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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2016

A N A C T

RELATING TO INSURANCE -- OFF-LABEL USES OF PRESCRIPTION DRUGS

Introduced By: Senators Walaska, Nesselbush, Sosnowski, Goldin, and Algiere

Date Introduced: February 25, 2016

Referred To: Senate Health & Human Services

(Attorney General)

It is enacted by the General Assembly as follows:

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

27-55-1. Definitions. -- For the purpose of this chapter, the following words and terms have the following meanings:

(1) "FDA" means the Federal Food and Drug Administration;

(2) "Health insurer" means all persons, firms, corporations or other organizations offering and assuring health services on a prepaid or primarily expense incurred basis including, but not limited to, policies of accident or sickness insurance, as defined in chapter 18 of this title, nonprofit hospital or medical service plans, whether organized under chapter 19 or 20 of this title or under any public law or by special act of the general assembly, health maintenance organizations, and any other entity, which insures or reimburses for diagnostic, therapeutic or preventive services to a determined population on the basis of a periodic premium;

(3) "Medical literature" means published scientific studies published in at least two (2) articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal;

(4) "Peer-reviewed medical journals" means a published study in a journal or other publication in which original manuscripts have been critically reviewed for scientific accuracy, validity and reliability by unbiased independent experts, and that has been determined by the

International Committee of Medical Journal Editors to have met its Uniform Requirements for Manuscripts Submitted to Biomedical Journals. It does not include publications or supplements to publications that are sponsored to a significant extent by a pharmaceutical manufacturing company or any health insurer, health care center, hospital service corporation, medical service corporation or fraternal benefit society that delivers, issues for delivery, renews, amends or continues a health insurance policy in this state.

~~(4)~~(5) "Standard reference compendia" means: (i) the United States Pharmacopoeia drug information, (ii) the American Medical Association drug evaluations, or (iii) the American Hospital Formulary Service drug information;

~~(5)~~(6) ~~"Drug" means the primary anti-cancer or antineoplastic agent or agents.~~ "Drug" or "drugs" means any substance prescribed by a licensed health care provider acting within the scope of the provider's license and that is intended for use in the diagnosis, mitigation, treatment or prevention of disease that is taken by mouth, injected into a muscle, the skin, a blood vessel or cavity of the body; applied to the skin; or otherwise assimilated by the body. The term includes only those substances that are approved by the FDA for a least one indication.

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

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

(c) No coverage is required under this chapter: (1) for any drug which has not been fully licensed or approved by the FDA, (2) for the use of any drug when the FDA has determined that use to be contraindicated, or (3) for any experimental drug not approved for any indication by the FDA. The provisions of this section apply to drugs used in the treatment for cancer or disabling or life-threatening chronic disease only and nothing in this section is construed to create, impair, alter, limit, modify, enlarge, abrogate or prohibit reimbursement for medications used in the treatment of any other disease or condition.

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

SECTION 3. This act shall take effect January 1, 2017.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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This act would define "peer-reviewed medical journals" and would provide that no health insurer issuing a policy which provides coverage for prescription drugs shall exclude coverage of any drug used for the treatment of disabling or life-threatening chronic disease on the grounds that the drug is considered "off-label" in that the drug has not been approved by the FDA for that indication, provided that the drug is recognized for treatment of that indication in one of the standard reference compendia, or in the medical literature.

This act would take effect January 1, 2017.

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