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September 6, 2023

Representative John Galloway  
Chair, Commerce Committee  
Pennsylvania State House of Representatives  
127 Irvis Office Building  
Harrisburg, PA 17120

**Re: Concerns regarding HB 1201**

Chair Galloway:

AdvaMed, the Advanced Medical Technology Association, appreciates the opportunity to provide comments regarding HB 1201.

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.

We appreciate Representative Neilsen's engagement on this legislation and are grateful for his consideration to this point. 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 – if 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 one key provision:

**Limited Data Set**

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. This exemption enables the sharing of protected health information for crucial purposes without compromising patient privacy.



We request adding a bullet to Section 9(a), creating a new (11): "*Information included in a limited data set as described at 45 C.F.R. 164.514(e), to the extent that the information is used, disclosed and maintained in the manner specified at 45 C.F.R. 164.514(e).*"

To date, fourteen states have passed their data privacy reform laws that include the healthcare amendments currently included in HB 1201 as well as the clause on limited data sets. We encourage the committee to follow suit and ensure that there continues to be alignment across the country.

Thank you Chair and we look forward to working with you and the committee on these amendments.

Sincerely,



Roxy Kozycky  
Director, State Government and Regional Affairs  
AdvaMed



# Health Data Privacy Priorities

## Safeguard Patient Data



AdvaMed members are committed to ensuring personal health data is protected and safeguarded. AdvaMed exemptions do not expand allowable use of data but instead ensure companies can continue to access appropriate health information while complying with all federal laws.

**IMPACT:** *AdvaMed model exemptions ensure a streamlined process for patients and providers and provide consistency across the country.*

## Continue Fostering Patient Centered Innovation



Patients are at the center of everything our members do. Our exemptions allow cutting-edge medical research that is vital for improving patient access, outcomes, and quality of life to continue uninterrupted.

**IMPACT:** *Existing federal privacy requirements govern how a research study and participants interact with their data. Without an exemption for this agreement in state legislation, important clinical studies could be irreparably compromised or invalidated.*

## Keep Quality of Care High, Costs Low



Health care should always put patients and their safety first. Our exemptions ensure physicians and patients have access to critical life or death information in a timely manner and ensure providers are not bogged down with duplicative paperwork.

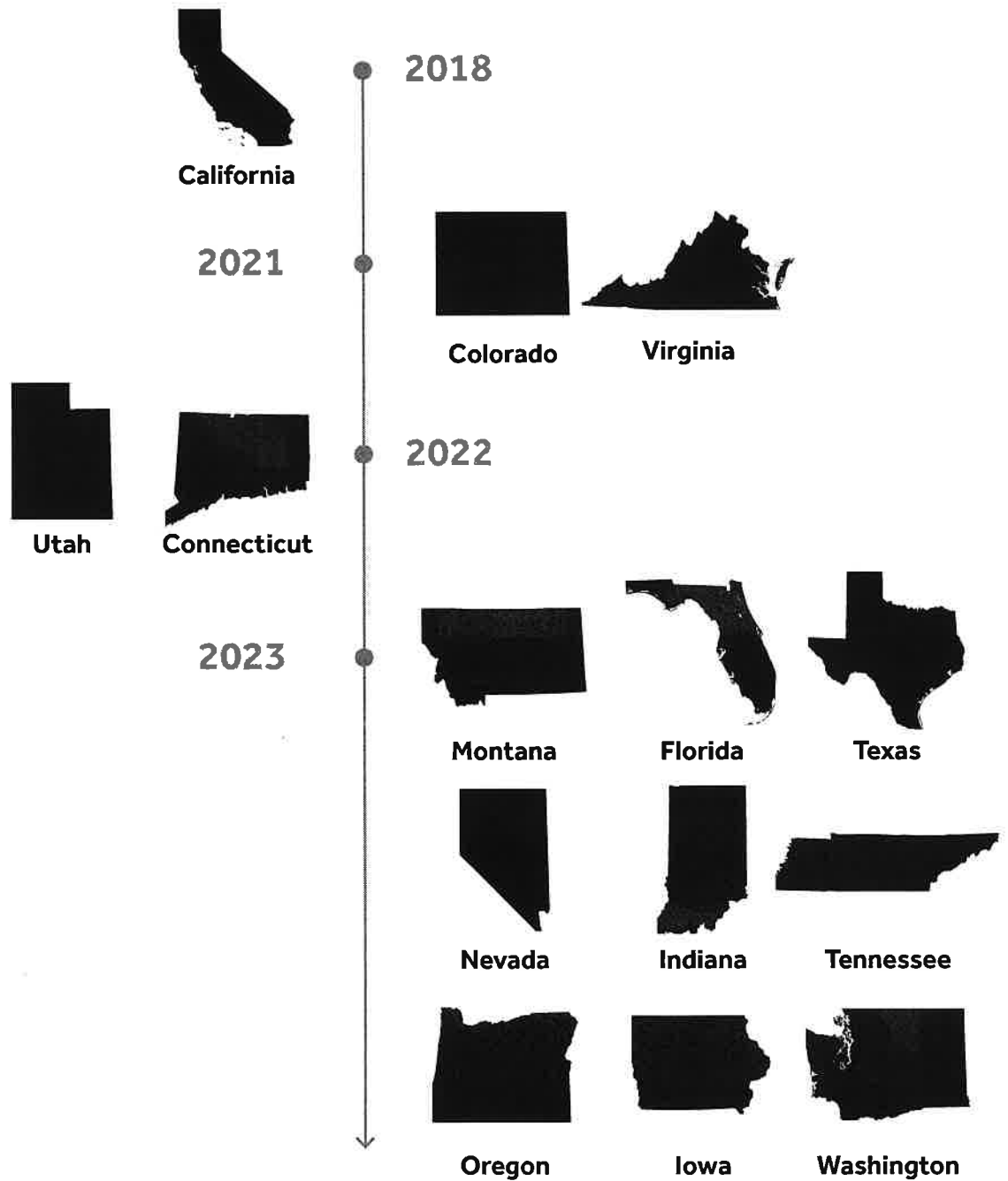
**IMPACT:** *An implantable device may be experiencing complications that require the manufacturer to contact the patient or provider to send important device recall information. Without an exemption, this critical information could not be shared.*

## Data Privacy in Action

A patient experiencing a heart attack may interact with a dozen different technologies to properly diagnose and treat the condition — e.g., diagnostics in the ambulance, vitals, electronic medical records, electrocardiogram, echocardiogram, pulse oximetry, fluoroscopy, anesthesia machine, implanted device, and many more.

Situations like these are already stressful enough for patients and families; repeating the consent process for every medical encounter creates additional burdens without any added benefit. For this reason, HIPAA and other federal regulations rely on notice rather than consent for certain uses and disclosures of health information.

## States with Enacted Data Privacy Laws



\*Note: All enacted legislation includes AdvaMed model exemptions

### Bottom Line

HIPAA has been on the books for almost 30 years, and while it is critical for protecting some patient data, it doesn't encompass the full breadth of recent advancements, innovation, and research within the medical technology industry. To keep pace with an ever-emerging field and the rapidly developing technologies that save lives and improve patient outcomes, critical exemptions for federally regulated data are necessary in state data privacy laws.