

2016 -- H 7471

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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2016

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A N A C T

RELATING TO INSURANCE - OFF-LABEL USES OF PRESCRIPTION DRUGS

Introduced By: Representatives Shekarchi, Ackerman, Gallison, Fogarty, and Kennedy

Date Introduced: February 04, 2016

Referred To: House Corporations

It is enacted by the General Assembly as follows:

1           SECTION 1. Section 27-55-2 of the General Laws in Chapter 27-55 entitled "Off-label  
2 Uses of Prescription Drugs" is hereby amended to read as follows:

3           **27-55-2. Prescription drug coverage.** -- (a) No health insurer issuing a policy which  
4 provides coverage for prescription drugs shall exclude coverage of any drug used for the  
5 treatment of cancer on the grounds that the drug has not been approved by the FDA for that  
6 indication, provided that the drug is recognized for treatment of that indication in one of the  
7 standard reference compendia, or in the medical literature. It is the responsibility of the  
8 prescribing physician to submit to the insurer documentation supporting the proposed off-label  
9 use or uses, if requested by the issuer.

10           (b) Any coverage of a drug which serves as the primary treatment required by this  
11 chapter shall also include medically necessary services associated with the administration of the  
12 drug.

13           (c) ~~No~~ Except as provided for in subsection (e) of this section, no coverage is required  
14 under this chapter: (1) for any drug which has not been fully licensed or approved by the FDA,  
15 (2) for the use of any drug when the FDA has determined that use to be contraindicated, or (3) for  
16 any experimental drug not approved for any indication by the FDA. ~~The provisions of this section~~  
17 ~~apply to drugs used in the treatment for cancer only and nothing in this section is construed to~~  
18 ~~create, impair, alter, limit, modify, enlarge, abrogate or prohibit reimbursement for medications~~  
19 ~~used in the treatment of any other disease or condition.~~

1 (d) Nothing in this section is construed to prevent the application of contractual  
2 deductibles or co-payment provisions or managed care review.

3 (e) No health insurer issuing a policy which provides coverage for prescription drugs  
4 shall exclude coverage of any drug when it is prescribed to treat a condition other than one for  
5 which the FDA approved it provided that:

6 (1) The drug prescribed is recognized by peer-reviewed medical literature generally  
7 recognized by the relevant medical community for off-label treatment of certain types of cancer  
8 or disabling or life threatening diseases. As used in this section, "peer-reviewed medical  
9 literature" means a published study in a journal or other publication in which original manuscripts  
10 have been critically reviewed for scientific accuracy, validity, and reliability by unbiased  
11 international experts, and that has been determined by the international committee of medical  
12 journal editors to have met its uniform requirements for manuscripts submitted to biomedical  
13 journals. "Peer-reviewed medical literature" does not include publications or supplements to  
14 publications that are sponsored to a significant extent by a pharmaceutical manufacturing  
15 company or any health insurer, health care center, hospital service corporation, medical service  
16 corporation, or fraternal benefit society that delivers, issues for delivery, renews, amends, or  
17 continues a health insurance policy in this state.

18 (f) The coverage required under subsection (e) of this section shall include medically  
19 necessary services associated with the administration of such drug.

20 (g) A drug use covered under subsection (e) of this section shall not be denied based on  
21 medical necessity except for reasons that are unrelated to the legal status of the drug use.

22 SECTION 2. This act shall take effect upon passage.

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EXPLANATION  
BY THE LEGISLATIVE COUNCIL  
OF

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- 1           This act would require insurance coverage for off-label prescription drugs when there is
- 2 evidence in peer-reviewed medical literature to support their use.
- 3           This act would take effect upon passage.

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