.

We applaud the FDA's recognition that a single method of communicating cybersecurity vulnerabilities does not adequately consider diverse audiences and requires communications to be tailored to different audiences. Recognizing the diversity of audiences is important so that

¹ Thaddeus Swanek, *The Evolution of Cybersecurity Threats During COVID-19 and What You Can Do About It*, U.S. Chamber of Commerce (September 30, 2020), <https://www.uschamber.com/series/above-the-fold/the-evolution-of-cybersecurity-threats-during-covid-19-and-what-you-can-do>.

information can be properly understood. It is important that any cybersecurity communications can be understood by all audiences and that cultural considerations such as language barriers are recognized. We support these efforts to develop communications that reach consumers through different mediums, but we encourage the FDA to work with other federal agencies to ensure these communications do not violate other existing laws and regulations. We are particularly concerned that such communications may conflict with provisions of the Telephone Consumer Privacy Act (TCPA) and we hope that the FDA will work with the Federal Communications Commission (FCC) to ensure better regulatory harmonization.

Cybersecurity vulnerabilities create unique challenges for healthcare stakeholders, as it is often unclear how extensive a cybersecurity breach is at the time of discovery. We appreciate FDA's recognition that communicating vulnerabilities as soon as possible is essential and that impacted entities should highlight that certain information is unknown at the time of disclosure. We are worried, however, that premature reporting even when a compromise has not been substantiated may create burdensome avenues for frivolous litigation. The Confidentiality Coalition hopes that FDA will work with stakeholders to provide good-faith disclosures to consumers; but provide protection so that these disclosures do not automatically invite potential litigation. This collaborative relationship will help build trust among stakeholders and encourage future transparency efforts.

The Confidentiality Coalition values the FDA's work in responding to the complex challenges of cybersecurity vulnerabilities and we look forward to working on these issues together. Please contact me at tgrande@hlc.org or (202) 449-3433 with any questions.

Sincerely,

A handwritten signature in black ink that reads "Tina O. Grande". The signature is written in a cursive, flowing style.

Tina O. Grande
Chair, Confidentiality Coalition and
Executive VP, Policy, Healthcare Leadership Council