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LC004543/SUB A
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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: Senators Walaska, Nesselbush, Sosnowski, Goldin, and Algieri

Date Introduced: February 25, 2016

Referred To: Senate Health & Human Services

(Attorney General)

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 or disabling or life-threatening chronic disease on the grounds that the drug
6 has not been approved by the FDA for that indication, provided that the drug is recognized for
7 treatment of that indication in one of the standard reference compendia, or in the medical
8 literature. It is the responsibility of the prescribing physician to submit to the insurer
9 documentation supporting the proposed off-label 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 coverage is required under this chapter: (1) for any drug which has not been fully
14 licensed or approved by the FDA, (2) for the use of any drug when the FDA has determined that
15 use to be contraindicated, or (3) for any experimental drug not approved for any indication by the
16 FDA. The provisions of this section apply to drugs used in the treatment for cancer or disabling or
17 life-threatening chronic disease only and nothing in this section is construed to create, impair,
18 alter, limit, modify, enlarge, abrogate or prohibit reimbursement for medications used in the
19 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 SECTION 2. This act shall take effect upon passage.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF

A N A C T

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

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

7 This act would take effect upon passage.

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