

MedChi

The Maryland State Medical Society

1211 Cathedral Street
Baltimore, MD 21201-5516
410.539.0872
Fax: 410.547.0915

1.800.492.1056

www.medchi.org

TO: The Honorable Thomas M. Middleton, Chair
Members, Senate Finance Committee
The Honorable Bryan W. Simonaire

FROM: Pam M. Kasemeyer
J. Steven Wise
Danna L. Kauffman

DATE: March 2, 2017

RE: **SUPPORT WITH AMENDMENT** – Senate Bill 572 – *Investigational Drugs, Biological Products, and Devices – Right to Try Act*

The Maryland State Medical Society (MedChi), which represents more than 7,000 Maryland physicians and their patients, **supports** Senate Bill 572, **with amendments**.

This legislation would allow drug manufacturers to provide certain investigational drugs, biological products and devices to patients. MedChi supports providing this option to patients, but wants to make sure that the law properly considers the provider/patient relationship. We have worked with the House and Senate sponsors to address certain concerns about how this legislation affects that relationship, and support the bill with amendments to be offered by the sponsors.

One amendment relates to the informed consent requirements in the bill. Many times, informed consent may be obtained orally, but this legislation requires that it be in writing, and that it contain very comprehensive and specific information. Accordingly, we believe a standard form should be developed by the Attorney General's Office in much the same way Advance Directive forms have been.

The second amendment clarifies the circumstances under which a provider can be disciplined for actions taken in this context. Under Section 21-2B-04, a Health Occupations Board may not take action against a provider for recommending that a patient access an investigational drug, so long as the recommendation is "consistent with medical standards of care." A drug or device that is investigational is, by definition, not yet consistent with standards of care. Accordingly, the second amendment eliminates that requirement, which would otherwise completely thwart the intent of the bill.

With these amendments, MedChi supports this legislation.

For more information call:

Pam M. Kasemeyer
J. Steven Wise
Danna L. Kauffman
410-244-7000