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May 22, 2023

Senator Anne Carney, Chair
Committee on Judiciary
State House, Room 438
Augusta, ME 04333

Representative Matt Moonen, Chair
Committee on Judiciary
State House, Room 438
Augusta, ME 04333

RE: LD 1705, An Act to Give Consumers Control over Sensitive Personal Data by Requiring Consumer Consent Prior to Collection of Data

Dear Chair Carney, Chair Moonen, and Members of the Health and Human Services Committee,

On behalf of the Advanced Medical Technology Association (AdvaMed), I am writing to request an amendment to LD 1705 to further ensure the safeguarding of patient data and provide consistency across states. 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.

AdvaMed advocates a patient-centered framework for the use and disclosure of health information. We believe this can be accomplished by (i) ensuring transparency around collection, use, and sharing of health information; (ii) ensuring that obtaining consent does not unduly delay or diminish the quality of patient care; and (iii) harmonizing new laws and regulations with existing health privacy and security laws and regulations, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules (HIPAA Rules), and relying on existing expertise within the U.S. Department of Health and Human Services (HHS) to address any gaps in existing health privacy and security laws as applied to the Medical Technology industry.

We have worked with legislators in Colorado, Virginia, Utah, Connecticut, and other states who share your goal of providing confidence to their constituents that their data privacy is secured.

While the bill includes an exemption for HIPAA, it remains insufficient. We ask that you consider adopting the following language so that critical healthcare data does not remain in the scope of LD 1705.

This Article/Chapter/Part does not apply to Information that is:

1. *Protected Health Information (PHI) subject to HIPAA & related regulations (45 CFR 160, 45 CFR 162, & 45 CFR 164)*
2. *Patient Identifying Information (PII) subject to 42 CFR 2 (SAMHSA-Confidentiality of Substance Use Disorder Patient Records)*
3. *Personal data used or shared in Research Conducted in accordance with one or more of the following policies for the Protection of Human Research Subjects: 45 CFR 46; International Conference on Harmonisation (ICH) Good Clinical Practice Guidelines (GCP); 21 CFR 50; or 21 CFR 56.*
4. *Created for purposes of the Federal Health Care Quality Improvement Act of 1986, and related regulations;*
5. *Patient Safety Work Product for purposes of 42 CFR 3, established pursuant to 42 USC 299b-21 through 299b-26;*
6. *Derived from any of the health care-related information listed in this subsection and De-identified in accordance with the requirements in 45 CFR 164 (HIPAA);*
7. *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);*
8. *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);*
9. *Information originating from, and intermingled to be indistinguishable with, or information treated in the same manner as PHI/PII that is maintained by:*
    - *A Covered Entity or Business Associate as defined by HIPAA and related regulations; or*
    - *A Program or a Qualified Service Organization as defined by 42 CFR 2 (SAMHSA)*
10. *Used only for Public Health Activities and purposes as described in 45 CFR 164.512(b);*
11. *Used only to address Evidentiary Requirements for Coding, Coverage, and Reimbursement associated with Medicare and other federal health care payers (Veteran's Health Administration, TRICARE, Children's Health Insurance Program (CHIP)), Tribal/Indian Health Services, State Medicaid and CHIP, and private insurance payers; and*
12. *Subject to [STATE-SPECIFIC MEDICAL PRIVACY LAW(S)]*

Private Right of Action

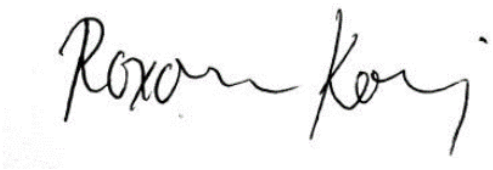
The US Chamber of Commerce, in a whitepaper released last year, demonstrates that private rights of action are inefficient and ineffective for addressing privacy concerns. In fact, private rights of action in the privacy context often:

- Undermine appropriate agency enforcement and allow plaintiffs' lawyers to set policy nationwide, rather than allowing expert regulators to shape and balance policy and protections
- Result in inconsistent and dramatically varied, district-by-district court rulings
- Lead to grossly expensive litigation and staggeringly high settlements that disproportionally do not benefit individuals whose privacy interests may have been infringed
- Hinder innovation and consumer choice by threatening companies with frivolous, excessive, and expensive litigation, particularly if those companies are at the forefront of transformative new technology

AdvaMed respectfully proposes the amendments discussed here and striking the private right of action, in furtherance of the principles espoused above. The proposed amendments would harmonize the Bill with existing laws and regulations, including HIPAA and the Illinois Biometric Information Privacy Act (BIPA), thereby promoting consistency and interoperability within the health care ecosystem. For these reasons, we urge you to take our concerns into consideration and adopt these exemptions in LD 1705.

Thank you for considering our request, please contact me rkozyckyj@advamed.org with any questions you may have.

Sincerely,



Roxy Kozyckyj
Director, State Government and Regional Affairs
Advanced Medical Technology Association (AdvaMed)