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## WISCONSIN LEGISLATIVE COUNCIL AMENDMENT MEMO

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**2017 Assembly Bill 69**

**Assembly Substitute  
Amendment 1**

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### **2017 ASSEMBLY BILL 69**

Assembly Bill 69 creates a method by which an eligible patient may gain access to an experimental treatment under certain circumstances. An experimental treatment under the bill is referred to as an “investigational drug, device, or biological product” and is defined as one that has not yet been approved for use by the federal Food and Drug Administration (FDA), but has successfully completed a phase one clinical trial, and remains under investigation or is pending approval by the FDA. The treatment also may not be the subject of a clinical trial that was closed due to the toxicity or lack of efficacy of the drug, device, or product.

An individual is considered an “eligible patient” under the bill if he or she:

- Has a terminal illness;
- Has considered all other available treatment options;
- Has received a treating physician’s recommendation or prescription order for the experimental treatment;
- Has given written informed consent to the use of the experimental treatment; and
- Possesses a written verification executed by his or her treating physician attesting that the patient meets all of the other conditions of eligibility.

In the case of any eligible patient, Assembly Bill 69 authorizes, but does not require, a manufacturer of an experimental treatment to make it available to the patient under certain conditions specified in the bill. Liability is limited for any manufacturer, distributor, pharmacist, practitioner, or other person who makes the experimental treatment available

under the conditions specified in the bill. Also, a physician is immune from civil or criminal liability or professional discipline based solely on a recommendation of an experimental treatment to an eligible patient to treat the patient's terminal illness, if the patient has given informed consent as provided under the bill.

Assembly Bill 69 also prohibits an official, employee, or agent of the state from blocking or attempting to block an eligible patient's access to an experimental treatment covered under the bill. The bill also provides that it does not alter the obligations of an eligible patient's insurer under the contract of insurance or applicable law.

### **ASSEMBLY SUBSTITUTE AMENDMENT 1**

Assembly Substitute Amendment 1 retains the requirements described above for an individual to be considered an eligible patient under the bill, and the Substitute Amendment adds two additional eligibility requirements, as follows:

- The patient is ineligible for or otherwise unable to participate in a clinical trial for the experimental treatment within 100 miles of his or her home address, or has been determined by his or her treating physician to be unsuitable to participate in a clinical trial for which he or she may be eligible; and
- The patient is aware of the potential costs that may be associated with or otherwise result from the use of the experimental treatment.

The Substitute Amendment also adds a reference to health care facilities in the list of persons for whom liability may be limited under the conditions specified in the bill.

### **BILL HISTORY**

On February 28, 2017, Representative Snyder offered Assembly Substitute Amendment 1 to Assembly Bill 69. On March 1, 2017, the Assembly Committee on Health recommended adoption of the Substitute Amendment and passage of Assembly Bill 69, as amended, on votes of Ayes, 10; Noes, 2. On March 7, 2017, the Assembly adopted Assembly Substitute Amendment 1, on a voice vote, and passed Assembly Bill 69, as amended, on a vote of Ayes, 85; Noes, 13.

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