

Chapter 678

(House Bill 740)

AN ACT concerning

President Jimmy Carter Cancer Treatment Access Act

FOR the purpose of prohibiting a certain insurer, nonprofit health service plan, or health maintenance organization from imposing a step therapy or fail–first protocol on an insured or an enrollee for a certain prescription drug used in the treatment of a certain cancer under certain circumstances; providing for the application of this Act; making stylistic and conforming changes; and generally relating to step therapy or fail–first protocols for prescription drugs to treat cancer under health insurance policies and contracts.

BY repealing and reenacting, with amendments,

Article – Insurance

Section 15–142

Annotated Code of Maryland

(2011 Replacement Volume and 2016 Supplement)

Preamble

WHEREAS, President Jimmy Carter announced in August 2015 that he had an aggressive form of melanoma skin cancer, and the tumors had spread from his skin into his liver and brain; and

WHEREAS, President Carter received treatment with surgery, radiation, and a new immunotherapy drug; and

WHEREAS, In December 2015, President Carter revealed that recent tests did not show any signs of the original cancer spots or any new ones; and

WHEREAS, Every Maryland resident with health insurance should have the same access to cancer drugs that President Carter had; now, therefore,

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Insurance

15–142.

(a) (1) In this section the following words have the meanings indicated.

(2) “Step therapy or fail–first protocol” means a protocol established by an insurer, a nonprofit health service plan, or a health maintenance organization that requires a prescription drug or sequence of prescription drugs to be used by an insured or an enrollee before a prescription drug ordered by a prescriber for the insured or the enrollee is covered.

(3) “Step therapy drug” means a prescription drug or sequence of prescription drugs required to be used under a step therapy or fail–first protocol.

(4) “Supporting Medical Information” means:

(i) a paid claim from an entity subject to this section for an insured or an enrollee;

(ii) a pharmacy record that documents that a prescription has been filled and delivered to an insured or an enrollee, or a representative of an insured or an enrollee; or

(iii) other information mutually agreed on by an entity subject to this section and the prescriber of an insured or an enrollee.

(b) (1) This section applies to:

(i) insurers and nonprofit health service plans that provide hospital, medical, or surgical benefits to individuals or groups on an expense–incurred basis under health insurance policies or contracts that are issued or delivered in the State; and

(ii) health maintenance organizations that provide hospital, medical, or surgical benefits to individuals or groups under contracts that are issued or delivered in the State.

(2) An insurer, a nonprofit health service plan, or a health maintenance organization that provides coverage for prescription drugs through a pharmacy benefits manager is subject to the requirements of this section.

(c) An entity subject to this section may not impose a step therapy or fail–first protocol on an insured or AN enrollee if:

(1) the step therapy drug has not been approved by the U.S. Food and Drug Administration for the medical condition being treated; or

(2) a prescriber provides supporting medical information to the entity that a prescription drug covered by the entity:

(i) was ordered by a prescriber for the insured or enrollee within the past 180 days; and

(ii) based on the professional judgment of the prescriber, was effective in treating the insured's or enrollee's disease or medical condition.

(d) **[This] SUBSECTION (C) OF THIS** section may not be construed to require coverage for a prescription drug that is not:

- (1) covered by the policy or contract of an entity subject to this section; or
- (2) otherwise required by law to be covered.

(E) AN ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE A STEP THERAPY OR FAIL-FIRST PROTOCOL ON AN INSURED OR AN ENROLLEE FOR A PRESCRIPTION DRUG APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION IF:

(1) THE PRESCRIPTION DRUG IS USED TO TREAT THE INSURED'S OR ENROLLEE'S STAGE FOUR ADVANCED METASTATIC CANCER; AND

(2) USE OF THE PRESCRIPTION DRUG IS:

(I) CONSISTENT WITH ~~BEST PRACTICES~~ THE U.S. FOOD AND DRUG ADMINISTRATION-APPROVED INDICATION OR THE NATIONAL COMPREHENSIVE CANCER NETWORK DRUGS & BIOLOGICS COMPENDIUM INDICATION FOR THE TREATMENT OF STAGE FOUR ADVANCED METASTATIC CANCER; AND

(II) SUPPORTED BY PEER-REVIEWED MEDICAL LITERATURE.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after October 1, 2017.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2017.

Approved by the Governor, May 25, 2017.