AdvaMed
Advanced Medical Technology Association

1301 Pennsylvania Avenue, NW
Suite 400
Washington, D.C. 20004
P :: 202.783.8700
F :: 202.783.8750
W:: AdvaMed.org

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Rep. Zack Stephenson, Chair
Commerce Finance and Policy
Minnesota House of Representatives
St. Paul, MN 55155

Rep. Carlie Kotyza-Witthuhn, Vice-Chair
Commerce Finance and Policy
Minnesota House of Representatives
St. Paul, MN 55155

RE: House File 2309 – Minnesota Consumer Data Privacy Act

Chair Stephenson, Vice-Chair Kotyza-Witthun, and Members of the Committee,

We appreciate your willingness to support the overall effort to provide confidence to your constituents that their data privacy is secured. HF 2309 would provide the residents of Minnesota with transparency and control over their personal data and provide new privacy protections and support this legislation with one additional amendment. AdvaMed appreciates the opportunity to provide comments regarding HF 2309 before the committee.

AdvaMed 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 450 members range from small, emerging companies to large multinationals and include traditional device, diagnostic, and digital health technology companies.

Unlike other industries, health care is already subject to extensive regulation at the federal level. Our work on 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.

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.

AdvaMed recommends the addition of two clarifying exemptions that were integrated into the consumer privacy laws adopted in other states to avoid negatively impacting patient care and research and development.

AdvaMed Recommended Amendments

(1) Add an exemption for information that is **maintained by an entity that meets the definition of Health Care Provider under HIPAA** (45 CFR 160.103) **to the extent that the entity maintains the information in the manner required of Covered Entities with respect to PHI under HIPAA** and related regulations (45 CFR 160, 45 CFR 162, & 45 CFR 164);

This exemption is not currently covered by Section Subd.2(a)(5)[1] or Subd.2(a)(3)(ii)[2] because some medical device companies are neither Covered Entities nor Business Associates with respect to certain patients, but do not have visibility into whether the data generated by their device is outside of HIPAA. Such companies often choose to handle all data received from their devices as a covered entity is obligated to handle PHI under HIPAA.

- If the physician utilizing the device does not accept insurance (e.g., concierge medicine), the clinician would not be a covered entity under HIPAA, and the HIPAA framework would technically not apply to the data collected from the device.
- The concierge physician's use and disclosure of that medical device's data is addressed through Subd.2(a)(3)(ii)'s exemption for health records. However, 144.291, subdivision 2(c)'s definition of "health record" is limited to the record kept by the health care provider as a result of the professional relationship established with the individual, which does not appear to extend to the medtech company.

Explanation & Examples:

No Direct Interface with the Patient. In many instances, medtech companies do not directly interface with patients--often, a physician is the individual who selects the device and chooses to use it with certain patients based on their clinical judgment.

[1] (5) Information originating from, and intermingled to be indistinguishable under this subsection that is maintained by a covered entity or business associate, or a program or qualified service organization as defined by 42 C.F.R. sec. 2.11;

[2] (3)(ii) Health records;

In certain scenarios, patient data collected by medical devices is not Protected Health Information (PHI) under HIPAA, as exemplified in the concierge physician example (described below).

Furthermore, some health care providers purchase medtech through third-party distributors. In some of those instances, the medtech company will not have a means of interacting with clinicians to ascertain whether or not the HCP is a Covered Entity (CE) under HIPAA.

- While some medtech companies can be CEs or Business Associates (BAs) depending on the services provided, the same companies may technically be neither a CE nor a BA in other scenarios with respect to the same type of device.

Some Health Care Providers (HCPs) are not Covered Entities (CEs) under HIPAA.

- HIPAA only regulates a Health Care Provider when it conducts certain transactions[3] related to health insurance coverage electronically.
    - A ***concierge physician*** *or* ***direct primary care physician*** who ***does not accept insurance*** will not engage in HIPAA-covered transactions (electronic transmissions of patient information related to insurance coverage) and, accordingly, will not be a Covered Entity under HIPAA. Thus, information from medical devices utilized by such concierge/direct primary care practices is not protected under HIPAA.
    - **Some medtech companies lack visibility into whether certain device data is within or outside of HIPAA and choose to apply HIPAA protections to all data received from such devices.**

      While a medtech company can be a CE or Business Associate (BA) under HIPAA, depending on the specific health care activities the company is performing, the same company can be neither a CE nor a BA with respect to the same devices in other scenarios (e.g., the concierge medicine example above).

[3] 45 C.F.R. 160.103 (Covered entity means . . . (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.
. . .
Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions: (1) Health care claims or equivalent encounter information. (2) Health care payment and remittance advice. (3) Coordination of benefits. (4) Health care claim status. (5) Enrollment and disenrollment in a health plan. (6) Eligibility for a health plan. (7) Health plan premium payments. (8) Referral certification and authorization. (9) First report of injury. (10) Health claims attachments. (11) Health care electronic funds transfers (EFT) and remittance advice. (12) Other transactions that the Secretary may prescribe by regulation.)

Such companies will handle all patient data from devices in both scenarios as a HIPAA CE must treat PHI *because they lack visibility into which scenario the patient falls under* (e.g., the devices were purchased through a third-party distributor, so the medtech company does not know the identity of the HCP).

Why the proposed exemption is necessary: There is no way for medical device manufacturers to tell whether data from certain devices technically falls outside of HIPAA, so all data is treated as though it is protected under HIPAA. The proposed exemption enables medtech companies to continue to support patient care uniformly for patients in both scenarios.

- For example, patient data from cardiac monitors used by HCPs who are Covered Recipients under HIPAA is excluded under HIPAA, while patient data from the same model cardiac monitors used by concierge physicians is regulated as personal data under the HB15 with respect to the medtech company even though the company treats data from both devices in the same way.
- Certain consumer rights that are inconsistent with patient care and regulatory obligations (e.g., the right to delete) would apply to the data from the concierge physician's cardiac monitor that is transmitted to the manufacturer.
- Medtech companies that do not have a direct interface with the patient will not be able to obtain the consumer's consent to process the data since the clinician selects, uses the device, and accesses the data/analysis produced by the company. In such cases, the company would need the HCP to obtain and document consent.
- Other health care providers that do not conduct HIPAA covered transactions also include free clinics, direct primary care/subscription-based care, cosmetic surgeons, and free-standing cosmetic surgery centers.
    - Although the data that qualifies as a Health Record[4] would be exempt for such providers' uses and disclosures, since a Health Record is limited to data kept by a health care provider, the exemption does not extend to patient data that is transmitted from the medical device to the manufacturer.

[4] "Health record" means a record, other than for financial or billing purposes, relating to an individual, kept by a health care provider as a result of the professional relationship established between the health care provider and the individual; MS 144.291, subdivision 2(c)

(2) Add an exemption for 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).

This exemption is not currently covered by Subd.2(3)(i) because there are instances where medtech companies and other Health Care Providers (HCPs) are neither Covered Entities (CEs) nor Business Associates (BAs). Still, they may receive patient data, where a limited set of such data would be beneficial to disclose for research purposes, public health activities, or healthcare operations.

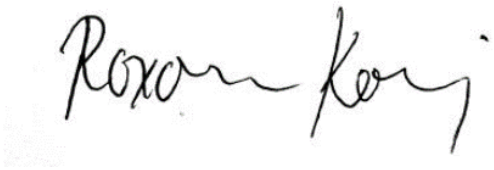
- The proposed exemption would exempt disclosures by a medtech company or other Health Care Provider that is neither a CE nor BA only if that limited data set information is used, disclosed, and maintained in the manner specified under the HIPAA privacy rule (45 CFR 164.514(e)).

Conclusion

To date, fourteen states have passed their data privacy reform laws that include the healthcare amendments currently included in HF 2309 as well as the requested language above. Most recently, New Hampshire passed their legislation inclusive of all key healthcare exemptions. 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