NOTICE OF INTENT TO ACT UPON REGULATION

Notice of Hearing for the Adoption, Amendment or Repeal of Regulations of
The Department of Business and Industry, Division of Insurance

The State of Nevada Department of Business and Industry, Division of Insurance ("Division"), (775) 687-0700, will hold a public hearing at **9:00 a.m. on October 20, 2015,** at the Division's office located at 1818 East College Parkway, 1st floor hearing room, Carson City, Nevada 89706. Interested persons may also participate through a simultaneous videoconference conducted at the Bradley Building, 2501 East Sahara Avenue, 2nd floor conference room, Las Vegas, Nevada 89104. The purpose of the hearing is to receive comments from all interested persons regarding the adoption, amendment or repeal of regulations that pertain to **chapters 689A and 695C** of the Nevada Administrative Code ("NAC").

The following information is provided pursuant to the requirements of Nevada Revised Statute ("NRS") 233B.0603 and the directives of the Governor:

LCB File No. R074-14. Prescription Drug Formularies.
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.

Statement of Purpose for LCB File No. R074-14. Prescription Drug Formularies.

(1) Why is the regulation necessary and what is its purpose?
The proposed regulation clarifies the parameters under which a prescription drug in a formulary may be removed from the formulary or moved among prescription benefit tiers (if applicable).

(2) What are the terms or substance of the proposed regulation?
Existing state law requires insurers and health maintenance organizations ("HMOs") using prescription drug formularies to notify policyholders or members of, among other things, how often the contents of the formulary are reviewed.[1] The Patient Protection and Affordable Care Act ("ACA") generally permits issuers of health benefit plans to deny coverage to an individual attempting to enroll outside of the annual open enrollment period and without a limited open or special enrollment period triggering event.[2] The Division of Insurance ("Division") has identified that individuals enrolling in coverage in whole or in part due to the perceived benefits of a particular prescription drug formulary may be disenfranchised if the formulary is materially altered during a plan year, leaving the insured or member with no recourse to change coverage. The proposed regulation clarifies that prescription drug formularies cannot be changed more frequently than annually, except in cases where the United States Food and Drug Administration has issued guidance on the safety of a particular prescription drug or rescinded approval of a drug.

(3) What is the anticipated impact of the regulation on the problem(s)?

[1] NRS 689A.405, 689C.281
[2] 45 C.F.R. § 147.104

The Division anticipates that the proposed regulation will grant consumers peace of mind knowing that formulary benefits will not be changed mid-plan year, except in cases of consumer safety. This should alleviate concerns regarding being "locked in" to coverage that may have less utility than was anticipated when it was purchased.

(4) Do other regulations address the same problem(s)? *No.*

(5) Are alternate forms of regulation sufficient to address the problem(s)? *None known.*

(6) What value does the regulation have to the public?
The Division anticipates that the proposed regulation will grant consumers peace of mind knowing that formulary benefits will not be changed mid-plan year, except in cases of consumer safety. This should alleviate concerns regarding being "locked in" to coverage that may have less utility than was anticipated when it was purchased.

(7) What is the anticipated economic benefit of the regulation?

a. Public
1. Immediate: *Unquantifiable. The Division anticipates reducing the incidence of purchasing health insurance that loses efficacy.*
2. Long Term: *Unquantifiable. The Division anticipates reducing the incidence of purchasing health insurance that loses efficacy.*

b. Insurance Business
1. Immediate: *None anticipated*
2. Long Term: *None anticipated*

c. Small Businesses
1. Immediate: *Unquantifiable. The Division anticipates reducing the incidence of purchasing health insurance that loses efficacy.*
2. Long Term: *Unquantifiable. The Division anticipates reducing the incidence of purchasing health insurance that loses efficacy.*

d. Small Communities
1. Immediate: *None anticipated*
2. Long Term: *None anticipated*

e. Government Entities
1. Immediate: *None anticipated*
2. Long Term: *None anticipated*

(8) What is the anticipated adverse impact, if any?

a. Public
1. Immediate: *None anticipated*
2. Long Term: *None anticipated*

b. Insurance Business

1. Immediate: *Unquantifiable. Insurers and HMOs will need to take measures to ensure their prescription drug formularies do not contribute to adverse selection risk.*

2. Long Term: *Unquantifiable. Insurers and HMOs will need to take measures to ensure their prescription drug formularies do not contribute to adverse selection risk.*

c. Small Businesses

1. Immediate: *None anticipated*
2. Long Term: *None anticipated*

d. Small Communities

1. Immediate: *None anticipated*
2. Long Term: *None anticipated*

e. Government Entities

1. Immediate: *None anticipated*
2. Long Term: *None anticipated*

(9) What is the anticipated cost of the regulation, both direct and indirect?

a. Enactment: *None anticipated.*
b. Enforcement: *None anticipated.*
c. Compliance: *None anticipated.*

(10) Does the regulation establish a new fee or increase an existing fee? *No.*

(11) Provide a statement which identifies the methods used by the agency in determining the impact of the proposed regulation on a small business, prepared pursuant to subsection 3 of NRS 233B.0608. *Attached.*

(12) Provide a description of any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates, and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, state the name of the regulating federal agency. *None known.*

(13) If the regulation is required pursuant to federal law, provide a citation and description of the federal law. *Not applicable.*

(14) If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, provide a summary of such provisions. *Not applicable.*

Persons wishing to comment upon the proposed action of the Division may appear at the scheduled public hearing or may address their comments, data, views or arguments, in written form, to the Division, 1818 East College Parkway, Suite 103, Carson City, Nevada 89706. **Written submissions must be received by the Division on or before October 13, 2015.** If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Division may proceed immediately to act upon any written submissions.

A copy of this notice and the regulation will be on file at the State Library, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation will be available at the offices of the Division, 1818 East College Parkway, Suite 103, Carson City, Nevada 89706, and 2501 East Sahara Avenue, Suite 302, Las Vegas, Nevada 89104, and in all counties in which an office of the agency is not maintained, at the main public library, for inspection and copying by members of the public during business hours. This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations, which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at **http://leg.state.nv.us/register/**. Copies of this notice and the proposed regulation will be mailed to members of the public upon request. A reasonable fee may be charged for copies if it is deemed necessary. This does not apply to a public body subject to the Open Meeting Law.

Upon adoption of any regulation, the agency, if requested to do so by an interested person, either before adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

Notice of the hearing was provided via electronic means to all persons on the agency's e-mail list for administrative regulation noticing, and this Notice of Intent to Act Upon Regulation was posted to the agency's Internet Web site at **http://doi.nv.gov/** and was provided to or posted at the following locations:

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

Department of Business and Industry
Division of Insurance
2501 East Sahara Avenue, Suite 302
Las Vegas, Nevada 89104

Legislative Building
401 South Carson Street
Carson City, Nevada 89701

Grant Sawyer Building
555 East Washington Avenue
Las Vegas, Nevada 89101

Blasdel Building
209 East Musser Street
Carson City, Nevada 89701

Capitol Building Main Floor
101 North Carson Street
Carson City, Nevada 89701

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

Nevada State Library & Archives
100 North Stewart Street
Carson City, Nevada 89701

Carson City Library
900 North Roop Street
Carson City, Nevada 89701

Churchill County Library
553 South Main Street
Fallon, Nevada 89406

Clark County District Library
833 Las Vegas Boulevard North
Las Vegas, Nevada 89101

Douglas County Library
P.O. Box 337
Minden, Nevada 89423

Elko County Library
720 Court Street
Elko, Nevada 89801

Esmeralda County Library
P.O. Box 430
Goldfield, Nevada 89013

Eureka Branch Library
P.O. Box 293
Eureka, Nevada 89316

Humboldt County Library
85 East 5th Street
Winnemucca, Nevada 89445

Lander County Library
P.O. Box 141
Battle Mountain, Nevada 89820

Lincoln County Library
P.O. Box 330
Pioche, Nevada 89043-0330

Lyon County Library
20 Nevin Way
Yerington, Nevada 89447

Mineral County Public Library
P.O. Box 1390
Hawthorne, Nevada 89415

Pershing County Library
P.O. Box 781
Lovelock, Nevada 89419

Storey County Clerk
P.O. Drawer D
Virginia City, Nevada 89440

Tonopah Public Library
P.O. Box 449
Tonopah, Nevada 89049

Washoe County Library
P.O. Box 2151
Reno, Nevada 89505-2151

White Pine County Library
950 Campton Street
Ely, Nevada 89301

Members of the public who would like additional information about the proposed regulations may contact Glenn Shippey, Actuarial Analyst, at (775) 687-0738, or via e-mail to gshippey@doi.nv.gov.

Members of the public who are disabled and require special accommodations or assistance at the hearing are requested to notify the Commissioner's secretary in writing at 1818 East College Parkway, Suite 103, Carson City, Nevada 89706, or by calling (775) 687-0700, no later than five (5) working days prior to the hearing.

DATED this 14th day of September, 2015.

AMY L. PARKS
Acting Commissioner of Insurance

BRIAN SANDOVAL
Governor

STATE OF NEVADA

BRUCE H. BRESLOW
Director

AMY L. PARKS
Acting Commissioner

DEPARTMENT OF BUSINESS AND INDUSTRY
DIVISION OF INSURANCE
1818 East College Pkwy., Suite 103
Carson City, Nevada 89706
(775) 687-0700 • Fax (775) 687-0787
Website: doi.nv.gov
E-mail: insinfo@doi.nv.gov

Notice of Intent to Act Upon Regulation & Hearing Agenda

LCB File No. R074-14, Prescription Drug Formularies

Agenda

Tuesday, October 20, 2015 • 9:00 A.M.

Location of Hearing:
Offices of the Division of Insurance
1818 E. College Pkwy., 1st Floor Hearing Room
Carson City, NV 89706
(Division Offices located in Suite 103)

Available via Videoconference at:
Offices of the Division of Insurance
2501 E. Sahara Ave., 2nd Floor Conference Room
Las Vegas, NV 89104
(Division Offices located in Suite 302)

1. **Call to Order.**

2. **Public Comment.**

3. **Presentation, Discussion and Adoption of Proposed Regulation. (For Possible Action)**
   LCB File No. R074-14, Prescription Drug Formularies.
   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.

4. **Public Comment.**

5. **Adjournment.**

Supporting public material for this meeting may be requested from Sue Dummar, Legal Secretary, Nevada Division of Insurance, 1818 E. College Parkway, Carson City, Nevada 89706, by e-mail to sdummar@doi.nv.gov, or by calling (775) 687-0704. In your request, please state that you are requesting meeting materials for LCB File No. R074-14, Prescription Drug Formularies, and provide the date of the meeting.

Note: Any agenda item may be taken out-of-order; items may be combined for consideration by the public body; and items may be pulled or removed from the agenda at any time. The Hearing Officer, within his/her discretion, may allow for public comment on individual agenda items. Public Comment may be limited to three minutes per speaker.

Members of the public are encouraged to submit written comments for the record.

We are pleased to make reasonable accommodations for attendees with disabilities. Please notify Sheri LeTourneau, Assistant to the Commissioner, at (775) 687-0771, a day prior to the meeting.

NOTICES FOR THIS MEETING HAVE BEEN POSTED IN ACCORDANCE WITH NRS 241 AT THE FOLLOWING LOCATIONS:
Nevada Division of Insurance, 1818 E. College Parkway, Suite 103, Carson City, Nevada 89706
Nevada Division of Insurance, 2501 E. Sahara Avenue, Suite 302, Las Vegas, Nevada 89104
Nevada State Legislative Building, 401 S. Carson Street, Carson City, Nevada 89701
Grant Sawyer State Office Building, 555 E. Washington Avenue, Las Vegas, Nevada 89101
Blasdel State Office Building, 209 E. Musser Street, Carson City, Nevada 89701
Nevada State Capitol, 101 N. Carson Street, Carson City, Nevada 89701
Nevada Department of Employment, Training and Rehabilitation, 2800 E. Saint Louis Avenue, Las Vegas, Nevada 89104
The State of Nevada Website (www.nv.gov)
The Nevada State Legislature Website (www.leg.state.nv.us)
The Nevada Division of Insurance Website (www.doi.nv.gov)

STATE OF NEVADA
DEPARTMENT OF BUSINESS & INDUSTRY
DIVISION OF INSURANCE

Determination of Necessity of Small Business Impact Statement
LCB File No. R074-14

A Regulation concerning the formularies of certain health benefit plans.

To Be Effective Upon Filing with the Secretary of State

1. BACKGROUND

The Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Reconciliation Act of 2010, as amended, collectively known as the Affordable Care Act (ACA) mandates that all health insurance sold on or after January 1, 2014 not meeting the requirements of 42 U.S.C. § 18011 pertaining to "grandfathered" plans offer a package of essential health benefits ("EHB"). There are ten categories of EHB, one of which is coverage for prescription drugs.

Regulations promulgated by the Center for Consumer Information and Insurance Oversight ("CCIIO") within the federal Department of Health and Human Services detail consumers' ability to purchase health insurance during open enrollment and special enrollment periods.[1] The practical effect of these regulations limits consumers' ability to change health insurance plans outside of the open enrollment except in limited circumstances; consumers are effectively "locked in" to their selection for a calendar year.

Additional guidance from CCIIO limits insurers' ability to make health insurance plan design changes during the calendar year. However, CCIIO interprets laws relating to the prescription drug EHB to apply only to the quantity of drugs offered in a formulary and not the method of their offering. This interpretation by CCIIO leaves open the possibility that an insurer could remove prescription drugs from a formulary, or move prescription drugs among different cost-sharing tiers, while still maintaining compliance with the numerical minimums enforced by CCIIO.

The Division of Insurance has identified this as a potential loophole wherein consumers needing certain specific prescription drugs may purchase a health insurance plan with a favorable formulary design only to have the prescription drug moved or removed during the plan year. Such a scenario would leave the consumer with little or no recourse to pursue other health insurance options until the following open enrollment period. The proposed regulation seeks to address this issue by requiring prescription drug formularies to remain constant for the entire benefit year once approved except in certain scenarios where the public well-being may be at risk.

2. DOES THE PROPOSED REGULATION IMPOSE A DIRECT AND SIGNIFICANT ECONOMIC BURDEN UPON A SMALL BUSINESS OR DIRECTLY RESTRICT THE FORMATION, OPERATION OR EXPANSION OF A SMALL BUSINESS? (NRS 233B.0608.1)(circle one)

☑ NO YES

[1] 45 C.F.R. § 147.104, 45 C.F.R. § 155.410 and 45 C.F.R. § 155.420

3. HOW WAS THAT CONCLUSION REACHED? (NRS 233B.0608.3)
The Division of Insurance does not believe that the proposed regulation imposes a significant economic burden upon small businesses. There should be no additional cost of compliance as the regulation does not require health insurers to take any proactive or reactive steps. The Division acknowledges the possibility that a formulary design or pricing decision made by a health insurer could lead to that insurer's plan being selected against but it is not anticipated that any associated economic impact would be significant.

I, Scott J. Kipper, Commissioner of Insurance for the State of Nevada, certify that, to the best of my knowledge or belief, a concerted effort was made to determine the impact of the proposed regulation on small businesses and that the information contained in the statement above is accurate. (NRS 233B.0608.3)

July 03, 2014
(DATE)

SCOTT J. KIPPER
Commissioner of Insurance

Small Business Impact Statement
LCB File No. R074-14

4. DESCRIPTION OF SOLICITATION
Not Applicable

5. SUMMARY OF COMMENTS RECEIVED FROM SMALL BUSINESSES (NRS 233B.0609.1.a)
Not Applicable

Other interested parties may receive a copy of this summary by contacting the Insurance Regulation Liaison of the Nevada Division of Insurance, Adam Plain, at (775) 687-0783 or aplain@doi.nv.gov.

6. ESTIMATED ECONOMIC EFFECT ON SMALL BUSINESSES THE REGULATION IS TO REGULATE (NRS 233B.0609.1.c)
Not Applicable

7. METHODS CONSIDERED TO REDUCE IMPACT ON SMALL BUSINESSES (NRS 233B.0609.1.d)
Not Applicable

8. ESTIMATED COST OF ENFORCEMENT (NRS 233B.0609.1.e)
Not Applicable

9. FEE CHANGES (NRS 233B.0609.1.f)
Not Applicable

10. DUPLICATIVE PROVISIONS (NRS 233B.0609.1.g)
Not Applicable

11. HOW WAS THE ANALYSIS CONDUCTED? (NRS 233B.0609.1.b)
Not Applicable

12. REASONS FOR CONCLUSIONS (NRS 233B.0609.1.h)
Not Applicable

I, Scott J. Kipper, Commissioner of Insurance for the State of Nevada, certify that, to the best of my knowledge or belief, the information contained in the statement above was prepared properly and is accurate. (NRS 233B.0609.2)

July 03, 2014
(DATE)

SCOTT J. KIPPER
Commissioner of Insurance

REVISED PROPOSED REGULATION OF THE

COMMISSIONER OF INSURANCE

LCB File No. R074-14

August 3, 2015

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.