PROPOSED REGULATION OF THE

COMMISSIONER OF INSURANCE

LCB File No. R074-14

August 12, 2014

EXPLANATION – Matter in (1) ***blue bold italics*** is new language in the original regulation; (2) ***green bold italic underlining*** is new language proposed in this amendment; (3) ~~red strikethrough~~ is deleted language in the original regulation; (4) ~~purple double strikethrough~~ is language proposed to be deleted in this amendment; (5) orange double underlining is deleted language in the original regulation that is proposed to be retained in this amendment; and (6) **green bold underlining** is newly added transitory language.

AUTHORITY: §1, NRS 679B.130, 687B.120 and 689A.710; §2, NRS 679B.130, 687B.120 and 689C.203; §3, NRS 679B.130 and 687B.120.

A REGULATION relating to health insurance; prohibiting certain health insurers that provide coverage for prescription drugs and use a drug formulary from making certain changes to the formulary after its approval by the Commissioner of Insurance; and providing other matters properly relating thereto.

Section 1. Chapter 689A of NAC is hereby amended by adding thereto a new section to read as follows:

1. An insurer that offers or issues a policy of health insurance which provides coverage for prescription drugs and uses a formulary approved by the Commissioner shall not:

(a) Except as otherwise provided in subsection 2, remove a prescription drug from the formulary; or

(b) Except as otherwise provided in subsection 5, ~~If~~ 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 ~~[from one tier to another]~~ to a tier with a larger deductible, copayment or coinsurance,

➥after the formulary is approved by the Commissioner.

2. An insurer described in subsection 1 may remove a prescription drug from a formulary at any time if:

(a) The drug is not approved by the United States Food and Drug Administration. This paragraph is not intended to prohibit a carrier from providing coverage for prescription drugs which are prescribed for off-label use by an appropriately licensed provider of health care services; ~~[or]~~

(b) 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. ~~[Before the drug may be removed from the formulary pursuant to this paragraph,]~~ Except as allowed by the Commissioner, the insurer must submit to the Commissioner ~~[a]~~ an informational plan to mitigate the effect on consumers of removing the drug from the formulary ~~[, but the plan need not be approved by the Commissioner before the drug is removed from the formulary.]~~ within 72 hours of the removal; or

(c) The prescription drug is approved by the United States Food and Drug Administration for use without a prescription.

3. An insurer removing a prescription drug from the formulary pursuant to subsection 2 of this section shall ensure that the formulary remains in compliance with the requirements of 45 C.F.R. § 156.122(a).

4. (a) An informational plan to mitigate the effect on consumers of removing a drug from a formulary submitted pursuant to subsection 2 shall indicate:

(1) The number of covered lives that are anticipated to be affected by the removal of the prescription drug from the formulary;

(2) The method or methods anticipated to be used to mitigate the effect on consumers of the removal of the prescription drug from the formulary. Applicable methods of mitigation may include, but are not limited to, addition of a prescription drug to a formulary or replacement by another course of treatment already covered by the health benefit plan; and

(3) The number of covered lives that are anticipated to be aided by each method of mitigation anticipated to be used.

➥ If there is no way to mitigate the effects of the removal of the prescription drug from the formulary the mitigation plan should indicate such.

5. A formulary that includes two or more tiers of benefits providing for different deductibles, copayments or coinsurance applicable to prescription drugs in each tier may move a prescription drug to a tier with a larger deductible, copayment or coinsurance if a generic drug alternative is added to the formulary.

6. A generic drug alternative added to the formulary pursuant to subsection 5 must be, in relation to the original prescription drug:

(a) A biosimilar drug licensed pursuant to 42 U.S.C. § 262(k); or

(b) A bioequivalent drug, as defined in 21 C.F.R. § 320.1(e).

7. The generic drug alternative added to the formulary pursuant to subsection 5 shall be added to the formulary:

(a) At the benefit tier originally occupied by the prescription drug; or

(b) At a benefit tier with a lower deductible, copayment or coinsurance than the benefit tier originally occupied by the prescription drug.

8. This section does not prohibit an insurer from:

(a) Adding prescription drugs to the formulary at any time; or

(b) [changing a] Changing the formulary if the change [is effective only for a policy of health insurance to be offered or issued by the insurer for a subsequent benefit year] occurs as part of the annual rate and form approval process under NRS 687B.120 and is applicable to policies sold on a policy year basis, as defined in 45 C.F.R. § 144.103.

9. The provisions of this section do not apply to grandfathered plans, as defined in NRS 679A.094.

Sec. 2. [Chapter 689C of NAC is hereby amended by adding thereto a new section to read as follows:

1. An insurer that offers or issues a policy of health insurance which provides coverage for prescription drugs and uses a formulary approved by the Commissioner shall not:

(a) Except as otherwise provided in subsection 2, 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 from one tier to another,

↳after the formulary is approved by the Commissioner.

2. An insurer described in subsection 1 may remove a prescription drug from a formulary at any time if:

(a) The drug is not approved by the United States Food and Drug Administration; or

(b) 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. Before the drug may be removed from the formulary pursuant to this paragraph, the insurer must submit to the Commissioner a plan to mitigate the effect on

~~*consumers of removing the drug from the formulary, but the plan need not be approved by the Commissioner before the drug is removed from the formulary.*~~

~~*3. This section does not prohibit an insurer from changing a formulary if the change is effective only for a policy of health insurance to be offered or issued by the insurer for a subsequent benefit year.*~~ ~~]~~ **(Deleted by amendment.)**

Sec. 3. Chapter 695C of NAC is hereby amended by adding thereto a new section to read as follows:

1. A health maintenance organization or insurer that offers or issues a policy of health insurance to an individual which provides coverage for prescription drugs and uses a formulary approved by the Commissioner shall not:

(a) Except as otherwise provided in subsection 2, remove a prescription drug from the formulary; or

(b) Except as otherwise provided in subsection 5, ~~*[If]*~~ ***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*** ~~*[from one tier to another]*~~ ***to a tier with a larger deductible, copayment or coinsurance,***

➥after the formulary is approved by the Commissioner.

2. A health maintenance organization or insurer described in subsection 1 may remove a prescription drug from a formulary at any time if:

(a) The drug is not approved by the United States Food and Drug Administration. This paragraph is not intended to prohibit a carrier from providing coverage for prescription drugs which are prescribed for off-label use by an appropriately licensed provider of health care services; ~~*[or]*~~

(b) 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. ~~***[Before the drug may be removed from the formulary pursuant to this paragraph,]***~~ ***Except as allowed by the Commissioner,*** ***the health maintenance organization or insurer, as applicable, must submit to the Commissioner*** ~~***[a]***~~ ***an informational plan to mitigate the effect on consumers of removing the drug from the formulary*** ~~***[, but the plan need not be approved by the Commissioner before the drug is removed from the formulary .]***~~ ***within 72 hours of the removal; or***

(c) The prescription drug is approved by the United States Food and Drug Administration for use without a prescription.

3. A health maintenance organization or insurer removing a prescription drug from the formulary pursuant to subsection 2 of this section shall ensure that the formulary remains in compliance with the requirements of 45 C.F.R. § 156.122(a).

4. (a) An informational plan to mitigate the effect on consumers of removing a drug from a formulary submitted pursuant to subsection 2 shall indicate:

(1) The number of covered lives anticipated to be affected by the removal of the prescription drug from the formulary;

(2) The method or methods anticipated to be used to mitigate the effect on consumers of the removal of the prescription drug from the formulary. Applicable methods of mitigation may include, but are not limited to, addition of a prescription drug to a formulary or replacement by another course of treatment already covered by the health benefit plan; and

(3) The number of covered lives that are anticipated to be aided by each method of mitigation anticipated to be used.

➥ If there is no way to mitigate the effects of the removal of the prescription drug from the formulary the mitigation plan should indicate such.

5. A formulary that includes two or more tiers of benefits providing for different deductibles, copayments or coinsurance applicable to prescription drugs in each tier may move a prescription drug to a tier with a larger deductible, copayment or coinsurance if a generic drug alternative is added to the formulary.

6. A generic drug alternative added to the formulary pursuant to subsection 5 must be, in relation to the original prescription drug:

(a) A biosimilar drug licensed pursuant to 42 U.S.C. § 262(k); or

(b) A bioequivalent drug, as defined in 21 C.F.R. § 320.1(e).

7. The generic drug alternative added to the formulary pursuant to subsection 5 shall be added to the formulary:

(a) At the benefit tier originally occupied by the prescription drug; or

(b) At a benefit tier with a lower deductible, copayment or coinsurance than the benefit tier originally occupied by the prescription drug.

8. This section does not prohibit a health maintenance organization or insurer from:

(a) Adding a prescription drug to the formulary at any time; or

(b) ~~[changing a]~~ Changing the formulary if the change ~~[is effective only for evidence of coverage to be offered or issued by the health maintenance organization or insurer, as applicable, for a subsequent benefit year]~~ occurs as part of the annual rate and form filing process under NRS 687B.120 and is applicable to policies sold on a policy year basis, as defined in 45 C.F.R. § 144.103.

9. The provisions of this section do not apply to grandfathered plans, as defined in NRS 679A.094.

Sec. 4. ***The provisions of this regulation become effective January 1, 2016.***