ADOPTED REGULATION OF THE

COMMISSIONER OF INSURANCE

LCB File No. R074-14

Effective January 1, 2016

EXPLANATION – Matter in *italics* is new; matter in brackets [omitted material] is material to be omitted.

AUTHORITY: §1, NRS 679B.130, 687B.120 and 689A.710; §2, NRS 679B.130 and 687B.120; §3, NRS 679B.130.

A REGULATION relating to health benefit plans; prohibiting certain persons that offer certain health benefit plans which provide coverage for prescription drugs and use a drug formulary approved by the Commissioner of Insurance from making changes to the formulary except under certain circumstances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law provides that any health insurance policy or contract, health care plan or certificate of coverage delivered or issued for delivery in this State must be filed with and approved as to form by the Commissioner of Insurance. (NRS 687B.120) For various forms of health insurance that provide coverage for prescription drugs, existing law requires that the insured or enrollee be notified by the insurer about whether the coverage is subject to a "formulary" or a list of covered drugs. If a formulary is used, the required notice must include specified information about the formulary and additional information must be made available to insureds, enrollees and providers of health care. (NRS 689A.405, 689B.0283, 689C.281, 689C.455, 695A.255, 695B.176, 695C.1703, 695F.153, 695G.163)

Section 1 of this regulation prohibits an individual carrier that offers a health benefit plan from removing a drug from its approved formulary unless the United States Food and Drug Administration: (1) does not approve the drug; (2) questions the clinical safety of the drug; or (3) approves the drug for use without a prescription. If the individual carrier's approved formulary includes two or more tiers of benefits providing for different deductibles, copayments or coinsurance applicable to the prescription drugs in each tier, **section 1** also prohibits the individual carrier from moving a brand name drug to a tier with a larger deductible, copayment or coinsurance, unless the individual carrier adds a generic alternative to the brand name drug at: (1) the tier from which the brand name drug is being moved; or (2) a tier that has a smaller deductible, copayment or coinsurance than the tier from which the brand name drug is being moved. **Section 2** of this regulation adopts the same provisions for individual coverage that is provided by a health maintenance organization. Other forms of health insurance are unaffected by this regulation.

- **Section 1.** Chapter 689A of NAC is hereby amended by adding thereto a new section to read as follows:
- 1. Except as otherwise provided in this section, an individual carrier that offers a health benefit plan which provides coverage for prescription drugs and uses a formulary that has been approved by the Commissioner pursuant to NRS 687B.120 shall not:
 - (a) Remove a prescription drug from the formulary; or
- (b) If the formulary includes two or more tiers of benefits providing for different deductibles, copayments or coinsurance applicable to the prescription drugs in each tier, move a drug to a tier with a larger deductible, copayment or coinsurance,
- → during the plan year for which the formulary was approved by the Commissioner.
 - 2. An individual carrier described in subsection 1 may:
 - (a) Remove a prescription drug from a formulary at any time if:
 - (1) The drug is not approved by the United States Food and Drug Administration;
- (2) The United States Food and Drug Administration issues a notice, guidance, warning, announcement or any other statement about the drug which calls into question the clinical safety of the drug; or
- (3) The prescription drug is approved by the United States Food and Drug Administration for use without a prescription.
- (b) If the individual carrier's formulary includes two or more tiers of benefits providing for different deductibles, copayments or coinsurance applicable to the prescription drugs in each tier, move a brand name prescription drug to a tier with a larger deductible, copayment or coinsurance if the individual carrier adds to the formulary a generic prescription drug that is

approved by the United States Food and Drug Administration for use as an alternative to the brand name prescription drug at:

- (1) The benefit tier from which the brand name prescription drug is being moved; or
- (2) A benefit tier that has a smaller deductible, copayment or coinsurance than the benefit tier from which the brand name prescription drug is being moved.
- 3. This section does not prohibit an individual carrier from adding a prescription drug to a formulary at any time.
 - 4. This section does not apply to a grandfathered plan.
 - 5. As used in this section:
 - (a) "Health benefit plan" has the meaning ascribed to it in NRS 687B.470.
 - (b) "Individual carrier" has the meaning ascribed to it in NRS 689A.550.
- **Sec. 2.** Chapter 695C of NAC is hereby amended by adding thereto a new section to read as follows:
- 1. Except as otherwise provided in this section, a health maintenance organization that offers a health benefit plan in the individual market which provides coverage for prescription drugs and uses a formulary that has been approved by the Commissioner pursuant to NRS 687B.120 shall not:
 - (a) Remove a prescription drug from the formulary; or
- (b) If the formulary includes two or more tiers of benefits providing for different deductibles, copayments or coinsurance applicable to the prescription drugs in each tier, move a drug to a tier with a larger deductible, copayment or coinsurance,
- → during the plan year for which the formulary was approved by the Commissioner.
 - 2. A health maintenance organization described in subsection 1 may:

- (a) Remove a prescription drug from a formulary at any time if:
 - (1) The drug is not approved by the United States Food and Drug Administration;
- (2) The United States Food and Drug Administration issues a notice, guidance, warning, announcement or any other statement about the drug which calls into question the clinical safety of the drug; or
- (3) The prescription drug is approved by the United States Food and Drug Administration for use without a prescription.
- (b) If the health maintenance organization's formulary includes two or more tiers of benefits providing for different deductibles, copayments or coinsurance applicable to the prescription drugs in each tier, move a brand name prescription drug to a tier with a larger deductible, copayment or coinsurance if the health maintenance organization adds to the formulary a generic prescription drug that is approved by the United States Food and Drug Administration for use as an alternative to the brand name prescription drug at:
 - (1) The benefit tier from which the brand name prescription drug is being moved; or
- (2) A benefit tier that has a smaller deductible, copayment or coinsurance than the benefit tier from which the brand name prescription drug is being moved.
- 3. This section does not prohibit a health maintenance organization from adding a prescription drug to a formulary at any time.
 - 4. This section does not apply to a grandfathered plan.
- 5. As used in this section, "health benefit plan" has the meaning ascribed to it in NRS 687B.470.
 - **Sec. 3.** This regulation becomes effective on January 1, 2016.

LEGISLATIVE REVIEW OF ADOPTED REGULATIONS INFORMATIONAL STATEMENT AS REQUIRED BY NRS 233B.066

LCB FILE NO. R074-14

The following statement is submitted by the State of Nevada, Department of Business and Industry, Division of Insurance ("Division") for adopted amendments to Nevada Administrative Code ("NAC") Chapter(s) 689A and 695C.

1. A clear and concise explanation of the need for the adopted regulation.

Proposed regulation R074-14 ("proposed regulation" or "R074-14") is needed to protect individuals in Nevada that choose a health insurance policy for an upcoming calendar year based upon the inclusion and cost of specific medications from experiencing adverse changes in coverage for those medications during the policy period. The Patient Protection and Affordable Care Act requires health insurance plans to file formularies listing covered drugs. 45 C.F.R. 156.122(a)(2). Nevada law also requires that any health insurance policy or contract, health care plan or certificate of coverage delivered or issued for delivery in this State be filed with and approved as to form by the Commissioner of Insurance ("Commissioner"). NRS 687B.120.1(a). For various forms of health insurance that provide coverage for prescription drugs, existing law requires that the insured or enrollee be notified by the insurer about whether the coverage is subject to a "formulary," a list of covered drugs. Formularies must include specified information and additional information must be made available to insureds, enrollees and providers of health care.

2. A description of how public comment was solicited, a summary of public response, and an explanation of how other interested persons may obtain a copy of the summary.

(a) A description of how public comment was solicited:

Public comment was solicited by e-mailing the proposed regulation, notice of workshop, notices of intent to act upon the regulation, and small business impact statement to persons on the Division's mailing list requesting notification of proposed regulations. The documents were also made available on the website of the Division, http://doi.nv.gov/, mailed to the main library for each county in Nevada, and posted at the following locations:

Department of Business and Industry Division of Insurance 1818 East College Parkway, Suite 103 Carson City, Nevada 89706

Legislative Building 401 South Carson Street Carson City, Nevada 89701 Department of Business and Industry Division of Insurance 2501 East Sahara Avenue, Suite 302 Las Vegas, Nevada 89104

Grant Sawyer Building 555 East Washington Avenue Las Vegas, Nevada 89101 Blasdel Building 209 East Musser Street Carson City, Nevada 89701 Capitol Building 101 North Carson Street Carson City, Nevada 89701

Nevada Department of Employment, Training and Rehabilitation 2800 E. Saint Louis Avenue Las Vegas, Nevada 89104

The Division distributed drafts of the proposed regulation with each proposed change from the initial announcement of the regulation in June 2014, until the adoption hearing held on October 20, 2015. Public comment was also solicited at a workshop held on July 29, 2014, and at the hearings held on August 12, 2014; November 12, 2014; and October 20, 2015. The public meetings took place at the offices of the Division, 1818 East College Parkway, Carson City, Nevada 89706, with simultaneous videoconferencing to the Bradley Building, 2501 East Sahara Avenue, Las Vegas, Nevada 89104.

(b) A summary of the public response:

The Division received 39 written comments, and 21 persons testified at the hearings regarding R074-14. The comments and testimony addressed primarily two issues:

- 1. Those who favor the regulation as a means to prevent a health insurance carrier from doing a "bait and switch" or simply changing the terms of agreement regarding coverage for prescription drugs during the plan year without notice to consumers or without recourse for consumers who may have selected a health plan based on the formulary coverage at the start of the plan year.
- 2. Those who oppose the regulation because they believe that it prevents a carrier from being able to react to changes in the prescription drug marketplace, such as when a new drug or a new generic form of a drug is approved by the FDA.

(c) An explanation of how other interested persons may obtain a copy of the summary:

The summary in part 2(b) above reflects the comments and testimony that transpired with regard to regulation R074-14. A copy of the summary may be obtained by contacting Cliff King, Chief Insurance Examiner, Life and Health Section, at (775) 687-0700 or cking@doi.nv.gov. This summary will also be made available by e-mail request to insinfo@doi.nv.gov.

3. The number of persons who:

(a) Attended each hearing: August 12, 2014: 28

November 12, 2014: 33 October 20, 2015: 22

(b) Testified at each hearing: August 12, 2014: 7

November 12, 2014: 9 October 20, 2015: 5

- (c) Submitted to the agency written statements: 39
- 4. A list of names and contact information, including telephone number, business address, business telephone number, electronic mail address, and name of entity or organization represented, for each person identified above in #3 (b) and (c), as provided to the agency:

See Exhibit 1.

5. A description of how comment was solicited from affected businesses, a summary of their responses, and an explanation of how other interested persons may obtain a copy of the summary.

Comments were solicited from affected businesses in the same manner as they were solicited from the public. Please see the description, summary and explanation provided above in response to question #2.

6. If after consideration of public comment the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change.

The original draft of the regulation was amended, incorporating comments and testimony received from the workshop and hearings that were considered essential for the regulation. Each comment was considered in the drafting of the regulation; however, comments that were not incorporated into R074-14 were not germane to the issue addressed by the proposed regulation.

- 7. (a) The estimated economic effect of the adopted regulation on the business which it is to regulate:
 - (1) Both adverse and beneficial effects:

Insurers state that the regulation will prevent them from being able to move certain drugs from one tier to another mid-year when another drug is either introduced or withdrawn from the marketplace. This may prevent the insurer from introducing "step" processes mid-year or taking other actions as new drugs are introduced.

(2) Both immediate and long-term effects:

In the short-term an insurer is prevented from changing the drug formulary to its advantage, however, it will be able to make the adjustment for that particular drug on the next renewal. In the long-term, this may make the pricing and moving movement of drugs in the formulary more stable.

- (b) The estimated economic effect of the adopted regulation on the public:
 - (1) Both adverse and beneficial effects:

The public will have the confidence that the drug plan included in their health benefit plans will remain stable for the one term of the policy. The public now complains that carriers conduct

"bait and switch" tactics when the carrier offers drugs at one price (or tier) when the policy is purchased, but then changes the formulary mid-year, and the consumer is stuck with the change until the next renewal.

(2) Both immediate and long-term effects:

In both the short- and long-term, consumers will benefit by having a stable formulary that they can rely on; no more bait-and -switch issues.

8. The estimated cost to the agency for enforcement of the adopted regulations.

There is going to be no additional cost to the Division for enforcement of R074-14.

9. A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates, and a statement explaining why the duplication or overlapping is necessary. If the regulations overlaps or duplicates a federal regulation, the name of the regulating federal agency.

There are no other state or government agency regulations that R074-14 duplicates.

10. If the regulation includes provisions that are more stringent than a federal regulation which regulates the same activity, a summary of those provisions.

There are no federal regulations that apply.

11. If the regulation establishes a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

The agency is not assessing a new fee or increasing an existing fee.