

1301 Pennsylvania Avenue, NW Suite 400

Washington, D.C. 20004 **P**:: 202.783.8700

**F**:: 202.783.8750 **W**:: AdvaMed.org

March 20, 2024

Senator Pamela Beidle, Chair Senate Finance Committee 3 East Miller Senate Office Building Annapolis, Maryland 21401 Senator Katherine Klausmeier, Vice-Chair Senate Finance Committee 3 East Miller Senate Office Building Annapolis, Maryland 21401

RE: HB 567, Maryland Online Data Privacy Act of 2024 – Adopt Senate Amendments on De-identified Data

Chair Beidle, Vice-Chair Klausmeier, and Members of the Committee,

AdvaMed appreciates the complex work before the committee and the overall effort of the sponsors to provide confidence to Maryland constituents that their data privacy is secured. HB 567 would provide the residents of Maryland with transparency and control over their personal data and provide new privacy protections. AdvaMed appreciates the opportunity to provide comments regarding HB 567 and respectfully requests that the committee adopt the language on de-identified data in the Senate companion bill.

AdvaMed member companies produce the medical devices, diagnostic products, and digital health technologies (collectively, "Medical Technologies") that are transforming health care through the potential for earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and lifeenhancing devices and other advanced medical technologies in the most appropriate settings.

## **Adopt Senate Language on De-identified Data**

AdvaMed recommends the committee adopt the Senate bill's language on de-identified data or alternatively use the clarifying language also proposed below.

## **Senate amendment, SB 641:**

(III) Information that is de-identified in accordance with the requirements for de-dentification set forth in 45 C.F.R. 164.514 that is derived from individually identifiable health information as described in HIPAA or personal information consistent with the human subject protection requirements of the U.S. Food and Drug Administration.

OR



# Supplement existing definition in HB 567:

**§14-4601.** 

(A) In this subtitle the following words have the meanings indicated.

. .

- (P) "De-identified data" means data that cannot reasonably be used to infer information about, or otherwise be linked to, an identified or identifiable individual, or a device linked to such individual, if the controller that possesses such data does all of the following:
  - (1) Takes reasonable measures to ensure that such data cannot be associated with an individual.
  - (2) Commits in publicly available terms and conditions or in a publicly available privacy policy to maintain and use the information in de-identified form; and
  - (3) Contractually obliges any recipients of the information to comply with all provisions of this subsection.

"De-identified data" also includes data de-identified in accordance with the requirements in 45 CFR 164 (HIPAA), where any recipients of such data are contractually prohibited from attempting to reidentify such data.

## Why Unify De-identified Data Definition with HIPAA.

Data de-identified under HIPAA may not be considered "de-identified data" under this bill. Some patient data controlled or processed by medtech companies is de-identified under the HIPAA and transmitted for analysis, research, development, or some other essential health care purpose. AdvaMed recommends adding a clarifying provision so that data de-identified under HIPAA can continue to be used for analysis, private research, and development that can advance scientific understanding and lead to improvements in care and innovative solutions. This can be accomplished by incorporating the Senate's language OR supplementing the definition of "de-identified data" with an additional sentence, as shown by the blue underlined text below.

#### Conclusion

AdvaMed appreciates this opportunity to offer comments. To date, fourteen states have passed their data privacy reform laws that include amendments similar to those requested above. Most recently, New Hampshire passed legislation inclusive of all key healthcare exemptions that allow healthcare delivery, research, and patient privacy to interact and proceed unimpeded. We encourage the committee to follow suit and ensure that there continues to be alignment across the country with respect to data privacy.



Thank you, Chair Beidle and Vice-Chair Klausemeier, for your consideration of our recommendations. We welcome any opportunity to serve as a resource, especially as it relates to medtech data privacy and security. If you have any questions or need additional information, please contact <a href="mailto:rkozyckyj@advamed.org">rkozyckyj@advamed.org</a>.

Respectfully submitted,

Senior Director, State Government and Regional Affairs

AdvaMed

