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The Medtech Association

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May 5, 2025

Senator Anne Carney, Chair
Committee on Judiciary
100 State House Station
Augusta, ME 04333

Representative Amy Kuhn, Chair
Committee on Judiciary
100 State House Station
Augusta, ME 0433

RE: LD 1822 – An Act to Enact the Maine Online Data Privacy Act

Chair Carney, Chair Kuhn, and Members of the Committee,

AdvaMed, the MedTech Association, is the largest medical technology association, representing the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our more than 600 members range from small, emerging companies to large multinationals and include traditional device, diagnostic, and digital health technology companies.

We appreciate Chair Kuhn's efforts to tackle this complex issue and engage on LD 1822 and her willingness to support the overall effort to provide confidence to Mainers that their data privacy is secured. LD 1822 would provide the residents of Maine with transparency and control over their personal data and provide new privacy protections.

We support this legislation and its goal to further clarify how healthcare now, and in the future, will be safeguarded for patients and their health care. Though this legislation does contain nearly all the language advancing these objectives, it is missing two key provisions that will help safeguard patient data by avoiding ambiguity while ensuring access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

Unique Nature of Medtech Health Data:

- **Clinician-Oriented:** Unlike consumer devices, medical devices are often chosen and used by clinicians, not by the patients themselves.
- **HIPAA and non-HIPAA health care providers:** Medtech companies often support health care providers (providers), and not all of those providers are HIPAA covered entities because of the structure of the HIPAA rules. To be safe, medtech companies apply HIPAA protections to all data received from provider-managed devices.
- **No Direct Patient Interface:** Many medical devices are designed to be operated solely by clinicians, with no direct interface for patients. Without a patient interface,

there is no direct means of obtaining and recording consent for data collected from non-HIPAA covered providers

We request adding the following language to Section §9604. 2. Exempt Data:

Q. *Information treated in the same manner as Protected Health Information that is maintained by a Covered Entity or Business Associate;*

R. *Information included in a Limited Data Set as described at 45 CFR 164.514(e), to the extent that the information is used, disclosed, and maintained in the manner specified at 45 CFR 164.514(e);*

Information Treated like HIPAA

The inclusion of this language is essential to avoid a negative impact on patient care and research and development in Maine. This language has been incorporated into privacy laws in CA, CO, CT, FL, IN, IA, KY, MD, MN, MT, NV, NH, OR, TN, TX, UT, VA, and WA. It will prevent unintended negative impacts on patient care and avoid unnecessary liability for disclosures of patient data that are enabled under HIPAA and critical to a functioning healthcare system.

A **real-world example** for why this amendment is crucial to enabling seamless patient care is described below.

A heart monitor manufacturer can be liable for sharing ECG recordings with a consulting healthcare provider (with instruction from the ordering provider) without the patient's explicit consent just because the ordering provider is not a HIPAA covered entity. In other words, because LD 1822 exempts only HIPAA covered entities but not non-covered providers, a medtech company will be held liable for treating any patient data gathered by their devices as HIPAA data, as if it originated from a provider who takes insurance. Since medtech companies often responsible for this sharing won't have direct interaction with the patient necessary to obtain this consent, they err on the side of caution and treat all data they receive as HIPAA data.

Here's how that could look:
The physician ordering the cardiac monitor is an ob-gyn physician who does not accept insurance, so they are not a covered entity and the data collected by that cardiac monitor falls outside of HIPAA. The ordering physician seeks a consult from a physician outside of her institution and logs into the medtech company's cloud platform to grant access to the consulting physician, which notifies the consulting physician by email to create an account or login if she already has an account to access the ECG recordings for this patient. The information collected by the cardiac monitor is technically not protected health information under HIPAA since the ordering physician does not accept insurance, so exemption I. would not apply and the medtech company would be liable for not obtaining affirmative express consent to disclose the ECG recording to the consulting provider. The heart monitor device only has a single button to mark events when a patient feels dizzy or has palpitations and does not have an interface to seek and record consent to share information.

Importantly, this amendment helps avoid any ambiguity on how patient data is treated. It does not enable a healthcare institution or provider that does not take insurance from sharing patient data with any outside entity, nor does omitting this amendment prevent them from doing so unless Maine state law explicitly prevents this.

Limited Data Sets Diversify and Strengthen R&D

This exemption enables the sharing of protected health information for crucial purposes without compromising patient privacy. Limited data sets may be used for research, public health activities, and health care operations purposes. The recipient need not be a covered entity or business associate but must nonetheless enter into a data use agreement requiring them to protect the information.

Allowing for the use of these critical data sets diversifies and expands the breadth of knowledge that goes into medical research and development, leading to more innovative and better researched medical devices and technology.

Conclusion

Unlike other industries, health care is already subject to extensive regulation at the federal level. Our goal for this bill – and similar legislation around the country – is focused on avoiding conflict between state and federal laws and ensuring both the continued delivery of high-quality patient care and ensuring essential health research is not disrupted.

AdvaMed has taken a leadership role throughout the country in ensuring that state-level data privacy legislation in 19 states recognizes the existing federal framework governing health data and medical device and technology products. We encourage the committee to follow suit and ensure that there continues to be alignment across the country.

Thank you for your consideration and we look forward to working with you and the committee on these amendments.

Sincerely,

Roxolana Kozyckyj
Senior Director, State Government and Regional Affairs
AdvaMed