**Maral Farsi, MPH**
**Regional Director**
**State Government Affairs**
980 9th Street, Suite 2100
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916.203.9085 | maral.farsi@cvscaremark.com

July 22, 2014

Honorable Scott J. Kipper
Nevada Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

Dear Commissioner Kipper:

CVS Caremark, representing over 1,543 employees and 87 locations in Nevada, wishes to convey our opposition to the Proposed Regulation of the Commissioner of Insurance (LCB File No. R074-14) addressing prescription drug formularies. CVS Caremark is the largest pharmacy healthcare provider in the United States with integrated solutions across the entire spectrum of pharmacy care. We proudly operate as the largest chain pharmacy in Nevada, offering our patients and clients integrated pharmacy and health operations statewide including: Pharmacy Benefit Management (PBM) services, Specialty Pharmacy, Mail-Order and Retail Pharmacy, Retail Health Clinics and distribution centers. Together, our businesses provide unparalleled service and capabilities to our clients, customers and patients as we strive to help them on their path to better health.

LCB File No. R074-14 would require that health insurers that provide prescription drug benefits make no changes to drug formularies during the plan year and would prevent insurers from removing drugs from formularies during a plan year. Clinically-based formularies are designed to offer members safe and effective drug choices, while allowing plans to promote cost-effective options through the use of lower cost medications and negotiating lower drug prices from manufacturers. Formulary design is a critical PBM tool that must be preserved in order to ensure safe, effective and cost-effective choices for plans and their beneficiaries. Our formularies are developed by clinical experts based on scientific evidence and standards of practice, including peer reviewed medical literature, well-established clinical practice guidelines and pharmacoeconomic studies. Cost considerations are only incorporated after clinical considerations, such as safety, efficacy and therapeutic advantage as compared to alternative.

These proposed regulations provisions would obstruct many of the cost-savings strategies we provide to our health plan clients in Nevada and sets an administrative hurdle of ensuring all formularies are coordinated only at the renewal date of a coverage plan despite the introduction of new drugs to the market that lower the overall cost of drugs. These rules give no consideration to the availability of drugs which change considerably through a year.

CVS Caremark supports plan design flexibility including in the design of formularies. If these regulations are finalized in their current form, the

prescription drug cost savings options available for Nevada employers, trusts and the state would be severely restricted which could lead to additional increases in the cost of healthcare. Furthermore, the purpose of drug formularies is to appropriately manage patient healthcare delivery—meaning that both cost and quality are considered when formulary design decisions are made. The end result of this type of disclosure will only result in increases to premiums and out of pocket costs for patients.

We respectfully ask you reconsider proposed regulations LCB File No. R074-14 due to the cost impact of these rules on businesses and individuals in Nevada. Thank you for considering our comments in your decision. Please contact me if you have any questions about our position at maral.farsi@cvscaremark.com or 916.203.9085.

Respectfully,

Maral Farsi, MPH

EXPRESS SCRIPTS®

Cynthia M. Laubacher
Senior Director, State Affairs
(916) 771-3328

July 22, 2014

The Honorable Scott J. Kipper
Commissioner
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

Attn: Adam Plain, Insurance Regulation Liaison

Re: Comments: LCB File No. R074-14: Prescription Drug Formularies

Dear Mr. Plain:

I am writing to share our concerns with the draft regulation that would seriously hamper our ability to manage prescription drug formularies on behalf of our plan sponsors – employers, health plans, unions and government health programs. Express Scripts provides integrated pharmacy benefit management services including formulary management, pharmacy claims processing, home delivery, specialty benefit management, benefit-design consultation, drug-utilization review, medical and drug data analysis services, as well as extensive cost-management and patient-care services for over 85 million Americans.

A prescription drug formulary is developed and managed by an independent Pharmacy & Therapeutic Committee comprised of physicians, pharmacists and other clinical experts. They generally meet at least quarterly to consider updates and changes, including new FDA-approved medications. Their recommendations are based on scientific evidence and clinical standards of practice.

The regulation as currently drafted prohibits P&T committees from making changes to a formulary during the benefit year after it is approved by the Commissioner, except under specified circumstances. We believe there are two circumstances that need to be provided for before this regulation is finalized.

1. The regulation prohibits moving a more expensive brand name drug to a higher cost tier when it loses patent protection and a generic equivalent enters the market. This language prohibits plan sponsors from incentivizing their members to use lower cost generics, resulting in higher costs for payers and patients.

2. The regulation threatens patient safety by prohibiting removal of a drug from a formulary pursuant to an FDA warning until the plan has notified the Commissioner's office as to how they plan to "mitigate" the effect on patients. Patient safety will be compromised which is wholly unacceptable.

For these reasons, we oppose adoption of these regulations. We appreciate your consideration of our comments. Should you have any questions, please feel free to contact me at (916) 771-3328.

Sincerely,

CYNTHIA M. LAUBACHER

PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

July 22, 2014

The Honorable Scott J. Kipper
Commissioner
Department of Business and Industry
Nevada Division of Insurance
1818 E. College Parkway
Suite 103
Carson City, NV 89706

Re: LCB File No. R074-14 – Prescription Drug Formularies

Dear Commissioner Kipper:

The Pharmaceutical Care Management Association (PCMA) is submitting the following comments to express our serious concern with the proposed prescription drug formulary regulations. PCMA is the national trade association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 216 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D.

Prescription drug formularies are the foundation of tools utilized by plan sponsors, including the state of Nevada, to manage ever-increasing prescription drug costs. Formularies are designed to take into consideration medical, scientific and cost-effectiveness data in order to provide the best value to patients and employers. Today, nearly all plan designs share some portion of drug costs with members using copayment or coinsurance. The proposed regulation as drafted all but eliminates the usefulness of formularies for plan sponsors and their members.

This proposed regulation interferes with an employer's or plan sponsor's ability to create a prescription drug benefit plan that meets the needs of their employees and members by imposing onerous restrictions on changes in prescription drug formularies during the current plan year. PBMs rely on Pharmacy and Therapeutics (P&T) Committees staffed by independent doctors, nurses, pharmacists, and academics who specialize in specific fields of medicine to develop evidence-based guidelines that are used in drug management programs. These guidelines are based on the latest clinical literature, standards of practice, expert consultation, and outcomes data. The P&T Committee takes on the complex task of evaluating thousands of competing drugs in terms of safety, cost, and clinical efficacy in order to provide recommendations to health plans and employers regarding formulary placement and coverage. We believe this proposed regulation will likely have a direct impact on the cost of health care coverage for all Nevada residents.

We appreciate your consideration of our comments. If you should have any questions, please do not hesitate to contact me.

Sincerely,

Barbara A. Levy
Vice President and General Counsel

Biotechnology Industry Organization

July 28, 2014

***BY ELECTRONIC DELIVERY***

Scott Kipper, Commissioner
Nevada Division of Insurance
1818 East College Parkway, Suite 103
Carson City, Nevada 89706

**Re: LCB File Number R074-14, Prescription Drug Formularies**

Dear Commissioner Kipper:

The Biotechnology Industry Organization (BIO) is pleased to submit comments on the proposed regulation issued by the Division of Insurance (DOI) on June 20, 2014, entitled "LCB File Number R074-14, Prescription Drug Formularies" (the "Proposed Rule").[1] BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics have greatly improved health outcomes for patients worldwide.

BIO commends the DOI's efforts in the Proposed Rule to prohibit issuers and carriers from removing drugs from plans' prescription drug formularies more frequently than annually, except in cases where the U.S. Food and Drug Administration (FDA) has issued guidance on the safety of a particular prescription drug or rescinded a drug's approval. We similarly support the proposed prohibition on moving drugs between tiers on a plan's formulary during a given plan year. Because many consumers enroll in healthcare coverage in whole or in part due to the perceived benefits of a particular prescription drug formulary, when a formulary is altered during a plan year, including with respect to the applicable cost-sharing, consumers are often left with no option to change coverage. BIO feels that the changes offered in the Proposed Rule provide important consumer protections to address this issue, and are necessary to alleviate consumer concerns of being locked into coverage that may have less utility than was anticipated when it was purchased. Nonetheless, BIO does have two suggestions for potential inclusion in the final regulation, discussed in detail below.

## I. BIO Encourages the DOI to Include Express Language Permitting Plans to Change Formularies Mid-Benefit Year to Add Newly Approved Drugs

As a representative of an industry that is devoted to improving health care through the discovery of new therapies, BIO believes that all consumers should have access to the newest, most innovative drugs as they receive approval from the FDA. As the DOI is no doubt aware, the FDA approves new therapies throughout the year, without regard to plan years. While there is no explicit prohibition against the addition of drugs to a formulary during a plan-year in the Proposed Rule, we strongly encourage the DOI to add language expressly permitting plans to change plan formularies mid-benefit year by adding newly approved drugs. The proposed regulation as it is written does not address issuers' and carriers' abilities to add newly approved drugs to their formularies mid-year, and we worry

[1] Nevada Commissioner of Insurance, LCB File Number R074-14, Prescription Drug Formularies (2014).

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that this omission may lead issuers and carriers to forego such formulary updates, which may in turn delay access to new therapies for many consumers in Nevada. BIO believes that all stakeholders—issuers, carriers, and most notably, consumers—could benefit from better clarity around the ability of plans to change their formularies throughout the year to add newly approved drugs, and urge DOI to include a written policy to this effect in its final regulation.

## II. BIO Encourages the DOI to Address Coverage Policies for Medical Benefit Drugs in its Final Rule

Although BIO supports the DOI's efforts in proposing consumer protections around mid-year changes to plans' prescription drug formularies, we are disappointed that the Proposed Rule does not address mid-year changes to plans' coverage policies for medical benefit drugs (i.e., therapies administered in a physician's office). We believe that consumers deserve the same protections—namely the knowledge that applicable coverage and cost-sharing policies will not undergo any significant changes during a plan-year—regardless of whether the therapies they take are covered under a plan's pharmacy or medical benefit. We feel that it is imperative for the DOI to prohibit issuers and carriers from making negative changes to **both** plans' prescription drug formularies and medical benefit drug coverage policies or cost-sharing requirements more frequently than once per year. We urge the DOI to include this language in either the Proposed Rule or in a future proposed regulation addressing this prohibition solely for medical benefit drugs.

## III. Conclusion

BIO appreciates the opportunity to comment on the proposed regulation, "LCB File Number R074-14, Prescription Drug Formularies." We look forward to continuing to work with the Nevada Division of Insurance and interested partners to ensure that all consumers have access to affordable health insurance that meets their needs year-long. Please feel free to contact me at (202) 962-9220 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/

Laurel L. Todd
Managing Director
Reimbursement and Health Policy

July 30, 2014

Nevada Division of Insurance
ATTN: Adam Plain
1818 E. College Pkwy., Suite 103
Carson City, NV 89706

RE: LCB File No. R074-14

The Nevada State Medical Association (NSMA) submits these comments regarding the proposed regulation titled LCB File No. R074-14, relating to drug formularies.

Section 2. (a) allows a drug to be removed from the formulary at any time if "The drug is not approved by the United States Food and Drug Administration." This language could adversely affect the quality of care in a number of age and condition specific instances. Pharmaceutical companies have little incentive to obtain FDA approval for each population that could benefit from a drug because doing so is cost and time prohibitive. These companies also know that a physician's desire to treat patients safely and effectively will result, at times, in the physician prescribing a medication for off label use. Licensed physicians may safely engage in this prescribing behavior, in consultation with the patient, due to their extensive medical training; unfortunately, this section of the regulation could potentially have the unintended consequence of severely limiting or altogether eliminating the ability to use medications in off label applications without placing a significant burden on the patient.

Off label use occurs in many specialties, but pediatric physicians must use their ability to prescribe for off label uses when treating the majority of their patients. Few of the drugs commonly prescribed to pediatric patients have FDA approval for that age range. This reality forces the pediatrician to prescribe medications that are not specifically approved for the patient, but which can be safely administered. This portion of the regulation could drastically limit pediatric patients access to medication.

It is also the case that some drugs are specifically designed, and thusly FDA designated, to treat gender-specific conditions. These gender-specific drugs have the potential to treat a member of the opposite gender's maladies more effectively than alternative courses of treatment. The drug Tamsulosin is a drug designed to treat men with prostate obstruction, but the drug can be

equally effective in treating a woman's small urethral stones. The method by which this drug works is known to be safe in both genders, but the drug is not FDA approved for use by women. Surgery might be the only viable alternative in such a case if drug treatment was unavailable.

The examples above are a small selection of the potential unintentional outcomes of the language in this proposed regulation based on present construction of the language.

It is clear that this language was written with the intention to protect patients but, as pharmaceutical companies do not generally use their resources to receive FDA approval for all classes of patients that may be in need of a drug, the proposed regulation may actually limit access to necessary medications. The NSMA believes that, as long as both physician and pharmacist inform the patient of potential known adverse side effects, a drug which is not specifically approved by the FDA for certain off label uses can be safely administered.

Our concerns may be remedied by changing the language in Section 2, Paragraph 2(a) to read "The drug has not been approved by the United States Food and Drug Administration for use in humans," or similar language which would clearly delineate that this statement is not intended to address off or on label use. The object would be so that carriers, providers and consumers would be able to clearly ascertain that the regulation is addressing "unapproved" drugs versus the specific use or treatment for which an approved drug is being administered.

The NSMA believes the standards ultimately adopted by the Division of Insurance as they relate to drug formularies and off label use, will play an important role in ensuring the provision of health care services within Nevada, and we appreciate the opportunity to participate in this process.

Sincerely,

Mitchell D. Forman, DO
President

Stacy M. Woodbury, MPA
Executive Director

Hometown Health's Concerns regarding the proposed regulation RO74-14:

1) Drug Patent expirations occurring throughout a plan year allows generic drug availability at a much lower cost. The inability to change cost-share for the brand drug during the plan year will hamper plan's ability move the branded drug to a higher tier/cost share in order move utilization the generic replacement, resulting in cost savings for both the member and the plan.

2) PBM contract/rebate terms with drug manufacturers change throughout the Plan year, allowing lower net pricing on contracted medications. Typically, these contracts are good for 2-3 years, so it's not unusual to make formulary changes for drugs that are therapeutically equivalent, and to preference those drugs at the lowest net cost; these contract changes occur throughout the plan year.

3) Drug manufacturer dynamics and antics, such as sudden/substantial price increases, elimination of rebates if Health Plans impose any Step edits on medications, coupon blitz, etc.

4) Shift from Rx drug status to OTC; typically OTCs are not a covered benefit – would this new reg require approval before the drug is removed from the formulary?

5) Clinical efficacy studies on many drugs are on-going, and as new evidence is published it becomes apparent that one drug in a therapeutic class may emerge as clinically superior to another.

6) Drug abuse patterns shift over time, and health plans institute formulary changes and utilization management tools (Prior Authorization) to help combat drug diversion and abuse.

7) Membership needs require formulary adjustments periodically as well.

8) Pharmacy Benefit Managers (PBMs) typically charge $75,000 to $100,000 to manage a formulary; if plans were forced to use separate formularies to accommodate this regulatory requirement, it will drive up administrative costs; and, ultimately premiums.

9) Benefit years vary between employer groups, which could confuse the provider community, because drug coverage changes would occur at different times of year, depending on the employer group.

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August 12, 2014

The Honorable Scott J. Kipper
Commissioner
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

Re: LCB File No. R074-14, version distributed August 5, 2014

Dear Commissioner Kipper,

Express Scripts appreciates the opportunity to comment on the recently amended proposed rule that seeks to address mid-year formulary changes by health plans. We maintain serious concerns with this regulation and strongly encourage the Division of Insurance to suspend work on this regulation and reconsider some policies contained therein that will harm patients across Nevada.

Express Scripts is the nation's largest pharmacy benefit manager, providing comprehensive benefits management for more than 85 million Americans. We work with plan sponsors, including carriers, employers, collective bargaining groups, and all levels of government, to build benefits that meet the needs of these payers and their beneficiaries.

We have both general and specific concerns about the proposed regulation, which we explain in detail below. Plans sponsors and patients would be harmed if this regulation is finalized by impeding access to medicines and increasing prescription drug costs. This regulation requires serious reconsideration.

***Drug Makers Are "Let Off the Hook" by the Rule***

Among the top priorities for plans sponsors and their patients are clinically sound prescription drug benefits that are cost effective. Should the proposed regulation be finalized in its current form, drug makers will know that they have a full year of guaranteed coverage for their products. Competition will be pushed aside and drug makers could raise the prices of their products at will. Today, drug makers know that plan sponsors would respond to rapid price increases by changing levels of coverage for most drugs and this keeps drug inflation largely stable. By creating plan-by-plan monopolies, plans will have far less leverage to negotiate with drug makers. Patients will pay more for their medications.

***It is Not Clear that the Regulation Allows Plans to Add New Drugs to Their Formulary***
The language used in the proposed rule doesn't clearly indicate whether a plan sponsor can add a new drug to their formulary if the drug comes to market after the formulary is finalized. The rule seems to treat these new products as a "move" among tiers. Plans and patients need clarity so medicines aren't withheld from patients while waiting for a new plan year to start. Patients need access to new medicines and this revised regulation could frustrate efforts to get medicines to patients who need them.

***Under the rule, plan sponsors cannot manage coverage for off-label uses of products (Section 1. 2. (a))***
Recent amendments to the regulation suggest that plans can remove products from a formulary that aren't approved for use in humans, but it doesn't address when a drug is approved for human use to treat one condition, but is used for other unapproved conditions. Some examples of these products are human growth hormone or cancer medications. Plans should have the ability to ensure the appropriate use for patients, while not being forced to cover medicines for recreational use or when not clinically appropriate. Without amendment, all patients will pay more to afford the use of off-label prescription drugs.

***The Regulation Doesn't Address How Plans Respond to Medication Shortages***
In the dynamic prescription drug supply chain, there are occasionally shortages of prescription drugs. These occur for myriad reasons, including manufacturers closing plants, and result in plans needing to make available different medications for their beneficiaries. Any final regulation needs to include an exception for managing medication shortages. Shortages are already frustrating for patients. Leaving inflexible benefits in place would only further harm patients.

***Brand Drug Makers Enjoy Extra Time as Favored Products (Section 1. 4.)***
The revised regulation attempts to address how plan sponsors can add new generic drugs to their formulary when they come to market. However, the plan sponsor is still not empowered to change the level of coverage for the brand product to promote the use of the generic. Generic drugs are the most obvious and effective way to control prescription drug spending. Plan sponsors need to have the flexibility to promote generics while simultaneously disadvantaging the brand product, all the while leaving comprehensive coverage in place for their beneficiaries. Patients win when generic drugs are promoted.

Moreover, the revised regulation includes "bioequivalent" when it refers to generic drugs, which will exclude a large market of generic drugs. Many older generic drugs do not have bioequivalence data available. And many new medications with controlled release (e.g. SR, XL, CR) formulations are not bioequivalent to each other because manufacturers use different technology to create the longer-lasting versions. This definitional language would cause patients to pay even more for these new generic drugs.

Express Scripts wants to continue to assist the Division of Insurance with these issues. To that end, please don't hesitate to reach out should you like any additional information on this matter.

All the Best,

Jonah C. Houts
Vice President, Government Affairs
Express Scripts
300 New Jersey Ave, NW Suite 600
Washington, DC 20001
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STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

**In Support of Nevada Division of Insurance Proposed Regulation of the Commissioner LCB File No.R074-14**

**August 12, 2014**

**Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) supports efforts to ensure continuiety of medical care and access to innovative biopharmaceutical products for all Nevadans. The amendments to Nevada Division of Insurance Proposed Regulation of the Commissioner LCB File No.R074-14 (R074-14), are an important step in helping to achieve that goal.**

PhRMA is a voluntary, non-profit organization representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA members are committed to finding tomorrow's cures and treatments for some of the most serious diseases. New medicines are an integral part of the healthcare system, providing doctors and their patients with safe and effective treatment options, extending and improving quality of life. PhRMA companies spent an estimated $51 billion in 2013 to discover and develop new medicines.

PhRMA applauds the Commissioner of Insurance's recognition of the importance of continuity of care and the negative effect that mid-year formulary changes can have on patients who rely on prescription drugs to manage health conditions, or who may be undergoing a more serious course of drug treatment. The proposed regulation would prohibit certain health insurers from removing a prescription drug from the formulary or moving a prescription drug to a tier with a larger deductible, copayment, or coinsurance after the formulary is approved by the Commissioner except under specified circumstances. We believe this is an important step to help protect access for patients.

PhRMA supports this approach, as it is critical for Nevada residents who are currently undergoing a course of therapy with one or more prescription drugs to continue to be able to access those drugs. Without this regulation, plans would be allowed to move drugs to higher cost-sharing tiers at any point during a year, or worse, remove drugs from their formularies entirely. Mid-year formulary changes impose a tremendous burden on enrollees, as well as on physicians and pharmacists.

Without the proposed protections, enrollees who select a particular plan based on their individual drug needs will have no assurances that the plan will maintain coverage for those particular drugs they need during the course of the enrollment year. For an enrollee who chooses a plan based on the favorable formulary status of a necessary therapy, such a change could create serious medical issues for the enrollee. In addition, these unexpected changes can be extremely financially burdensome.

Enrollees are likely to pick a particular plan due to coverage of specific drugs. This is particularly true for individuals with chronic conditions who typically are able to anticipate at least some of their prescription needs during the course of a plan year. Where a plan is permitted to remove a drug from the formulary or move a drug to a more expensive cost-sharing tier during the course of a plan year, the enrollee is required to pay for a necessary therapy out-of-pocket, while simultaneously paying premiums to a plan that fails to offer the very benefits that induced the patient to enroll in the first place. In essence, the individual is forced to commit to a plan, while, absent this regulation, the plan is not required to make the same commitment to the enrollee.

Any changes in plan requirements, especially ones so central to enrollee access, should mirror the annual enrollment cycle in order to ensure that enrollees have reasonable access to the therapies and the co-pays that induced them to enroll in the first place. In addition to preventing plans from imposing burdensome cost-sharing on enrollees, this regulation will support physicians and pharmacies, as mid-year formulary changes can be difficult for physicians and pharmacists to implement.

For all of these reasons, PhRMA believes that the proposed regulation R074-14 is an important step towards ensuring Nevada enrollees have access to affordable, medically necessary drugs through their insurers.

**America's Health Insurance Plans**

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Washington, DC 20004

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www.ahip.org


August 19, 2014

Adam Plain
Insurance Regulation Liaison
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

**Re: LCB File No. R074-14: Prescription Drug Formularies Proposed Rule**

Dear Mr. Plain,

I write today on behalf of America's Health Insurance Plans (AHIP) to provide comments on the Nevada Division of Insurance's proposed rules on prescription drug formularies.

AHIP is the national trade association representing the health insurance industry. AHIP's members provide health and supplemental benefits to more than 200 million Americans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid. Our members offer a broad range of health insurance products in the commercial marketplace and also have demonstrated a strong commitment to participation in public programs. Health plans have been committed to providing consumers with affordable products that offer robust networks of quality, cost-efficient providers. We appreciate the opportunity to provide comments on this proposed rule.

Prohibiting health plans from making changes to their formularies except annually would prohibit consumers from receiving life enhancing medications that become available and would severely restrict health plans' abilities to manage their prescription drug formularies in a cost effective and consumer focused way. Formularies, which are developed based on scientific evidence and clinical standards, are often changed within a year due to a number of circumstances that this proposed regulation does not take into consideration. One such circumstance occurs when generic equivalents are introduced into the market. When such generics enter the market, plans should be allowed to move the more expensive brand name drug to a higher cost tier and make the more cost effective generic available to members.

Plans should also be allowed to protect their members by removing a drug from a formulary as soon as an FDA warning on that drug is issued. Patient safety will be threatened in the time it would take for the plan to develop and submit a mitigation plan to the Division, as the regulation requires.

Additionally, it is important to understand that there are not custom formularies for each product. A set of formularies are developed and packaged with a drug benefit. Because product benefit years do not all run on the same benefit year timetable, this one year restriction period will become effective and expire at different times of the calendar year for each separate product. This creates an unmanageable and very confusing system for consumers.

Finally, we believe that the provisions proposed in this regulation do nothing to address the underlying issue of the exorbitant pharmaceutical costs facing our entire health care system. While many breakthrough drugs are coming into the market, giving the hope of living longer and healthier lives, these drugs come at a cost that threatens the sustainability of the overall health care system. The question of whether the prices being charged for some new drugs are rational and allow people access to the innovative medications is where the real focus should be.

For all of these reasons, we oppose the adoption of these regulations. We look forward to continued discussions with you on this important issue. If you have any questions, please do not hesitate to contact me at gcampbell@ahip.org (971-599-5379).

Sincerely,

Grace Campbell
Regional Director

**ARTHRITIS FOUNDATION, PACIFIC REGION**
c/o 3460 E. Sunset Road, Suite K105
Las Vegas, NV 89120
tel: (702) 367-1626
fax: (702) 367-6381
website: www.arthritis.org/nevada

September 11, 2014

The Honorable Scott J. Kipper
Commissioner
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

**RE: SUPPORT Proposed Regulation R074-14**

Dear Insurance Commissioner Kipper,

The Arthritis Foundation, Pacific Region, which represents more than 464,000 adults and 2,300 children with doctor-diagnosed arthritis in Nevada, supports the proposed regulation R074-14 and thanks you for your leadership on this issue.

Arthritis is an umbrella term for more than 100 conditions, such as rheumatoid arthritis (RA), juvenile arthritis, lupus, osteoarthritis (OA), ankylosing spondylitis (AS), and fibromyalgia. A common misconception about arthritis is that it affects a more senior population; however, two-thirds of people with arthritis are under the age of 65. In addition, arthritis is the leading cause of long-term disability in the United States and costs our economy $128 billion.

Continuity of care for patients with arthritis is vital to the management of their condition. Until there is a cure for arthritis, many patients rely on prescription drugs to manage their symptoms, prevent disease regression and achieve a medicated remission. However, mid-year drug formulary changes have the potential to cause a drastic and negative effect on a patient's health and well-being.

The proposed regulations would prohibit health insurers from removing a prescription drug from their formulary or moving a prescription drug to a tier with a larger deductible, copayment, or coinsurance after the formulary is approved by the Commissioner, except under specific circumstances. Without this regulation, plans would be allowed to move drugs to higher cost-sharing tiers at any point during the year, or worse, remove drugs from their formulary altogether.

Mid-year formulary changes impose severe burdens on patients, as well as our patients' providers and pharmacists. Any changes in plan requirements, especially ones so central to enrollees' access, should mirror the annual enrollment cycle in order to ensure the enrollees have reasonable access to the therapies and the co-pays that induced them to enroll in the first place.

For these reasons, we SUPPORT the proposed regulation R074-14 and view this as an important step forward in protecting Nevada's patients' access to affordable medications.

Sincerely,

Krystin Herr
Director of Advocacy
Arthritis Foundation, Pacific Region
kherr@arthritis.org · cell (916) 502-2979

September 12, 2014

Nevada Division of Insurance
ATTN: Adam Plain
1818 E. College Pkwy., Suite 103
Carson City, NV 89706

***Via email***
***aplain@doi.nv.gov***

RE: LCB File No. R074-14

Dear Adam,

After participating in the August hearing and discussion this week regarding R074-14, the Nevada State Medical Association (NSMA) submits these additional comments regarding the proposed regulation relating to drug formularies.

Section 2 Paragraph 2(a) and Section 3 Paragraph 2(a) both allow a drug to be removed from the formulary at any time if "The drug is not approved by the United States Food and Drug Administration." This language could adversely affect the quality of care in a number of age and condition specific instances. Pharmaceutical companies have little incentive to obtain FDA approval for each population that could benefit from a drug because doing so is cost and time prohibitive. These companies also know that a physician's desire to treat patients safely and effectively will result, at times, in the physician prescribing a medication for off label use. Licensed physicians may safely engage in this prescribing behavior, in consultation with the patient, due to their extensive medical training; unfortunately, these two sections of the regulation could potentially have the unintended consequence of severely limiting or altogether eliminating the ability to use medications in off label applications without placing a significant burden on the patient.

Off label use occurs in many specialties, but pediatric physicians must use their ability to prescribe for off label uses when treating the majority of their patients. Few of the drugs commonly prescribed to pediatric patients have FDA approval for that age range. This reality forces the pediatrician to prescribe medications that are not specifically approved for the patient, but which can be safely administered. This portion of the regulation could drastically limit pediatric patient access to medication.

It is also the case that some drugs are specifically designed, and thusly FDA designated, to treat gender-specific conditions. These gender-specific drugs have the potential to treat a member of the opposite gender's maladies more effectively than alternative courses of treatment. The drug Tamsulosin is a drug designed to treat men with prostate obstruction, but the drug can be equally effective in treating a woman's small urethral stones. The method by which this drug works is known to be safe in both genders, but the drug is not FDA approved for use by women. Surgery might be the only viable alternative in such a case if drug treatment was unavailable. The examples above are a small selection of the potential unintentional outcomes of the language in this proposed regulation based on present construction of the language.

It is clear that this language was written with the intention to protect patients but, as pharmaceutical companies do not generally use their resources to receive FDA approval for all classes of patients that may be in need of a drug, the proposed regulation may actually limit access to necessary medications. The NSMA believes that, as long as both physician and pharmacist inform the patient of potential known adverse side effects, a drug which is not specifically approved by the FDA for certain off label uses can be safely administered.

Initially we had suggested to remedy our concerns by amending the language in Section 2 Paragraph 2(a) and Section 3 Paragraph 2(a) to read "The drug has not been approved by the United States Food and Drug Administration for use in humans." This language caused substantial discussion at the August hearing. Therefore, the NSMA respectfully withdraws this proposed amendment and instead requests the Commissioner consider adding a new Paragragh 4 to both Section 2 and Section 3 which would read:

> *"4. This section 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."*

The object would be so that carriers, providers and consumers would be able to clearly ascertain that the regulation is addressing drugs which have ***not been approved*** by the FDA at all versus the specific use or treatment for which an "approved" drug is being administered.

The NSMA believes the standards ultimately adopted by the Division of Insurance as they relate to drug formularies and off label use, will play an important role in ensuring the provision of health care services within Nevada, and we appreciate the opportunity to participate in this process.

Sincerely,

Mitchell D. Forman, DO
President

Stacy M. Woodbury, MPA
Executive Director

EPILEPSY FOUNDATION® epilepsy therapy project

Stronger Together

8301 Professional Place East, Suite 200, Landover, MD 20785-2353

September 15th, 2014

Commissioner Scott Kipper
Nevada Division of Insurance
1818 E. College Pkwy., Suite 103
Carson City, NV 89706

Dear Commissioner Kipper:

On behalf of the Epilepsy Foundation and our Nevada chapter, the Epilepsy Foundation of Nevada, we support the formulary draft proposed rules, which aim to ensure that people living with chronic conditions, including epilepsy, maintain uninterrupted access to lifesaving medications, but we caution against any amendments to weaken this protection by allowing for generic substitution and undermining the intent of the rule.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of more than 2.8 million Americans living with epilepsy and seizures. The Epilepsy Foundation of Nevada represents the more than 25,000 state residents living with epilepsy. Together we work to foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime. For the majority of people living with epilepsy, anti-epilepsy drugs (AEDs) are the most common and most cost effective treatment for controlling and/or reducing seizures. But there is no "one size fits all" treatment option for epilepsy, and the response to brand name AEDs and their generic versions can be different for each person.

We support the draft proposed rules that would prevent health plans from removing drugs from a formulary, or moving them to a more expensive tier, during the plan benefit year. We are concerned that a proposed amendment to the rule would allow generic substitution, undermining the intent of the proposed rule to protect patients against formulary changes during the plan year that can negatively impact their health. Generic drugs can lead to savings for plans and patients, but not when it leads to breakthrough seizures and significant side effects. People living with chronic conditions depend on consistent and affordable access to the same medication each month to avoid medical complications, like breakthrough seizures, and maintain their quality of life.

Maintaining seizure control with minimal side effects requires careful evaluation and monitoring by the physician and patient. To change, limit, or deny access to medications could be extremely dangerous. People living with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures and related complications, serious injury, and even death. It also significantly increases medical costs related to preventable seizures, along with lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities.

While many patients can safely switch between different formulations of the same epilepsy medication, consent must be obtained from the individual with epilepsy and their physician before any such substitutions are made to avoid potentially life-threatening breakthrough seizures.

The amount of medication delivered by one AED may differ from the amount delivered by another AED that the Food and Drug Administration (FDA) deems "equivalent," and the medication may be delivered at a different rate. There is growing evidence that these variations, however slight, can mean the difference between seizure control and breakthrough seizures and other negative consequences. If a patient is switched to a generic version of a drug to contain costs, and loses seizure control, this quickly eliminates any short-term savings from the switch. Meanwhile, the concurrent human costs borne by patients and their families can be immeasurable.

Because of the critical role anti-epilepsy drugs play in achieving and maintaining seizure control, people with epilepsy often select a health plan primarily because their lifesaving medications are covered by the plan. Removing or reclassifying a drug can lead to interruptions, delays, and medication substitution, with dangerous consequences. For these reasons, the Epilepsy Foundation opposes formulary changes that limit or restrict access to appropriate medications and physician-directed care.

The Epilepsy Foundation and the Epilepsy Foundation of Nevada urge the Commissioner to protect Nevada residents by enacting rules that limit a health plan's ability to remove, or reclassify to a higher tier, a drug after a formulary is approved by the Commissioner for a plan benefit year. Please do not hesitate to contact Angela Ostrom, COO & Vice President Public Policy at 301-918-3766 or aostrom@efa.org, with any questions or concerns.

Sincerely,

Danielle Marano
Executive Director
Epilepsy Foundation of Nevada

Philip M. Gattone, M.Ed.
President & CEO
Epilepsy Foundation

Nathaniel Counts, J.D.
Mental Health America
2000 N Beauregard St.
Alexandria, VA 22311

September 16, 2014

The Honorable Scott J Kipper
Commissioner
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

Dear Insurance Commissioner Kipper:

Mental Health America would like to extend its support for Proposed Regulation R074-14, and commend the efforts of the Division of Insurance to ensure that individuals have access to the care they need. The proposed regulation benefits all individuals with health needs that require access to specific medications, but it has special importance for individuals with mental health needs.

When insurers remove medications from their formularies mid-year it is dangerous, expensive, and unfair.

Removing medications that address mental health needs, such as anti-depressants and anti-psychotics, from formularies mid-year is dangerous. These medications are not interchangeable – each medication is unique,[1] and each individual is unique,[2] and this results in profound variations in medication effectiveness and side-effects.[3] Because of the variation in the individual experience of each medication, loss of access to a medication can be devastating. Sudden discontinuation of a medication can cause severe physical and mental health problems for the individual.[4] As the individual searches for a new medication that is effective, they may experience long gaps in effective care with a variety of painful physical and cognitive side-effects along the way, and there may not even be any other medication on the formulary that is effective. In fact, studies have shown

[1] For example, risperidone is 4-[2-[4-(6-fluorobenzo[d]isoxazol-3-yl)-1-piperidyl]ethyl]-3-methyl-2,6-diazabicyclo[4.4.0]deca-1,3-dien-5-one, while clozapine is 8-Chloro-11-(4-methylpiperazin-1-yl)-5H-dibenzo[b,e][1,4]diazepine.

[2] *See* Julia Kirchheiner *et al.*, *Pharmacogenetics of antidepressants and antipsychotics: the contribution of allelic variations to the phenotype of drug response*, 9 MOLECULAR PSYCHIATRY 442 (2004) ("At present, antidepressant and antipsychotic drug responses can best be explained as the combinatorial outcome of complex systems that interact at multiple levels.").

[3] *See, e.g.*, Jeffrey A. Lieberman *et al.*, *Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia*, 353 N.E.J.M. 1209 (2005).

[4] *See, e.g.*, Steven C. Dilsaver, *Withdrawal Phenomena Associated with Antidepressant and Antipsychotic Agents*, 10 DRUG SAFETY 103 (1994); J. Moncrieff, *Does antipsychotic withdrawal provoke psychosis? Review of the literature on rapid onset psychosis (supersensitivity psychosis) and withdrawal-related relapse*, 114 ACTA PSYCHIATRICA SCANDINAVICA 3 (2006).

that, when access to medications is restricted, individuals often simply stop taking medication entirely rather than taking one of the preferred medications, and they will go untreated.[5] Ultimately, removal of a medication from a formulary mid-year is dangerous for the individual.

Removal of medications that address mental health needs from formularies mid-year is expensive. Insurance companies remove expensive medications from the formularies with the mistaken belief that it will save money. As explored above, medication removal prevents some individuals from receiving the care they need. When individuals experience interruptions in treatment, it often necessitates acute care, such as emergency department visitation or extended hospitalization, which is dramatically more expensive than the medication.[6] Increased costs also include lost productivity and even incarceration, which fall directly upon taxpayers. Prohibiting insurance companies from removing medications from their formularies will prevent unnecessary expenditures for all.

When insurance companies remove medications from their formularies mid-year, it is unfair. Many individuals choose their insurance plan based on whether the medication they are taking is on the formulary. When their medication is removed, the consumer's choice of insurance is defeated, and they must continue to pay for coverage they cannot change. This practice then contravenes the spirit of the private health insurance market and insurance companies should not be permitted to remove medications from their formulary mid-year.

Mental Health America applauds the Division of Insurance for its proposed regulation that stops a practice that is dangerous, expensive, and unfair. We would only caveat this to say that Mental Health America would not be opposed to a revision allowing insurance companies to move medications to a lower deductible tier. Thank you for standing up for the consumers of Nevada. Please do not hesitate to contact Mental Health America with further questions.

Sincerely,

Nathaniel Counts, J.D.
Policy Associate

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[5] *See* Stephen B. Soumerai *et al.*, *Use Of Atypical Antipsychotic Drugs For Schizophrenia In Maine Medicaid Following A Policy Change*, 27 HEALTH AFF. (MILLWOOD) w185 (2008); William Vogt *et al.*, *Medicaid cost control measures aimed at second-generation antipsychotics led to less use of all antipsychotics*, 30 HEALTH AFF (MILLWOOD) 2346 (2011); Chrsitine Lu *et al.*, *Unintended Impacts of a Medicaid Prior Authorization Policy on Access to Medications for Bipolar Illness*, 48 MEDICAL CARE 4 (2010).

[6] *See* Safiya Abouzaid *et al.*, *Economic Impact of Prior Authorization Policies for Atypical Antipsychotics in the Treatment of Schizophrenia*, 14 POPULATION HEALTH MANAGEMENT 247 (2010) ("Sensitivity analyses show that small increases in hospitalizations will make PA the more costly option."). *See also* Joel F. Farley *et al.*, *Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications*, 30 CLINICAL THERAPEUTICS 1524 (2008) (finding dramatic cost off-sets in Georgia for outpatients visits after prior authorization policy).

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Planned Parenthood®
Act. No matter what.

Nevada Advocates for Planned Parenthood Affiliates, Inc.

September 19. 2014

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

**RE: Comments Regarding Proposed Regulation LCB File No. R074-14**

Dear Commissioner Kipper:

Nevada Advocates for Planned Parenthood Affiliates (NAPPA) greatly appreciates the opportunity to submit comments regarding the Nevada Division of Insurance's ("Division") August 12, 2014 proposed regulation R074-14, with proposed amendments ("Proposed Regulation"). These regulations deal with prescription drug coverage and prohibited changes to drug formularies after approval by the Commissioner of Insurance. As a trusted women's health care provider and advocate, NAPPA supports the Division's commitment to ensuring that Nevadans have access to quality, affordable health care and continuous, timely access to the medications they need to stay healthy.

NAPPA is the independent, non-partisan, nonprofit education, legislative and political advocacy arm of Planned Parenthood's two affiliates (Planned Parenthood Mar Monte and Planned Parenthood Rocky Mountains). Planned Parenthood's three Nevada health centers handle over 48,000 patient visits each year. We offer a sliding fee scale as many of our patients have nowhere else to go for basic health care. We are proud of our long record of quality care – over 35 years in Nevada – always affordable, confidential, culturally appropriate, and welcoming to our clients. We offer this feedback on behalf of our health center operations as well as on behalf of our clients.

We support the Division's commitment to ensuring continuity of care and recognition that mid-year formulary changes may have adverse and often detrimental effects on Nevada consumers. The proposed regulation would prohibit health insurers from removing a prescription drug from the plan formulary or moving a prescription drug to a tier with a larger deductible, copayment, or coinsurance after the formulary is approved for use by the Commissioner, with limited exceptions.

We thank the Division for taking this important step to help protect consumers from unpredictable changes in coverage or out-of-pocket costs and ensure that Nevada consumers have continuous access to the preventive and therapeutic drugs they need. Without this regulation, plans would be allowed to move drugs to higher cost-sharing tiers at any point during a coverage year, or worse, remove drugs

entirely from the plan's formulary mid-year. Many consumers make specific decisions about health insurance coverage based, at least in part, on the formulary composition and coverage of the prescription drugs they currently use. This proposed regulation is essential to protect consumers from mid-year coverage and cost sharing changes that may have a detrimental impact on their lives. At the very least, this proposed regulation is critical to alleviate the tremendous burden that mid-year formulary changes impose on enrollees, health care providers, and pharmacists, and will help enable providers and pharmacist to successfully treat and care for Nevada consumers without mid-year disruptions.

Consistent prescription drug coverage is particularly important when it comes to contraception. Contraception is most effective when a woman has access to the birth control method that meets her needs, which depends on consideration of side effects, differences in permanence and reversibility of contraceptives, and a woman's personal preferences.[1] Not all contraceptives are clinically appropriate for all women; therefore, access to *all* contraceptive methods is critical to ensure that a woman can find the birth control method that meets her needs and reproductive goals – ultimately improving the health and lives of women and their families. The Affordable Care Act made important strides towards this goal by requiring new and non-grandfathered health insurance plans to cover all Food and Drug Administration (FDA) approved contraceptive methods with no cost sharing to the consumer. This proposed regulation ensures that women have consistent access to the contraceptive methods that best meet their needs.

**While we support the Division's proposed regulation, we urge the Division to clarify that health plans must still comply with section 2713 of the Public Health Service Act (PHS), as added by section 1001 of the ACA, since it is a distinct legal standard from the proposed regulation.** As noted above, section 2713 of the PHS and implementing guidance require new and non-grandfathered health plans to cover specific recommended preventive services, including women's preventive health services, without cost sharing. This includes coverage with no cost sharing for all FDA-approved contraceptive methods.[2] Several FDA-approved contraceptive methods are available without a prescription, and the Department of Health & Human Services has specified that FDA-approved contraceptive methods available without a prescription must be covered without cost sharing as part of the law's requirement.[3]

As currently drafted, the proposed regulation may cause confusion by seeming to allow an insurer to remove a prescription drug from a formulary if the drug is approved by the FDA for use without a prescription. Regardless of FDA-approval for use without a prescription, health plans subject to section 2713 of PHS must continue provide coverage of critical women's preventive health services, including all FDA-approved contraceptives. To reduce any confusion regarding the two separate standards and

[1] Joanne Noone, *Finding the Best Fit: A Grounded Theory of Contraceptive Decision Making in Women*, 39 Nursing Forum 4 (2004).
[2] HRSA Guidelines for Women's Preventive Health Services (Aug. 1, 2011); Amendment to the Preventive Services Interim Final Rule, 76 Fed. Reg. 46621 (Aug. 3, 2011).
[3] The Center for Consumer Information & Insurance Oversight (CCIIO), *Affordable Care Act Implementation FAQs-Set 12*, Question #15, U.S. Department of Health and Human Services (2013).

prevent inappropriate reductions in women's preventive health coverage, we urge the Division to clarify an insurer's continued obligation to meet section 2713 of the PHS. We recommend the Division include the following clarification to ensure women have consistent access to the coverage and care they need.

**Proposed Regulation**

Section 1 of Chapter 689A and Section 3 of Chapter 695C of NAC are hereby amended by adding….

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

(c) The prescription is approved by the United States Food and Drug Administration for use without a prescription. *Except that an insurer offering or issuing a policy of health insurance subject to Public Health Service Act Section 2713, implementing regulations, and guidance, must comply with such requirements and provide coverage without cost sharing for recommended preventive health items and services that are FDA-approved and available without a prescription.*

This addition to Chapter 689A Section 1(2)(c) and Chapter 695A Section (3)(2)(c) will make clear that insurers must continue to meet standards in section 2713 of the PHS and will help improve access to contraceptive services for Nevada women.

Thank you for the opportunity to offer written feedback regarding drug formulary standards for Nevada. We look forward to working with you as you move forward on this importance consumer protection. Please let me know if I can provide additional information.

Thank you!

Elisa Cafferata
Nevada Advocates for Planned Parenthood Affiliates
550 W Plumb Lane, c/o UPS Mail #B-104, Reno, NV 89509
ecafferata@NevadaAdvocates.org
775-412-2087

**National Multiple Sclerosis Society**
Southern California & Nevada Chapter

**NEVADA Field Offices**

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September 26, 2014

The Honorable Scott J. Kipper
Commissioner
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

**RE: MS Society Support for Proposed Regulation R074-14**

Dear Commissioner Kipper,

The National Multiple Sclerosis Society strongly voices its support of the proposed regulation R074-14. We greatly appreciate your reaching out and recognizing the devastating impact Nevadans living with MS can face when their health plan changes drug benefits and increases members' cost-sharing requirements.

People living with MS rely on expensive prescription medications to manage their disease. The cost of drugs approved for relapsing remitting forms of MS average approximately $60,000 annually, and most health plans utilize tiered drug benefits with cost-sharing requirements as high as 50%. Studies document a direct correlation between the cost of patients' medications and their compliance with the doctor prescribed treatment. Therefore, unplanned increases in consumers' out-of-pocket costs, which often result from mid-year changes in drug tiers, may force them to cut back on doses, go without essential medications or switch drugs for reasons having nothing to do with their health.

An individual maintaing a consistent course of these medications is critical in preventing worsening health status; decreased independence and even job loss. Mid-year formulary changes are beneficial when new therapies become available, but burdensome when they increase cost-sharing. Disruptions in coverage are the last thing families need to be struck with while coping with an already unpredictable disease.

The types of drug formulary considerations and patient safeguards that help achieve access to affordable coverage and care most likely to achieve optimal treatment outcomes and quality of life for persons with MS are:

- Robust drug formularies that expand as new, evidence-based drug treatments gain marketing approval by the US Food & Drug Administration;

- No removal of drugs from the formulary during the contract period unless new evidence of potential safety risks or other warnings are issued by the US Food & Drug Administration;

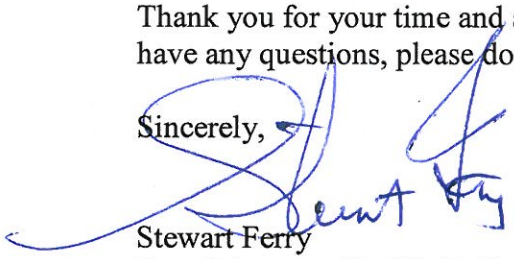
- Other continuity of coverage and access safeguards to assure uninterrupted treatment during changes in provider networks, employer or patient circumstances during the contract period;

- Ample notice of planned changes to formularies, tiers and cost-sharing (at least 60 days prior to the new contract period) to allow patients and their prescribers time to adjust as necessary; and

- No changes to tiering placement or cost-sharing requirements for covered drugs during the contract period

Thank you for your time and attention regarding this important matter. If you have any questions, please don't hesitate to contact me at 510-872-0731

Sincerely,



Stewart Ferry
State Director of Public Policy
The National MS Society-- Nevada

October 1, 2014

Scott J. Kipper
Commissioner
Nevada Division of Insurance
1818 East College Parkway, Suite 103
Carson City, Nevada 89706

Re: LCB File Number R074-14, Proposed Regulation for Prescription Drug Formularies

Dear Commissioner Kipper,

The National Hemophilia Foundation (NHF) and Hemophilia Federation of America (HFA) advocate on behalf of individuals with hemophilia and related bleeding disorders, leading the nationwide fight to ensure access to affordable medical care and services. In partnership with the Nevada Chapter of NHF, we are writing to express our support for LCB File Number R074-14 regarding prescription drug formularies. This proposed regulation would limit the ability of health insurers to make changes to drug formularies (more than once a year) after they have already been approved. It is often the case that when the drug formulary changes, already expensive drugs are placed into higher tiers resulting in costly treatment for patients who are part of chronic disease groups. Given the unique needs of the population that we serve, accessibility and affordability are of paramount importance to NHF and HFA. Thus, we commend the Nevada Division of Insurance for taking a pivotal step in the direction of increased access and affordability by proposing regulation R074-14.

Hemophilia and other bleeding disorders occur when a person is deficient in or lacks one of several proteins necessary for the blood to clot. Many individuals experience spontaneous internal bleeding that can result in severely damaged joints, or sometimes death. Treatment entails the infusion of clotting factor (derived either from human plasma or manufactured through recombinant technology) to compensate for missing or defective blood proteins. It is, therefore, imperative that members of the bleeding disorders community have full access to treatment, and that they not endure the threat of cost-prohibitive roadblocks such as those imposed when drug formularies are changed and drugs are placed onto higher tiers.

As you move forward, NHF, the Nevada Chapter of NHF, and HFA are hopeful that you will continue to consider the needs of the bleeding disorders community by keeping the following things in mind:

- Clotting factor is a biologic. Specialty tiers usually include biologics and other drugs requiring special administration. Drugs placed in specialty tiers typically require exorbitant patient cost-sharing. Patients have historically paid a percentage of the cost of these drugs, from 25% to 33% or more in coinsurance, rather than a fixed co-payment.

- The yearly cost for clotting factor can be as high as $300,000 per year for a person with severe hemophilia and can exceed $1 million for a person who develops an inhibitor. While in most cases the ACA limits the total out-of-pocket costs ($6,600 for an individual or $13,200 for a family of four in 2015) patients may be required to pay each year, individuals with bleeding disorders will likely meet this out of pocket maximum in one to three months if they are



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subjected to extremely costly coinsurance payments. It is not feasible for most Americans to adjust to this significant financial burden in such a short period of time.

- We understand that the intent of requiring higher patient cost-sharing for drugs and biologics is to reduce reliance on these expensive drugs and incentivize patients to choose lower-cost generic alternatives. However, there are no generic alternatives to clotting factor therapies.

- Medical Benefit Drugs: Many drugs requiring specialized administration, including factor, are covered under the medical benefit rather than the pharmacy benefit. While medical benefit drugs are not tiered, the regulation does not prohibit plans from making similar restrictive changes to the coverage for these drugs by dropping coverage and/or significantly increasing the cost sharing required of patients. Please extend the regulation's protections to medical benefit drugs as well.

The reality is that placing drugs in a specialty tier makes these medically necessary treatments unaffordable for most Americans. People with bleeding disorders who cannot afford specialty tier pricing may delay or go without treatment, resulting in disability and other complications that can lead to increased long-term healthcare costs. The implementation of proposed regulation R074-14 would maintain the integrity of Nevada's healthcare system – ensuring that the health insurance plan deemed to be appropriate and then selected during an enrollment period remains intact (appropriate and affordable) at least for the duration of the year that follows.

Above all, NHF, the Nevada Chapter of NHF, and HFA value patient care. We are confident that this proposed regulation would go a long way towards promoting accessible and affordable healthcare for individuals with bleeding disorders, and members of various other chronic disease groups. We appreciate the opportunity to share our comments. If you have any questions or require additional information, please do not hesitate to contact Michelle Rice at mrice@hemophilia.org or Katie Verb at k.verb@hemophiliafed.org.

Sincerely,

Michelle Rice

Vice President, Public Policy and Industry Relations
National Hemophilia Foundation

Katie Verb

Manager, Policy and Advocacy
Hemophilia Federation of America

Kelli Walters

Executive Director
Nevada Chapter of National Hemophilia Foundation



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SPEAC
STATE PATIENTS EQUAL ACCESS COALITION

October 1, 2014

The Honorable Scott J Kipper
Commissioner
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

**RE: LCB File Number R074-14, Prescription Drug Formularies**

Dear Commissioner Kipper,

The State Patients Equal Access Coalition (SPEAC) appreciates the opportunity to comment on this proposed regulation, whose policies are critical to ensuring access to treatments for cancer patients. SPEAC is a patient-focused coalition which works to ensure that cancer patients have appropriate access to all approved anticancer regimens including, but not limited to, oral and intravenous drugs, intramuscular injections, surgery, radiation, and transplantation. SPEAC believes that all cancer patients should have access to the anticancer regimens recommended by their physicians and should not be forced to choose a less appropriate treatment option, or possibly forego treatment, simply because of inordinate out-of-pocket costs due to differences in the mechanism of delivery.

SPEAC members support the provisions of the proposed regulation, which would prohibit health insurers from making harmful changes to their formularies mid-year. Thank you for recognizing that insurer practices such as dropping coverage of previously-covered prescription drugs, as well as moving drugs to a higher formulary tier, pose barriers to patients accessing medically-necessary treatments. Prescription drug coverage is a key benefit design reviewed by consumers when selecting a plan and as such, consumers must have confidence that their plan will not substantially change during the plan year. We support the prohibition on plans making restrictive benefit design changes outside of the annual open enrollment process. Mid-year changes preclude enrollees from selecting a new plan that better meets their needs.

We have two additional suggestions for the final regulation to ensure that cancer patients have robust drug coverage:

Medical Benefit Drugs: Many physician-administered drugs, including anticancer treatments and blood products, are covered under the medical benefit rather than the pharmacy benefit. While medical benefit drugs are not tiered, the regulation does not prohibit plans from making similar restrictive changes to the coverage for these drugs by dropping coverage and/or significantly increasing the cost sharing required of patients. Please extend the regulation's protections to medical benefit drugs as well.

Additions to the Formulary for Newly Approved Treatments: We are concerned that the prohibition on making formulary changes could lead plans to think they are not allowed to add newly-approved treatments to their formularies mid-year. Cancer patients must have access to the newest, most innovative therapies, which are approved by the FDA throughout the year with no regard for health insurance plan years. Please make it explicit that the regulation does not prohibit the addition of newly-approved drugs to the formulary.

SPEAC
STATE PATIENTS EQUAL ACCESS COALITION

We hope to ensure that cancer patients have full access to appropriate therapies, regardless of the delivery mechanism. SPEAC appreciates the opportunity to comment on this proposed regulation, which marks an important step forward in protecting Nevada patients' access to medications. If you have any questions or would like any additional information, please contact Meghan Buzby, International Myeloma Foundation, at 410-252-3457 or mbuzby@myeloma.org.

Sincerely,

AIM at Melanoma
Association of Community Cancer Centers (ACCC)
Cancer Support Community (CSC)
Community Oncology Alliance (COA)
International Cancer Advocacy Network (ICAN)
International Myeloma Foundation (IMF)
Leukemia & Lymphoma Society (LLS)
National Patient Advocate Foundation (NPAF)
Nevada Affiliates of Susan G. Komen®
Nevada Oncology Society
Ovarian Cancer National Alliance (OCNA)
Society of Dermatology Physician Assistants (SDPA)
Susan G. Komen®

Biotechnology Industry Organization

October 6, 2014

**BY ELECTRONIC DELIVERY**

Scott Kipper, Commissioner
Nevada Division of Insurance
1818 East College Parkway, Suite 103
Carson City, Nevada 89706

**Re: Proposed Amendment to LCB File Number R074-14, Prescription Drug Formularies**

Dear Commissioner Kipper:

The Biotechnology Industry Organization (BIO) is pleased to submit comments on the proposed amendment to the regulation issued by the Division of Insurance (DOI) on August 5, 2014, entitled "LCB File Number R074-14, Prescription Drug Formularies" (the "Proposed Amendment"). We note that we commented earlier on the proposed regulation issued by the DOI on June 20, 2014 under the same name (the "Proposed Rule").

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics have greatly improved health outcomes for patients worldwide.

As we articulated in our July 28, 2014 comment letter on the earlier version of this regulation, BIO commends the DOI for its proposed prohibition on moving drugs between tiers on a plan's formulary during a given plan year. As we noted previously, because many consumers enroll in healthcare coverage in whole or in part due to the perceived benefits of a particular prescription drug formulary, when a formulary is altered during a benefit year, including with respect to the applicable cost-sharing, consumers are often left with no option to change coverage. BIO therefore feels that the changes offered in the Proposed Rule provide important consumer protections to address this issue, and are necessary to alleviate consumer concerns of being locked into coverage that may have less utility than was anticipated when it was purchased. We further believe that many of the changes made by the Proposed Amendment serve to further strengthen these protections by providing useful clarification. BIO writes to ensure that certain changes made by the Proposed Amendment do not inadvertently undermine the important protections the DOI is working to promote.

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bio.org

## I. BIO Encourages the DOI to Define the Term "Bioequivalent Generic Drug Alternative."

As noted previously, BIO believes that the prohibition on moving drugs to a higher formulary tier during a given benefit year is an important protection for the insured patients of Nevada. Notably, however, proposed Section 4 creates an exception to this protection to the extent that a "bioequivalent generic drug alternative" is added to the formulary either: (1) at the benefit tier originally occupied by the drug; or (2) at a lower benefit tier. While the drafting note indicates that the intent of this new section was to permit "the promotion of generic drug alternatives outside of existing statutory allowances concerning mandatory substitution"—indicating that its intent is to apply only to small-molecule generic products—we are concerned that, without further clarification, this exception could be interpreted to extend to biosimilars. We note that such an interpretation would undermine the otherwise-applicable patient protections for those patients who rely on biologic therapies. This is because approval as a biosimilar by the U.S. Food and Drug Administration (FDA) does not necessarily indicate therapeutic equivalence, meaning that a biosimilar is not necessarily a therapeutically appropriate option for patients taking the biologic reference product.

The Biologics Price Competition and Innovation Act (BPCIA)—enacted as part of the Patient Protection and Affordable Care Act of 2010—created a new federal approval process for biosimilar biologics.[1] Notably, in enacting the BPCIA, Congress recognized that the preexisting legal and regulatory construct for approving generic drugs would be inappropriate for biosimilar products due to scientific differences between the two classes of products.

Specifically, longstanding federal law requires small-molecule generic drugs to establish that they are the "same" as (*i.e.*, pharmacologically equivalent to) a previously approved drug product across an array of variables (*e.g.*, active ingredient(s), dosage form, route of administration, strength, labeling, conditions of use) as a condition of approval by the FDA.[2] By contrast, due to the complex structure of biologics and the associated manufacturing processes, biosimilars must be shown to be "highly similar to"—but not the "same as"—an innovator/reference biologic in terms of structural characteristics.[3]

In addition, to receive a regulatory designation as "therapeutically equivalent", generic small-molecule drugs must demonstrate "bioequivalence," meaning that they must display comparable bioavailability (*i.e.*, the rate and extent to which the active ingredient is absorbed from a drug product and becomes available at the site of action), with their reference products. Because the active ingredients of a generic drug and its reference product must be the same and bioequivalence between the two products must be demonstrated, it can be concluded that the effects of both drugs are expected to be

[1] Pub. L. No. 111-148 (March 23, 2010) (Patient Protection and Affordable Care Act, Title VII – Improving Access to Innovative Medical Therapies, Subtitle A—Biologics Price Competition and Innovation) (codified as Public Health Service Act § 351(k)).

[3] Public Health Service Act § 351(k).

identical and, therefore, it does not matter, in nearly all circumstances, which drug a patient receives at a given time.[4]

By contrast, biosimilars are highly similar, but not clinically identical, to their reference products, and as reflected by the two different standards set forth in the BPCIA, interchangeability is not intrinsic to a biosimilar's analytical attributes and the equivalence of its biodistribution. In other words, federal law recognizes that merely being approved as a biosimilar does not, in and of itself, provide sufficient showing that the product may be freely substituted with the reference product.[5]

In light of the unique approval pathway for biosimilars, the important patient protections extended by the Proposed Rule would be undermined for a patient under a course of treatment involving a biologic product if the Proposed Amendment were interpreted to allow his or her insurance plan to move that biologic to a higher cost-sharing tier merely because a biosimilar were introduced to the formulary, as there would be no guarantee that the biosimilar would be therapeutically appropriate for that patient. Accordingly, we urge the DOI to confirm, in any final regulation, that the term "bioequivalent generic drug alternative" applies only to chemically-synthesized, small-molecule medications, including generic drugs.[6]

## II. BIO Encourages the DOI to Include Consistent Language In Each Section of the Proposed Amendment.

In Section 1 of the Amendment, the DOI adds new section 689A.4 to the Nevada Administrative Code, which, as noted above, allows plans to move a prescription drug to a tier with a larger deductible, copayment or coinsurance if a bioequivalent generic drug alternative is added to the formulary. This proposed section further stipulates that, for this exception to apply, the new bioequivalent generic drug alternative must be added to the formulary either: (1) at the benefit tier originally occupied by the prescription drug; or (2) at a benefit tier with a lower deductible, copayment or coinsurance than the benefit tier originally occupied by the prescription drug.

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[4] Biological equivalence is also a requisite in order for a generic drug to be substitutable for a branded drug under Nevada state law. See Nev. Rev. Stat. § 639.2583(1)(b) ("Except as otherwise provided in this section, if a practitioner has prescribed a drug by brand name and the practitioner has not indicated, by a method set forth in subsection 5, that a substitution is prohibited, the pharmacist who fills or refills the prescription shall dispense, in substitution, another drug which is available to him or her if the other drug: . . . [i]s biologically equivalent to the drug prescribed by brand name . . . ").

[5] While the FDA may affirmatively designate a biosimilar as "interchangeable," the Agency may only do so after an additional determination that: (1) the biosimilar can be expected to produce the *same* clinical results as the reference product *in any given patient*; and (2) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. Moreover, the scientific and legally distinct standard for interchangeable biologics versus biosimilars means that a non-interchangeable biosimilar is not held to the interchangeability standard in regulatory review and thus one cannot claim that this non-interchangeable biosimilar has the features of an interchangeable biologic. See Public Health Service Act § 351(k)(4) (emphasis added).

[6] We note that the Centers for Medicare & Medicaid Services (CMS) uses a similar standard for purposes of the Medicare Part D program. Specifically, the Medicare Part D program generally limits "[r]emoval or placement in a less preferred tier of a brand name drug" to circumstances when either "an A-rated generic or multi-source brand name equivalent" is added "at a lower tier or cost to the beneficiary." CMS, Medicare Prescription Drug Benefit Manual Ch. 6 – Part D Drugs and Formulary Requirements, § 30.3.3.2, available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf.

We note, however, that similar limiting language is not included in the proposed amendments made by Sections 2 and 3 of the Proposed Amendment to Chapters 689C and 695C of the Nevada Administrative Code, respectively. We assume that the DOI's intent was for Section 4 to apply only where the new bioequivalent generic drug is added to the formulary either: (1) at the benefit tier originally occupied by the prescription drug; or (2) at a lower benefit tier. Indeed, the relevant drafting note in Section 1 of the Proposed Amendment states that "the generic drug must be added to a tier equivalent to or better than the tier occupied by the original prescription drug prior to being removed." Accordingly, we urge the DOI to similarly specify as much in Sections 2 and 3 of the Proposed Amendment.

## III. Conclusion

BIO appreciates the opportunity to comment on the Proposed Amendment. We look forward to continuing to work with the DOI and interested partners to ensure that all consumers have access to affordable health insurance that meets their needs throughout each benefit year. Please feel free to contact me at (202) 449-6384 if you have any questions or we can be of further assistance. Thank you for your attention to this important matter.

/s/

Erin Estey Hertzog, J.D., M.P.H.
Director, Reimbursement & Health Policy

Anthem

9133 W Russell Road
Las Vegas, NV 89148

October 10, 2014

Adam Plain
Insurance Regulation Liaison
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

**RE: LCB File No. R074-14: Prescription Drug Formularies Proposed Rule - Oppose**

Dear Mr. Plain

On behalf of Anthem Blue Cross and Blue Shield of Nevada, I must write in opposition to the recent proposed rule regulating the development of our health plan formularies (LCB File No. R074-14). Anthem Blue Cross and Blue Shield of Nevada (Anthem) is one of the state's largest health benefits companies serving more than one-quarter of a million Nevadans. Our membership includes enrollees in the individual and group markets and combined with our Amerigroup membership family we are proud to be the State's largest partner in serving low-income and high-risk members throughout the State.

At a time when the shared goals of issuers and the state government should be primarily focused on the implementation of health care reform and improving access to health care coverage for all Nevadans, we believe this proposed regulation serves as an unwarranted distraction for the following reasons:

**Creates New Regulatory Burdens Leading to Costly Consumer Consequences**

At the federal level, our nationally-branded WellPoint subsidiary has sought public policy solutions that seek to mitigate the relentless trend of increasingly rising drug prices. Working alongside various industry and government partners we have pushed for greater transparency in the Federal Food and Drug Administration's (FDA) new Breakthrough Therapy Designation and we have sought solutions for state Medicaid agencies to ensure proper coverage reimbursement. Requiring Anthem and other health plans to make changes to their formularies on only an annual basis would prohibit consumers from receiving potentially needed medications as they become available while severely restricting our ability to provide enhanced medical management of prescription drug formularies in a cost effective and consumer focused way. From a cost perspective, these types of misguided regulatory solutions simply disguise the true consumer cost by shifting the cost of the coverage of these drugs to beneficiaries.

As an example, while the stated goal of this regulation generally prohibits certain insurers from: (1) removing a drug from the formulary; or (2) reclassifying the drug in the formulary to make a different deductible, copayment or coinsurance amount applicable to the drug, we note that the end result of these proposed changes will not successfully shield consumers from the problem of high cost drugs. Even if initial costs to the member were shielded for chronic higher-tiered specialty drug users, members will subsequently experience greater costs for their health care coverage in the form of higher premiums and copayments due to the increased cost and complexity in providing for medical and outpatient prescription drug benefits.

Anthem

**Needlessly Usurps Existing Health Plan Policies and Established Federal Protections**

Most importantly, by attempting to clarify the conditions under which Anthem and other health plans may remove drugs from their formulary, the department fails to consider existing health plan policies regarding formulary developments which are fully intended to pro-actively limit the costs incurred by the consumer. One such circumstance occurs when generic equivalents are introduced into the market. When such generics enter the market, we agree with the recent modifications to the regulations allowing health plans to move these drugs to formularies with higher cost sharing. However, per current plan policy, plans should also be allowed the option to remove the more expensive brand name drug from the formulary in an effort to make the more cost effective generic available to members. In these instances Anthem Blue Cross and Blue Shield plans have established a very detailed communication strategy to notify our members of this benefit change on the formulary alerting our members when corresponding generics are now an available alternative. Continuing to allow health plans to exercise this reasonable plan design option saves costs while ensuring continuity of care is provided to the member.

Additionally, many of these regulations are duplicative as the Affordable Care Act (ACA) establishes specific out-of-pocket (OOP) limits which already provide a level of cost protection for tiered pharmacy drugs. These limits - $6,400 for individuals and $12,800 for families in 2014 - apply to the combined total, prescription and medical out-of-pocket costs that members would have to pay under a health insurance plan.

In conclusion, as a solutions-focused health organization we continue to engage policymakers in seeking creative solutions that ensure greater pharmaceutical manufacturer transparency in light of unjustifiable trends in drug prices so that payers (including both the government and issuers) and consumers can more accurately forecast and understand the true drivers of recent drug costs. While we would welcome more discussion on the topic of drug costs, we believe the present proposed regulatory solution is both misplaced and burdensome, failing to account for the necessary detailed nuances of health plan formulary development. As such we must oppose these proposed regulations as issued.

Sincerely,

Tracey Woods
Senior Director, Government Relations

Tracey Woods
Government Relations Director

**American Cancer Society Cancer Action Network**
691 Sierra Rose Drive | Suite A | Reno, NV 89511
**www.acscan.org**

October 10, 2014

RECEIVED
OCT. 13, 2014
DIVISION OF INSURANCE
STATE OF NEVADA

The Honorable Scott J. Kipper
Commissioner
Division of Insurance
Department of Business and Industry
1818 East College Parkway, Suite 103
Carson City, NV 89706

Comments sent by email to: aplain@doi.nv.gov

Re: Comments on Drug Formulary Proposed Rule LCB File No. R074-14, Draft Propose Amendment 8/05/2014

Dear Commissioner Kipper:

The American Cancer Society Cancer Action Network (ACS CAN) thanks you for the opportunity to comment on the current draft of the proposed rule related to the prescription drug formularies in the state of Nevada. ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

Overall we are pleased with the current direction of the proposed rule which attempts to ensure that individuals in Nevada have access to the prescription drugs that they need. Access to medically necessary drugs is vitally important to cancer patients – including the 14,450 Nevada residents who are estimated to develop cancer in 2014.[1]

As the Nevada Division of Insurance continues its work to finalize the proposed rule on prescription drug formularies, we welcome the opportunity to work with you and your office to further refine the proposed rule. We offer the following specific comments and requests for further clarification of the draft rule:

***Sec. 1.1 Removing or changing a prescription drug's placement on a formulary tier***

The current draft of the proposed rule prohibits a health insurer that provides prescription drug coverage under a formulary to remove the drug from the formulary or move the drug to a higher formulary tier without Commissioner approval.

1. American Cancer Society, Cancer Facts & Figures 2014, available at http://www.cancer.org/acs/groups/content/@research/documents/webcontent/acspc-042151.pdf.

ACS CAN supports the proposed language, which we believe provides an important protection to consumers. As you work to finalize the proposed rule, we urge you to add a requirement that the Division of Insurance review formularies to determine the extent to which a health plan imposes utilization management edits (e.g., prior authorization, step therapy requirements, etc.), and that health insurers be prohibited from adding new utilization management edits during the plan year without approval from the Commissioner. While some utilization management edits may be necessary, such tools can hinder patients' ability to access a prescription drug, particularly when they are added mid-year. Thus the Commissioner should review the entire formulary to determine whether utilization management edits are necessary or whether they are included as ways to hinder patients' access to prescription drugs.

*Sec. 1.2 Approval of Formulary Changes*

The proposed draft would allow a plan to remove a prescription drug from a formulary at any time if the drug is no longer approved by the Food and Drug Administration (FDA) for use in humans, if the FDA calls into question the safety of the drug; or, if the drug is approved by the FDA for use without a prescription (e.g., over-the-counter).

ACS CAN supports the proposed changes. While the proposed change would allow a drug to be removed from the formulary if there is a question about the safety of the drug, we urge the Commissioner to also include language that would permit a formulary change in those instances where there is new credible data or information regarding the effectiveness of the drug.

In addition, we also urge the Commissioner to consider including clarifying language to ensure that health plans can add drugs to their formularies, reduce copayment or coinsurance, or delete utilization management tools at any time during the plan year. Such policies will allow health plans to expand their formularies and reduce cost-sharing for individuals.

***Additional Items***

As the Division of Insurance continues to work to revise its formulary requirements, we encourage consideration of some additional policies. The proposed language fails to include a requirement that health plans notify the effected enrollee of any formulary changes. While this requirement may be included elsewhere in the Nevada health plan regulations, we believe such notice is an important consumer policy and should be specifically included in this section of the Nevada regulations.

In addition, consumers need access to information – like a plan's formulary – in order to make an informed decision in choosing a plan that best meets their needs. We urge the Division of Insurance to require that health plans' formulary information be provided in a publicly available format (e.g., a web-based format that can be readily accessible to the public).

Finally, we note that many cancer drugs are often covered under an enrollee's medical benefit rather than the pharmacy benefit. We urge the Division of Insurance to consider adopting requirements that health plans be prohibited from imposing restrictive changes to prescription drugs provided under medical benefit. In addition, we urge the Division of Insurance to require plans to clarify that some prescription drugs not found on the formulary are covered by the medical benefit.

Thank you for your time and consideration of our comments. We look forward to working with you and the Division of Insurance staff to ensure cancer patients has affordable access to the prescription drugs that will best help them fight their disease. If you have any additional questions, please do not hesitate to contact me at 775-828-2206

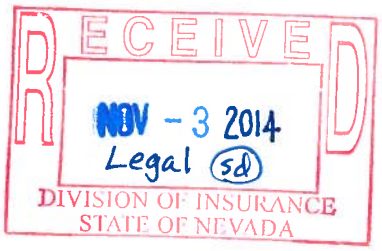
Sincerely,

Tom McCoy, J.D.
NV Government Relations Director
American Cancer Society Cancer Action Network
691 Sierra Rose Drive, Suite A
Reno, NV 89511
Tom.mccoy@cancer.org

Immune Deficiency Foundation

The National Patient Organization Dedicated to Advocacy, Education and Research for Primary Immunodeficiency Diseases

October 31, 2014




The Honorable Scott Kipper
Commissioner of Insurance
Division of Insurance
1818 East College Pkwy, Suite 103
Carson City, NV 89706

c/o: Adam Plain
Insurance Regulation Liaison

**RE: Support for Proposed Regulations R074-14 and R049-14**

Dear Commissioner Kipper:

The Immune Deficiency Foundation (IDF) is the national patient organization dedicated to improving the diagnosis and quality of life of individuals with primary immunodeficiency diseases (PI) through advocacy, education and research. We write today in support of proposed regulations R074-14 and R049-14, which provide additional consumer protections for individuals purchasing health insurance.

R074-14 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. Federal law and guidance limit consumers' ability to change health insurance plans outside of the open enrollment except in limited circumstances so that consumers are effectively "locked in" to their selection for a calendar year. At the same time, regulations allow health insurers to remove prescription drugs from a formulary, or move prescription drugs among different cost-sharing tiers, while still maintaining compliance. The Division of Insurance has correctly identified this as a 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.

For patients with PI, this poses a serious threat to patient safety. Primary immunodeficiency diseases occur in persons born with an immune system that is either absent or hampered in its ability to function. Many patients with PI rely on the complex biologic treatment immunoglobulin (Ig) therapy to replace the antibodies their bodies do not naturally produce. With lifelong immunoglobulin therapy, patients with PI are able to live normal, healthy and productive lives. In recent years there has been a steady increase in the use of coinsurance cost-sharing with patients who need expensive specialty drugs such as Ig therapy. A coinsurance requirement of 20, 30 or 40% on this lifesaving medication can easily cost a family thousands of dollars per month. Without this regulation, patients with PI could easily purchase a health plan thinking that their Ig therapy is covered with a flat copayment and then find it has been changed mid-year to a specialty tier with coinsurance cost sharing. The proposed regulation would protect our vulnerable patients from this scenario.

R049-14 outlines a procedure for a carrier wishing to apply for a network plan to have the application deemed adequate. We appreciate the attempt to mitigate some of the issues consumers, providers, facilities and insurers may experience in ensuring adequate access to medical care. It is an important quality of this regulation that it applies to the adequacy of all network plans in Nevada without regard to their status as a QHP.

40 West Chesapeake Avenue, Suite 308, Towson, MD 21204
www.primaryimmune.com | info@primaryimmune.org | 800.296.4433 | 410.321.6647 | Fax: 410.321.9165

We support the creation of regulation that requires health plans to have an adequate number of providers to serve members in each geographic service, but because of the diversity of clinical manifestations, patients with PI may be cared for by immunologists, allergists, rheumatologists, otolaryngologists, pulmonologists, gastroenterologists, infectious disease specialists and hematology-oncologists. While we recognize that it would be nearly impossible to specifically outline every medical specialty as a necessary category of health care in the regulation, it is unclear how patients with PI who rely on expert treatment by a variety of specialists would be protected by the categories outlined in the regulation. The categories outlined are not all-inclusive and patients with rare diseases may need access to specialists not included. There should be a mechanism for patients, especially those who have rare and chronic conditions requiring the expertise of specialists to manage, to have access to their needed specialists whether in-network or out of network without incurring large out-of-pocket expenses.

Thank you for the opportunity to comment on these proposed regulations. Should you have any questions please contact Emily Hovermale at 443-632-2544 or at ehovermale@primaryimmune.org.

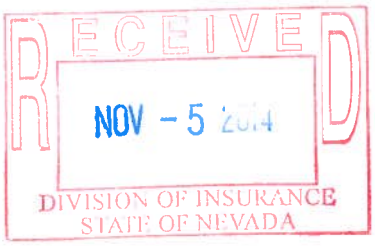
Sincerely,

Lawrence A. LaMotte
Vice President, Public Policy

American Diabetes Association®

**Support Proposed Regulation R074-14**

November 3, 2014




The Honorable Scott J. Kipper
Commissioner, Nevada Division of Insurance
Department of Business and Industry
1818 East College Parkway, Suite 103
Carson City, NV 89706

Dear Commissioner Kipper:

I am writing on behalf of the American Diabetes Association to express support for the proposed regulation R074-14. Diabetes is a chronic disease for which there is no cure. It is the seventh leading cause of death afflicting 29.1 million Americans and nearly 178,000 Nevadans. Diabetes is a major cause of kidney disease, non-traumatic amputation of the lower extremities, new cases of blindness among adults, heart disease and stroke.

Access to prescription medication is critical to diabetes management. Prescription medications are needed to control blood glucose levels for people with both type 1 and type 2 diabetes. Additionally, people with diabetes may need other prescription medications to prevent or treat one or more of the life-threatening and disabling complications associated with the disease.

The Association supports the proposed regulation which prohibits insurers from removing prescription medications from formularies and moving prescription medications to a higher tier within a plan year. These practices jeopardize the health of patients with diabetes by disrupting continuity of care and burdening patients with unanticipated increased cost-sharing which may result in patients being unable to afford medications essential to maintaining their health.

If the proposed regulation is not adopted, consumers will continue to be locked into plans with little or no recourse, even if a plan changes during a plan year. The Association also supports the regulation requirement that insurers provide a mitigation plan addressing continuity of care for patients when drugs are removed from a plan formulary to lessen health issues arising from interruption of medical regimens.

The Association appreciates the opportunity to provide input on the proposed regulation. If you have questions; or if the Association can be of any assistance to you in this matter, please feel free to contact me at (916) 541-7198 or via email at lmurdock@diabetes.org.

Sincerely,

Lisa Murdock
Managing Director, State Government Affairs & Advocacy
168 Stonington Way
Folsom, CA 95630

Biotechnology Industry Organization



November 4, 2014

**BY ELECTRONIC DELIVERY**

Scott Kipper, Commissioner
Nevada Division of Insurance
1818 East College Parkway, Suite 103
Carson City, Nevada 89706

**Re: Proposed Amendment to LCB File Number R074-14, Prescription Drug Formularies**

Dear Commissioner Kipper:

The Biotechnology Industry Organization (BIO) is pleased to submit comments on the proposed amendment to the regulation issued by the Division of Insurance (DOI) on October 14, 2014, entitled "LCB File Number R074-14, Prescription Drug Formularies" (the "Second Proposed Amendment"). We note that we commented earlier on the proposed regulation issued by the DOI on June 20, 2014 under the same name (the "Proposed Rule"), as well as the proposed amendment thereto issued on August 5, 2015 (the "First Proposed Amendment").

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics have greatly improved health outcomes for patients worldwide.

As we articulated in both our July 28, 2014 comment letter on the Proposed Rule and our October 6, 2014 comment letter on the First Proposed Amendment, BIO commends the DOI for its proposed prohibition on moving drugs between tiers on a plan's formulary during a given plan year. As we noted previously, because many consumers enroll in healthcare coverage in whole or in part due to the perceived benefits of a particular prescription drug formulary, when a formulary is altered during a benefit year, including with respect to the applicable cost-sharing, consumers are often left with no option to change coverage. BIO therefore feels that the changes offered in the Proposed Rule provide important consumer protections to address this issue, and are necessary to alleviate consumer concerns of being locked into coverage that may have less utility than was anticipated when it was purchased. We further believe that many of the changes made by the First and Second Proposed Amendment serve to further strengthen these protections by providing useful clarification. BIO writes to request that DOI modify the Second Proposed Amendment to ensure these protections will benefit patients who rely on biologic therapies. We also write to support the

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proposed language that expressly allows insurers to add prescription drugs to their formularies at any time.

## I. BIO Encourages the DOI to Specify that Term "Generic Drug Alternative" Does Not Apply to Biosimilars or, at a Minimum, Applies only to Interchangeable Biosimilars.

As noted previously, BIO believes that the prohibition on moving drugs to a higher formulary tier during a given benefit year is an important protection for the insured patients of Nevada. Notably, however, the First Proposed Amendment created an exception to this protection to the extent that a "bioequivalent generic drug alternative" is added to the formulary either: (1) at the benefit tier originally occupied by the drug; or (2) at a lower benefit tier. The Second Proposed Amendment then changed the operative term to "generic drug alternative" and added a definition of this term to include: (1) a biosimilar drug licensed pursuant to 42 U.S.C. § 262(k); or (2) a bioequivalent drug, as defined in 21 C.F.R. § 320.1(e). BIO is very concerned that defining the term "generic drug alternative" to include all biosimilars approved under § 262(k) will undermine the otherwise-applicable patient protections for those patients who rely on biologic therapies.

The Biologics Price Competition and Innovation Act (BPCIA)—enacted as part of the Patient Protection and Affordable Care Act of 2010—created a new federal approval process for biosimilar biologics, codified at 42 U.S.C. § 262(k).[1] Due to the complex structure of biologics and the associated manufacturing processes, in order to qualify for regulatory marketing approval under this pathway, biosimilars must be shown on the basis of analytical non-clinical and clinical data to be "highly similar" to—but not the same as—an innovator/reference biologic in terms of structural characteristics with an absence of clinically meaningful differences, understood to mean having equivalent efficacy and non-inferior safety.[2] In fact, minor differences with the active ingredient (e.g., N- or C- terminal truncations or differences in post-translational modifications) are expected and permitted, provided that such differences are not expected to affect safety and effectiveness and are justified and explained by the sponsor.

In light of the unique approval pathway for biosimilars, the important patient protections extended by the Proposed Rule would be undermined for a patient under a course of treatment involving a biologic product to the extent his or her insurance plan were permitted to move that biologic to a higher cost-sharing tier merely because a biosimilar were introduced to the formulary, as there would be no guarantee that the biosimilar would be therapeutically appropriate for that patient. Accordingly, we continue to strongly urge the DOI to define the term "generic drug alternative" such that it does not include biosimilar products. To the extent the DOI does not implement this recommendation, at a minimum, we urge the DOI to limit the applicability of "generic drug alternative" to those biosimilars that have been designated as interchangeable.

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[1] Pub. L. No. 111-148 (March 23, 2010) (Patient Protection and Affordable Care Act, Title VII – Improving Access to Innovative Medical Therapies, Subtitle A—Biologics Price Competition and Innovation).

[2] 42 U.S.C. § 262(i)(2). The biosimilar must also share "the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling" as the reference product. 42 U.S.C. § 262(k)(2).

Notably, the BPCIA established another, separate pathway under which the U.S. Food and Drug Administration (FDA) may affirmatively designate a biosimilar approved under § 262(k) as interchangeable. This pathway, codified under § 262(k)(4), allows the FDA to make a determination of interchangeability only after an additional determination that: (1) the biosimilar can be expected to produce the same clinical results as the reference product in any given patient; and (2) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.[3] The scientific and legally distinct standard for interchangeable biologics versus biosimilars means that a non-interchangeable biosimilar is not held to the interchangeability standard in regulatory review and thus one cannot claim that this non-interchangeable biosimilar has the features of an interchangeable biologic. Accordingly, to the extent the DOI includes any biosimilars in the definition of "generic drug alternative," we urge the DOI to ensure the term applies only to interchangeable biosimilars approved under 42 U.S.C. § 262(k)(4).

## II. BIO Encourages the DOI to Clarify Why Section 2 of the Proposed Rule Has Been Deleted.

The Second Proposed Amendment deleted the entirety of Section 2 of the Proposed Rule, which had extended the prohibition on moving drugs to a higher formulary tier during a given benefit year to health insurance plans offered by small employers, regulated under Chapter 689C of the Nevada Administrative Code. BIO urges the DOI to articulate why this section has been deleted, as well as how the state will ensure that the important patient protections added by the Proposed Rule will be extended to Nevada residents enrolled in such plans.

## III. BIO Supports The Addition of Language Expressly Allowing Issuers to Add Drugs to the Formulary During the Benefit Year.

As a representative of an industry that is devoted to improving health care through the discovery of new therapies, BIO believes that all consumers should have access to the newest, most innovative drugs as they receive approval from the FDA. As the DOI is no doubt aware, the FDA approves new therapies throughout the year, without regard to plan years. We therefore strongly support the language added by the Second Proposed Amendment that expressly permitts plans to change plan formularies mid-benefit year by adding prescription drugs. BIO believes that all stakeholders—issuers, carriers, and most notably, consumers—will benefit from this enhanced clarity around the ability of plans to change their formularies throughout the year by adding drugs.

## IV. Conclusion

BIO appreciates the opportunity to comment on the Second Proposed Amendment. We look forward to continuing to work with the DOI and interested partners to ensure that all consumers have access to affordable health insurance that meets their needs throughout each benefit year. Please feel free to contact me at (202) 449-6384 if you have any questions or we can be of further assistance. Thank you for your attention to this important matter.

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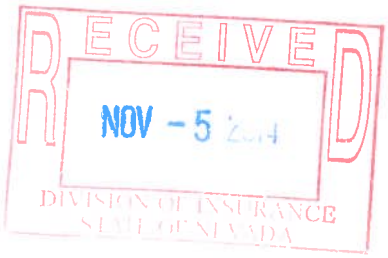
[3] 42 U.S.C. § 262(k)(4) (emphasis added).

/s/

Erin Estey Hertzog, J.D., M.P.H.
Director, Reimbursement & Health Policy

ConsumersUnion®

POLICY & ACTION FROM CONSUMER REPORTS




November 4, 2014

Honorable Scott Kipper
Commissioner
Division of Insurance
Department of Business and Industry
1818 East College Parkway, Suite 103
Carson City, NV 89706

Dear Commissioner:

Consumers Union, that advocacy division of Consumer Reports, offers the following comments on drug formulary proposed rule LCB file No. R074-14. Consumers Union employs a dedicated staff of lobbyists, grassroots organizers, and outreach specialists who work with the organization's more than 1,000,000 online activists to influence policy in the marketplace in favor of the consumer interest. In particular, our Health Campaign actively works to expand coverage and improve consumer protections in the health care marketplace.

Overall, Consumers Union believes that by limiting the ability of insurers to make formulary changes midyear this proposed rule will protect consumers from either losing coverage entirely or having to pay more for a drug between open or special enrollment periods. The proposed rule would help ensure that consumers get the benefits they signed up for when choosing the plan to begin with. It will also protect consumers financially who might have to pay out of pocket for the cost of a drug they use.

While we support the rule, the following changes could improve the proposal:

Section 1. 4: The proposed rule requires insurers to provide an informational plan to mitigate the effect on consumers of removing a drug or changing it to a higher cost tier under the proposed exceptions. The informational plan must describe the number of individuals expected to be impacted by removal of the drug, and a plan for mitigating it. The informational plan must also indicate how many people would be impacted by a mitigation strategy.

**Discussion:** This proposed rule doesn't actually require a plan to mitigate removal of a drug from a formulary in the instances it permits midyear removal of drugs from a formulary or midyear movement of drugs to a higher cost tier. The proposed rule only provides that plans must create a written description of their mitigation plan. Consumers would benefit from an actual requirement that plans mitigate the impact of removal of drug from the market under the proposed rule's allowed exceptions to midyear formulary change.

**Consumers Union Recommendation:** This provision should be strengthened to require plans to mitigate the loss of the drug rather than just present a mitigation plan. Requirements for mitigation should include:

- covering an alternative clinically beneficial therapy or drug if available (if they don't already);
- providing a mechanism for allowing consumers to receive a transitional supply of a drug dropped or moved to a higher tier, in the event of compelling need (assuming of course that the drug is safe and effective to use).

Section 1. 5: The proposed rule allows for removal midyear of a drug or placement in a higher cost tier if a generic alternative is added to the formulary. The generic alternative must be added to the formulary at the benefit tier originally occupied by the prescription drug or a benefit tier with a lower deductible or copayment.

**Discussion:** While generic drugs are generally lower cost, given recent price increases in the generic market and concerns that certain non-innovator alternatives, such as biosimilars, do not in all instances lower costs appreciably. It would be best to specify that midyear changes are acceptable (outside of the enumerated exceptions) only if a same or lower cost generic is made available.

**Consumers Union Recommendation:** Add the language "lower cost," before the word generic.

Consumers Union views this proposal as a step forward for consumers and supports proposed rule LCB file No. R074-14. However, we note that these reforms, while mitigating the harm to consumers from midyear changes to formulary, will not fix underlying discriminatory design issues that may place undue cost sharing on certain populations.

Increasingly, plan designs include tiering and cost sharing for specialty drugs that place needed prescribed medication out of reach of insured consumers. This rule would only limit the ability of insurers to make changes that surprise consumers and deprive them of a benefit upon which they may have factored their decision to choose a certain plan. We would hope that in the future, the Nevada Insurance Commissioner would consider policies that might address some of these worrisome and potentially discriminatory trends arising in the marketplace. Finally, the rule doesn't require plans to notify consumers about formulary changes. We think the rule can and should be strengthened by adding a consumer notification requirement for midyear changes.

Sincerely,

Lisa Swirsky

Lisa Swirsky
Senior Policy Analyst

**Maral Farsi, MPH**
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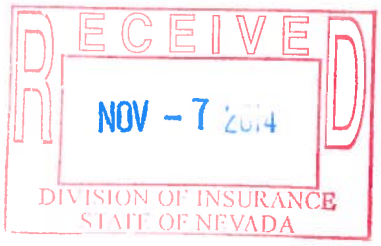
November 4, 2014




Honorable Scott J. Kipper
Nevada Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

Dear Commissioner Kipper:

CVS Health represents over 1,543 employees and 87 locations in Nevada and we wish to convey our ongoing opposition to the revised Proposed Regulation of the Commissioner of Insurance (LCB File No. R074-14) addressing prescription drug formularies.

CVS Caremark is the largest pharmacy healthcare provider in the United States with integrated solutions across the entire spectrum of pharmacy care. We proudly operate as the largest chain pharmacy in Nevada, offering our patients and clients integrated pharmacy and health operations statewide including: Pharmacy Benefit Management (PBM) services, Specialty Pharmacy, Mail-Order and Retail Pharmacy, Retail Health Clinics and distribution centers. Together, our businesses provide unparalleled service and capabilities to our clients, customers and patients as we strive to help them on their path to better health.

LCB File No. R074-14, in its newest version, has amendments that do not sufficiently address concerns we have previously conveyed to your office. The inability for health plans and PBMs to make mid-year market changes may ultimately increase health care costs for Nevada consumers. The United States' Department of Health and Human Services has described in guidance for the Affordable Care Act that plans may make periodic formulary changes, recognizing the market dynamics with respect to prescription drug prices. HHS did not find a need to prohibit mid-year formulary changes as long as adequate notice was provided to affected beneficiaries.

As we have said, the proposed regulations would obstruct many of the cost-savings strategies we provide to our health plan clients in Nevada and add administrative costs by requiring a informational plan describing effects on patients. In making formulary changes, cost considerations are only incorporated after clinical considerations—and even then, physicians have the ability to request authorization for their patients to secure access to necessary drugs. We again respectfully ask you reconsider proposed regulations by increasing the frequency of permitted annual formulary changes. Thank you for considering our comments in your decision regarding LCB File No. R074-14. Please contact me if you have any questions about our position at maral.farsi@cvscaremark.com or 916.203.9085.

Please contact me if you have any questions or concerns.

Sincerely,

Maral Farsi, MPH

**HIV Health Care Access Working Group (HHCAWG)**

November 4, 2014

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

To Whom It May Concern,

We are writing on behalf of the HIV Health Care Access Working Group ("HHCAWG") – a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV-related health care and support services. We thank you for your commitment to implementing the Affordable Care Act ("ACA") in ways that ensure access to comprehensive HIV prevention, care, and treatment, and appreciate the opportunity to comment on Nevada Proposed Regulation R074-14, regulating prescription drug formularies. As the Department of Business and Industry ("DOBI") reviews this proposed regulation, we urge you to consider the ACA's intent to increase access to meaningful health care coverage, particularly for individuals living with serious, chronic and complex conditions such as human immunodeficiency virus ("HIV"). We believe that R074-14 is crucial in protecting the rights of all Nevada consumers in general seeking comprehensive coverage of their prescription drug needs from their health care insurers and Nevada consumers living with HIV in particular. We strongly urge its adoption.

**The Current Insurance Industry Practice of Switching Formulary Tiering Structures After Enrollment Undermines Access to Life-Saving Care**

R074-14 addresses current industry practices that allow insurers to change formulary tiering structures, medications covered, and cost-sharing obligations after the close of the open enrollment period. These industry practices undermine access to quality care for Nevada consumers, particularly for Nevada residents living with chronic conditions, such as individuals living with HIV.

Consumers often consider plan formularies and the cost of obtaining necessary medications as major factors in selecting their health insurance plans. Yet, because insurers are currently allowed to change the formulary design in a plan after individuals are locked-in to a plan, consumers often find themselves, despite their research, enrolled in plans that no longer meet their care and treatment needs. We are seeing plans in several states, such as Nevada, impose requirements with respect to specialty tiering and cost-sharing only after the open enrollment period ended. In other cases, insurance plans have removed medications from their formularies after open enrollment. Troubling practices in other states also include an insurer informing enrollees with HIV subsequent to the open enrollment period that it was re-classifying some of the most widely prescribed medications for HIV treatment as specialty drugs. These medications are referred to as "singe tablet regimens" because they combine three medications into one drug

and greatly simplify adherence to HIV treatment. As a result of the specialty classification, beneficiaries face challenging changes to cost-sharing responsibilities. Another insurer during open enrollment, classified several HIV medications as Tier 2 drugs, which did not mandate use of mail-order pharmacies. However, subsequent to enrollment, when beneficiaries sought to access these HIV medications, they were informed by the plan that these medications could only be obtained through a mail-order pharmacy, increasing the difficulty of obtaining these medications.

These "bait and switch" actions prevent enrollees from obtaining the treatment they need to stay healthy, consistent with the nationally recognized standards for HIV treatment,[1] as they can make previously affordable medications inaccessible due to increased cost or other barriers. Unfortunately, since the switch occurs after open enrollment, these individuals then find themselves "stuck" in a plan that does not serve their medical needs for up to a year before they can select a different plan. These practices undermine a major purpose of the ACA, which is to increase the transparency of health plan offerings and to empower consumers to make an informed choice about which plan best suits their needs.

**These Actions Constitute Illegal Discrimination Against Individuals Living with HIV**

The ACA prohibits health insurance issuers with qualified health plans ("QHPs") from discriminating against individuals on the basis of disability. All QHPs must provide coverage of Essential Health Benefits ("EHB"), and a plan does not provide coverage of EHB "if its benefit design, or the implementation of its benefit design, discriminates based on . . . present or predicted disability . . . or other health conditions."[i] Disability includes HIV, even when a person is in the asymptomatic phase of the illness.[ii]

The industry practices listed above have the effect of discouraging people with HIV from accessing the care they need to stay engaged in care and health. These actions are inconsistent with the current standard of care for HIV as outlined by the Department of Health and Human Services ("HHS") [iii] and are discriminatory against individuals living with HIV.

**The Recognized Standard of HIV Care Requires Consistent, Uninterrupted Access to Multiple HIV Medications**

A combination of multiple antiretroviral medications is necessary to suppress HIV and the most effective combination depends on factors unique to the individual. Left untreated, HIV can replicate by the billions every day, and as it does so, it mutates rapidly. Indeed, HIV has the highest mutation rate of any virus due to its uniquely error-prone process of transforming RNA into DNA. Because it mutates so rapidly, HIV quickly adapts and becomes immune to drugs when treated with only one type of drug at a time or when treatment is interrupted, even briefly.

HHS guidelines describe the current "state of knowledge" and establish the medical standard of care for the "optimal use" of antiretroviral agents for the treatment of HIV infection in adults and

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[1] See U.S. Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.* Available at: http://aidsinfo.nih.gov/guidelines.

adolescents in the United States.[iv] The guidelines are a living document that is updated as new treatments become available or new research studies are published. The guidelines include "recommended" regimens and "alternative" regimens[2] and are available online at: http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0.[v]

The multi-drug treatment has proven remarkably successful in improving immune function and overall health, delaying the onset of AIDS, and extending life expectancy to near-normal for people with HIV. Proper use of medications has reduced deaths from 50,874 in 1995 to 8,963 in 2001.[vi] The dramatic reduction in deaths is evidence that HIV treatment is literally lifesaving treatment for people with HIV. Furthermore, in addition to saving the lives of those with HIV, treatment greatly benefits other members of the general public.[vii] By reducing the amount of virus in an HIV-infected individual's bodily fluids, treatment reduces the risk of transmission from infected individuals to their sexual partners by approximately 96% (or more).[viii] Treatment also prevents HIV+ women from transmitting the virus to their newborn children.[ix]

To obtain all of these benefits, HIV medications must be taken daily without interruption.[x] Delaying treatment causes long-term damage to vital organs[xi] and allows HIV to mutate extensively as it replicates throughout the body, risking the possibility that one of those mutations will make the virus drug resistant.[xii] Furthermore, due to HIV's high mutation rate, even minor interruptions in the medication regimen can lead to drug resistance, which results in increased viral replication, higher infection rates, and reduced functioning of the immune system.[xiii]

Effective treatment, therefore, requires giving patients and doctors the needed flexibility to find, through a combination of testing and/or trial and error, the regimen that works best for each individual as quickly as possible.[xiv] Even once a regimen has been found to work for an individual, treatment may stop working due to viral mutations or the individual may develop toxic side effects.[xv] In such instances, the patient must be allowed to switch their drug regimen quickly.[xvi]

All plans should comply with the ACA's nondiscrimination requirements by allowing medical providers to follow standard medical guidelines to provide appropriate care and treatment to their patients with HIV. At a minimum, all recommended drug regimens—including those described as the "alternative" regimens to first-line regimens—should be available and affordable to HIV patients without requiring the use of mail-order pharmacies, prior authorizations or other utilization management techniques that may delay access to treatment.

**The DOBI Must Take Action to Enforce Non-Discrimination Mandates**

The DOBI must ensure that none of the plans offered through the state health insurance exchange are employing a discriminatory benefit design or engaging in discriminatory marketing practices. In fact, a state may not make available through its health insurance exchange any health plan that does not provide EHB. 45 C.F.R. § 156.125. An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, *present or predicted disability*, degree of medical

[2] For some individuals, the recommended regimens may not be effective. Therefore an alternative regimen may be the preferred regiment for some patients. (HSS Guidelines at F-4).

dependency, quality of life, *or other health conditions*. 45 C.F.R. § 156.125(a). In addition to this very specific prohibition on discriminatory benefit designs, the ACA and its implementing regulations impose more general prohibitions against discrimination based on disability. *See* 42 U.S.C. § 18116 and 45 C.F.R. 156.200.[3] HIV is a qualifying disability even in its asymptomatic stage. *See* 42 U.S.C. § 12101 *et seq*.

The non-discrimination provisions described above were incorporated into the Public Health Service Act ("PHS Act") by the ACA "Each State enforces PHS Act requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State."[xvii] Accordingly, the DOBI has an obligation to ensure health insurers who participate in the marketplace and the QHPs offered therein do not discriminate against individuals living with HIV.[xviii]

**R074-14 Addresses Anti-Discrimination Concerns Regarding Post-Enrollment Formulary Changes**

R074-14 addresses some of the anti-discriminatory concerns around post-enrollment changes to formulary tiering. R074-14 forbids insurers and health maintenance organizations ("HMOs") from removing drugs from the formulary during the plan year and after open enrollment, except in cases where the United States Food and Drug Administration ("FDA") has issued guidance on the safety of a medication or rescinded approval of that drug. This prohibition includes moving drugs from a lower cost-sharing tier to a higher cost-sharing tier. In cases where the FDA has issued guidance on the medication, the insurer or HMO must submit a mitigation plan to the Nevada Commissioner of Insurance (the "Commissioner") that addresses the effect the change will have on consumers as well as the methods used to mitigate the effect. Another important provision of the regulation is that health plans may add prescriptions drugs to the formulary during the plan year.

By preventing insurers and HMOs from changing their formularies outside of the open enrollment period, R074-14 reduces the chances that enrollees will be trapped into plans that do not serve their health care needs. While this provision is important for all Nevada consumers of health care, it is especially critical for Nevadans living with HIV. HIV is a chronic, serious condition that can be controlled only through a comprehensive and highly coordinated medication regime. A change in a plan's formulary, especially if it is to move high cost HIV medications into a higher cost sharing tier or to remove a medication from the formulary entirely, can be discriminatory against individuals living with HIV. This is especially true if the purpose of the formulary change is to avoid providing comprehensive services to individuals living with HIV, who tend to cost more to insure and treat than the general population due to their greater medical needs. Because R074-14 helps protect the needs of Nevada consumers, including those living with HIV, HHCAWG urges you to implement this regulation.

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[3] While 45 C.F.R. § 156.200 specifically allows "appropriately utilizing reasonable medical management techniques," the failure to provide doctors with the ability to follow the standard of care and expeditiously place their patients on necessary treatments for which time is of the essence is, by definition, neither an "appropriate" or "reasonable" use of medical management techniques.

HHCAWG also urges you to consider further regulations protecting the rights of consumers. For example, we believe a prohibition on any changes post-open enrollment that would mandate use of a mail-order pharmacy for medications for which mail-order pharmacies were not previously required is also necessary. This will improve consumers' abilities to access the treatment they need through the pharmacies and providers with the appropriate expertise and with whom they have pre-existing relationships.

**Conclusion**

We strongly support the proposed regulation R074-14 and urge the DOBI to implement it as currently drafted. The current practices of some health insurers are inconsistent with the clinical recommendations maintained by HHS and create barriers to necessary treatment. These actions are outside the realm of "reasonable medical management" and are discriminatory.

The DOBI must not permit any insurers or HMOs that perpetuate these actions and policies to have their plans sold on the marketplace and/or otherwise ensure that they cease to discriminate and comply with these federal laws. By implementing R074-14, the DOBI would take an important step to make clear to all insurers that these practices will not be tolerated.

Should you have any questions about these recommendations, please do not hesitate to contact the HHCAWG co-chairs, Robert Greenwald (Treatment Access Expansion Project) at rgreenwa@law.harvard.edu: Amy Killelea (National Alliance of State and Territorial AIDS Directors) at Akillelea@nastad.org; or Andrea Weddle (HIV Medicine Association) at aweddle@idsociety.org.

Respectfully submitted by the HIV Health Care Access Working Group Steering Committee,

AIDS Action Baltimore | AIDS Action Committee of MA | AIDS Alliance for Women, Infants, Children, Youth & Families | AIDS Foundation of Chicago | The AIDS Institute | AIDS Project Los Angeles | AIDS Treatment Data Network | AIDS United | American Academy of HIV Medicine | Association of Nurses in AIDS Care | Community Access National Network | Communities Advocating Emergency AIDS Relief (CAEAR) Coalition | Gay Men's Health Crisis | Georgia AIDS Coalition | Harlem United | Health and Disability Advocates | HealthHIV | HIVictorious, Inc. | HIV Medicine Association | HIV Prevention Justice Alliance | Housing Works | L.A. Gay & Lesbian Center | Moveable Feast | National Alliance of State and Territorial AIDS Directors | National Minority AIDS Council | The National Working Positive Coalition| Project Inform | San Francisco AIDS Foundation | South Carolina Campaign to End AIDS| Treatment Access Expansion Project | Treatment Action Group | VillageCare

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[i] ACA §1311(c)(1)(A)(i); 45 CFR §156.125, 45 CFR §156.200 (e), 45 CFR §156.225, and 45 CFR § 147.104(e); see also ACA §1557(a).

[ii] *E.g., Bragdon*, 524 U.S. at 630-647 (1998) (ADA); *Doe v. County of Centre, Pa.*, 242 F.3d 437, 447 (3d Cir. 2001) (Rehabilitation Act); *Chalk v. United States Dist. Ct.*, 840 F.2d 701, 704-709 (9th Cir. 1988) (Rehabilitation Act).

[iii] US Dep't of Health and Human Servs., *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* (last updated Feb. 12, 2014).
[iv] *See* HHS Guidelines at A-I to A-2.
[v] HHS Guidelines at F-4.
[vi] Denis H. Osmond, *Epodemiology of HIV in the United States*, at Table 3 (2003)
[vii] HHS Guidelines at E-4 ("The expanded use of ART to treat individuals with CD4 counts >500 cells/$mm^3$ has also demonstrated public health benefits . . . because the risk of HIV transmission is associated with level of viremia, from a public health standpoint, this reduction in community viral load can potentially reduce new HIV infections at the community level.").
[viii] D. Donnell, et al., *Heterosexual HIV-1 Transmission After Initiation of Antiretroviral Therapy: A Prospective Cohort Analysis*, 375 Lancet 2092, 2095 (Jun. 2010) ("ART use by HIV-1 infected participants was associated with a 92% reduction in risk of transmission"); *see also* HHS Guidelines at A-1 ("[E]ffective treatment of HIV-infected individuals with ART is highly effective at preventing transmission to sexual partners.") & E-1 ("[H]igh plasma HIV RNA is a major risk factor for HIV transmission and use of effective ART can reduce viremia and transmission of HIV to sexual partners.").
[ix] HHS Guidelines at I-20 ("In pregnant women, an additional goal of therapy is prevention of perinatal transmission of HIV with a goal of maximal viral suppression to reduce the risk of transmission of HIV to the fetus and newborn . . . .").
[x] HHS Guidelines at i-ii ("Antiretroviral therapy (ART) is recommended for all HIV-infected individuals to reduce the risk of disease progression . . . ," including patients with a CD4 cell count >500/$mm^3$. "The recommendation for initiation of ART in patients with early infection" is "'should be offered' . . . .").
[xi] HHS Guidelines at E-1 ("[Delaying treatment causes] cardiovascular disease (CVD), kidney disease, liver disease, neurologic complications, and malignancies.").
[xii] HHS Guidelines at H-4 ("Persistent HIV RNA levels >200 copies/mL often are associated with evidence of viral evolution and drug resistance mutation accumulation; this is particularly common when HIV RNA levels are >500 copies/mL.") (footnotes omitted), D-1 ("Maximal and durable suppression of plasma viremia delays or prevents the selection of drug-resistance mutations, preserves CD4 T-cell numbers, and confers substantial clinical benefits, all of which are important treatment goals."), & C-10 ("Transmission of drug-resistant HIV strains is well documented and associated with suboptimal virologic response to initial antiretroviral therapy (ART).").
[xiii] HHS Guidelines at H-1 ("Discontinuing or briefly interruption therapy in a patient with viremia may lead to a rapid incase in HIV RNA and a decrease I nCD4 cell could and increase the risk of clinical progression") D-2 (Suboptimal adherence may result in reduced treatment response") & I-5 ("A large randomized controlled trial of patient with chronic HIV infection found that treatment interruption was harmful in terms of increased risk of AIDS and non-AIDS events).
[xiv] HHS Guidelines at D-2 ("Regimens should be tailored for the individual patient to enhance adherence and thus improve long term treatment success. Individual regimen choice is based on such considerations as expected side effects, convenience, comorbidities, interactions with concomitant medications, and results of pretreatment genotypic drug-resistance testing.").
[xv] HHS Guidelines at H-2 (listing potential causes of virologic failure).
[xvi] HHS Guidelines at H-4 ("Once virologic failure is confirmed, generally the regimen should be changed as soon as possible to avoid progressive accumulation of resistance mutations."), & D-1 ("When initial suppression is not achieved or is lost, rapidly changing to a new regimen with at least two active drugs is required.").
[xvii] 45 CFR 150.201; see also Fed. Registrar Vol. 78, No. 37 at 12847 (Feb. 25, 2013).
[xviii] While HHS has clarified that the anti-discrimination provisions are not meant to prevent the implementation of "reasonable medical management" techniques such as prior authorization, "an issuer . . .could not [for example] implement prior authorization in a manner that discriminates on the basis of membership in a particular group based on factors such as…disability…that are not based on nationally recognized, clinically appropriate standards of medical practice evidence or not medically indicated and evidence based." Fed. Registrar Vol. 78, No. 37 at 12847 (Feb. 25, 2013)

Nevada Association of Health Plans



**VIA ELECTRONIC MAIL ONLY**

November 4, 2014

Adam Plain
Insurance Regulation Liaison
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706
Aplain@doi.nv.gov

**RE: LCB File No. R074-14: Prescription Drug Formularies Proposed Rule - Oppose**

Dear Mr. Plain:

On behalf of the Nevada Association of Health Plans ("NvAHP"), I write in opposition to the proposed rule regulating the development of our health plan formularies (LCB File No. R074-14). NAHP opposes the proposed regulations on the basis that the citations cited as authority fail to establish the Department of Insurance ("DOI") has the authority to preclude changes to formularies without prior review and approval. NvAHP respectfully requests that, prior to promulgating final regulations, the DOI provide the Nevada citations under which the authority to do so is enabled. To the extent the Department cannot provide citations that establish the DOI has such authority, NvAHP opposes the proposed regulations for the reasons described herein.

I. The Department Has Yet to Identify Statutory Authority That Shows It May Regulate Prescription Formularies

The Department cites numerous code sections in the proposed regulations as apparent authority: *§ 1, NRS 679B.130, NRS 687B.120, and NRS 689A.710; § 2, NRS 679B.130, NRS 687B.130, NRS 687B.120 and NRS 689C.203; § 3, NRS 679B.130 and NRS 687B.120.* A copy of these statutes, as well as additional authority is attached to this response. The statutes cited under the proposed regulations tend to provide the DOI with authority to issue regulations to enforce state and federal law; and, review and approve forms. In addition, the DOI cites the statutory prohibition on prohibited trade practices, presumably because the intent of the proposed regulations is aimed at limiting the possibility of prohibited trade practice occurring.

Notably, none of the statutes cited as authority clearly provide the DOI with the authority to regulate changes to formularies. Indeed, state law appears limited to ensuring that insurers comply with notice requirements; *see NRS 689A.405 and NRS 689C.281.* None of the statutes in which the word "formulary" appears in Nevada's Code are cited by the Department as

authority, presumably because these statutes do not provide authority to issue the proposed regulations. *See also NRS § 689A.0404; NRS 689B.0365.*

II. The DOI's Authority to Regulate Formularies Must be Consistent with Authority Provided Under State law

With respect to the proposed regulations, NvAHP has identified no statutes that grant authority to the DOI to review and approve changes to formularies. NvAHP understands that, historically, the DOI has not interpreted its enabling statutes to grant authority to review and approve changes of formularies.

As the DOI may be aware, "in every instance, the power to adopt regulations to carry out a particular function is limited by the terms and grant of authority pursuant to which the function was assigned." *See NRS 233B.040.* "A regulation shall not extend, modify or conflict with any law of this state or the reasonable implications thereof." *See Division of Ins. v. State Farm Mut. Auto. Ins. Co., 116 Nev. 290, 294 (Nev. 2000.)*

NvAHP's review of state statutes indicates that the legislature intended and allowed insurers to include or exclude drugs, without prior review and approval. Specifically, state statutes require only that insurers: (1) disclose whether a formulary is used; (2) provide an explanation of how often contents of formulary are reviewed; (3) specify the procedure and criteria for determining which prescription drugs are included and excluded; and, (4) provide a telephone number whereby an insured may request additional information about the formulary. *See e.g. NRS § 689A.405.* If a formulary is used, state law requires that: (1) Information regarding whether a specific drug is included in the formulary; and (2) the insurer provide access to the most recent list of drugs in the formulary. *Id.*

The plain language of these requirements clearly states that insurers may include or exclude medications on a formulary. Notably lacking from these requirements is any suggestion that the list of specific drugs, or changes thereto, be reviewed and approved prior to use. As such, the legislature's intent under state law would be rendered meaningless by the proposed regulations.

Moreover, the proposed regulations appear to state that the justification for proposing the regulations is to address a federal loop-hole or absence of federal regulation, rather than enforce state law. The proposed regulations state:

> 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. 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.

(Emphasis added) *See LCB File No. R074-14 at 16*.

The absence of federal law or regulation, however, is not a grant of authority or a basis upon which the DOI may promulgate regulations. Instead, the DOI's authority to promulgate regulations is limited to administering state law or as required to ensure compliance with federal law or regulation. *See NRS 679B.130*. In this case, the proposed regulations conflict with state law as changes to formularies are permitted so long as an insurer complies with *NRS 689A.405*. No federal law exists that provides authority to regulate formularies as prescribed by the proposed regulations, therefore there is no preemption of *NRS 689A.405. See LCB File No. R074-14 at 6.*

III. State Statutes Prohibiting Unfair Trade Practices Do Not Grant Authority to Review and Approve Formulary Changes

State statutes prohibiting unfair trade practices, by their plain terms, do not grant authority to review and approve formulary changes. *See e.g. NRS 689A.710*. The word formulary is not even used. Though the DOI suggests that a change to a formulary could be characterized as an unfair trade practice, it's clear that a change to a formulary, by itself, does not constitute an unfair trade practice. Just because an insurer makes a change to a formulary does not mean that the change is intended to discourage an applicant to enroll because of health status. It is questionable at best whether the DOI could penalize an insurer for simply making a change to a formulary. In any event, the *NRS 689A.710* provides the DOI with only the following enforcement mechanism, which does not include reviewing and approving changes prior to use:

> **NRS 686A.160 Enforcement: Prohibited practices.** If the Commissioner has cause to believe that any person has been engaged or is engaging, in this state, in any unfair method of competition or any unfair or deceptive act or practice prohibited by NRS 686A.010 to 686A.310, inclusive, and that a proceeding by the Commissioner in respect thereto would be in the interest of the public, the Commissioner may issue and serve upon such person a statement of the charges and a notice of the hearing to be held thereon. The statement of charges and notice of hearing shall comply with the requirements of NRS 679B.320 and shall be served upon such person directly or by certified or registered mail, return receipt requested.

Therefore, the DOI appears to be assuming authority that is not granted under state law to close what it views as a federal loop-hole. Under such a basis it is difficult to imagine the limits of such authority, and for this reason we must object.

IV. The DOI's Authority to Review and Approve Forms Does not Extend to Formularies

State law does not expressly grant authority to review and approve formularies and, historically, the DOI has not required that changes to formularies be filed and approved before use. *See e.g. NRS 687B.120.* The word formulary isn't used. Clearly, state statutes using the term "formulary" do not contemplate that changes are subject to filing and approval before use. *See e.g. NRS 687B.120.* Moreover, state law expressly limits the DOI's review to ensuring the criteria specified under *NRS 689A.405* and *687B.120* are met.

Therefore, the DOI appears to be assuming authority that is not granted under state law to close what it views as a federal loop-hole. Under such a basis it is difficult to imagine the limits of such authority, and for this reason we must object.

V. Federal Guidance

As stated in the proposed regulations, even federal guidance does not support the notion that changes to formularies amount to changes to plan designs requiring filing and approval. Although federal guidance currently "limits insurers' ability to make health insurance plan design changes during the calendar year . . . 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." *See LCB File No. R074-14 at 16.*

Although the DOI refers to such federal guidance as establishing a "loop-hole," it mischaracterizes the nature of the issue. Other than the DOI's stated opinion, there is no evidence to suggest federal regulators failed to consider the implications of permitting insurers from making changes to formularies without prior approval from state regulators. To the contrary, federal guidance suggests that review and approval of formularies should be limited to ensuring that the quantity of drugs is sufficient, and state regulators should continue to apply state law that permits changes to formularies without prior review and approval.

It is highly concerning the DOI has proposed promulgating regulations in order to close "loop holes" in federal regulations, especially because the state of Nevada has not clearly acted to grant the DOI authority to do so. In this instance, it seems clear the DOI is interpreting long standing Nevada laws, which bear little resemblance to the proposed regulations and under which final regulations have previously been promulgated, in order to close what it has determined to be a federal loop hole. It's particularly telling the DOI does not propose to amend the regulations that have previously been promulgated under the cited statutes, but instead proposes to promulgate an entirely new section of code.

Under such a basis it is difficult to image the limits of such authority and for this reason we must object.

VI. NvAHP Respectfully Requests that the DOI Promulgate the Proposed Regulations Only If the Authority to Do So is Clearly Prescribed Under State or Federal Law

While we understand the DOI's well-meaning intentions, its authority to promulgate regulations is limited to the authority granted to it by the state of Nevada. In this case, we believe that the

Department's cited authority is questionable at best. NvAHP respectfully requests that, prior to promulgating final regulations, the DOI provide the Nevada citations under which the authority to do so is enabled. To the extent the Department cannot provide citations that establish the DOI has such authority, NvAHP opposes the proposed regulations for the reasons described herein.

Respectfully submitted,

Mike Murphy

Mike Murphy, *President*

**NVAHP Members:**
**Anthem Blue Cross and Blue Shield Nevada**
**Health Plan Nevada**
**Prominence Health**

**America's Health Insurance Plans**

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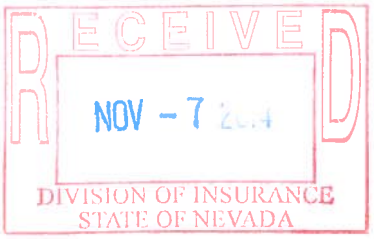


November 5, 2014

Adam Plain
Insurance Regulation Liaison
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

**Re: LCB File No. R074-14: Prescription Drug Formularies Proposed Rule**

Dear Mr. Plain,

I write today on behalf of America's Health Insurance Plans (AHIP) to provide comments on the Nevada Division of Insurance's proposed rules on prescription drug formularies.

AHIP is the national trade association representing the health insurance industry. AHIP's members provide health and supplemental benefits to more than 200 million Americans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid. Our members offer a broad range of health insurance products in the commercial marketplace and also have demonstrated a strong commitment to participation in public programs. Health plans have been committed to providing consumers with affordable products that offer robust networks of quality, cost-efficient providers.

AHIP acknowledges and appreciates the important revisions and considerations that the Division has made to the proposed regulations thus far based on comments received. However, we continue to be concerned that the proposed regulation tries to create a solution for which there is no problem. Additionally, we believe the Division's approach in this proposal is inconsistent with the intent of the statute; and actually establishes policy that extends beyond the authority of the Division as established by Nevada case law.

As the Commissioner continues to consider comments, we offer the following specific concerns.

The proposal continues to severely restrict health plans' abilities to manage prescription drug formularies in a cost effective and consumer focused way. Formularies developed based on scientific evidence and clinical standards are changed throughout formulary development process, based on clinical evidence, warnings, the release of new prescription drugs, or when drugs are pulled from the market by the FDA. Restricting the ability of health plans to make formulary changes to only one time per year, would be detrimental not only to potential cost savings for consumers and employer groups, but also to quality care based on clinical evidence,

and the consumer protections based on plans taking actions in formularies to address new adverse drug interactions or FDA notices.

If the problem the Division seeks to resolve is continuity of the care for consumers, Nevada law *(NRS 689B.0368)* already provides for continuity of care for prescription drugs. Thus, the proposed changes to existing formulary processes are not needed.

Another key point is the Division's definition of generic drug alternatives in Sections 1(6) and 3(6) - which is incorrect. Neither biosimilar drugs nor bioequivalent drugs are generic drugs. Generic drugs are chemically identical to the brand name drug. Biosimilars are made with live cells, so they can never be identical to the biologic brand. Biosimilars can be determined interchangeable by the FDA but they should not be classified as generics in this manner. Further, it is premature to address biosimilars at this time due to the fact that none have yet been approved by the FDA for use in the United States.

Finally, we continue to voice our overarching concern that the provisions contained in this proposed regulation do nothing to address the underlying issue of exorbitant pharmaceutical costs facing our entire health care system. And worse, this proposal could impair health plans' abilities to make important prescription drug benefits affordable for consumers. While many breakthrough drugs are coming into the market, giving the hope of living longer and healthier lives, these drugs come at a cost that threatens the sustainability of the overall health care system. The real question that needs to be addressed is whether prices are being charged for some new drugs are rational and allow people access to the innovative medications.

We look forward to continued discussions with you on this important issue. If you have any questions, please do not hesitate to contact me at gcampbell@ahip.org (971-599-5379).

Sincerely,

Grace Campbell

Grace Campbell
Regional Director

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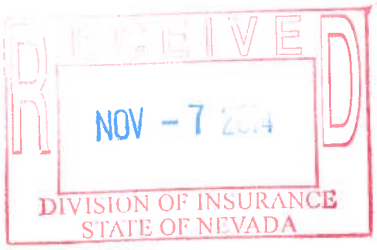
Cynthia M. Laubacher
Senior Director, State Affairs
(916) 771-3328

November 5, 2014




The Honorable Scott J. Kipper
Commissioner
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706

Attn: Adam Plain, Insurance Regulation Liaison

Re: Comments: LCB File No. R074-14: Prescription Drug Formularies

Dear Mr. Plain:

I am writing to share our concerns with the draft regulation regarding prescription drug formularies. The proposed regulation is unnecessary and the most recent draft contains confusing and ambiguous provisions that will create chaos for plans and patients.

Express Scripts provides integrated pharmacy benefit management services on behalf of our plan sponsors – employers, health plans, unions and government health programs. Our services include formulary management, pharmacy claims processing, home delivery, specialty benefit management, benefit-design consultation, drug-utilization review, medical and drug data analysis services, as well as extensive cost-management and patient-care services for over 85 million Americans.

This is a regulation in search of a problem. Every plan has a formulary exceptions process to ensure patients have access to drugs if they are not available on a formulary. Additionally, state and federal laws already regulate formularies extensively, including changes to those formularies. Nevada Revised Statutes Chapter 689B.0368 provides for continuity of care should a plan delete a drug from the formulary.

Second, under the ACA, effective September 23, 2012, a mid-year change to a plan, as outlined in the summary of benefits provided at the start of the plan year, triggers a 60-day notice to plan members prior to the effective date of the change. [1] This requirement provides patients

[1] Federal Register, Vol. 77, No. 40 Tuesday, February 30, 2012. Page 8677, B. Notice of Modification

and prescribers with ample time to make any necessary adjustments or pursue continued coverage available through the plan's exceptions process.

**Section 2(b)**

This section states that "Except as allowed by the Commissioner, the insurer must submit to the Commissioner an informational plan to mitigate the effect on consumers of removing the drug from the formulary within 72 hours of the removal..." This gives the Commissioner undefined authority that makes it impossible to know whether a mitigation plan will actually be required and under what circumstances. Will insurers be expected to consult with the Commissioner prior to submitting their mitigation plan in order to determine whether it will be, in fact, required? Upon what basis will the Commissioner have authority to override this requirement? This will create confusion, chaos and an untenable situation for both the Commissioner and insurers.

**Section 3.**

This section states an insurer must comply with 45 C.F.R. Section 156.122(a). The regulation fails to reference the remainder of that section, which is listed below, which renders this draft regulation unnecessary:

> 156.122 (c) A health plan providing essential health benefits must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan.

Thus, if a drug is deleted mid-year, plans are already required to have an exceptions process in place to ensure patients have access to necessary medications, regardless of whether the medication is on the formulary.

**Section 4.**

The language requires the filing of a mitigation plan when a drug is deleted from a formulary, within 72 hours of the deletion. Yet federal law, with limited exceptions, requires plans to provide patients with 60 day notice of a plan change. This proposed requirement thus creates an unnecessary additional reporting burden on plans for no apparent reason. Is it the intent of the Commissioner to have authority to approve or disapprove a plan? If so, on what basis?

**Sections 5, 6 and 7.**

We appreciate your attempt to address our concern with prior versions of the regulation that would prevent us from adding generics when they become available. However, the current language is confusing and unnecessarily complicated.

As a pharmacy benefit manager, we typically make changes twice a year; at the start of the plan year and on July 1st. However, new drugs can come to market at any time. For instance, the extremely expensive drug Sovaldi (which is used to treat Hepatitis C) is expected to have competition in early 2015. Under this rule, we would be prohibited from using the formulary to incentivize patients to use the less expensive drug by moving Sovaldi to a higher tier or

deleting it altogether. We firmly believe this flexibility is necessary to help control costs for plan sponsors and their members.

For these reasons, we respectfully oppose adoption of this draft regulation, as it will serve only to protect pharmaceutical company market share while increasing prescription drug costs for plan sponsors and their members.

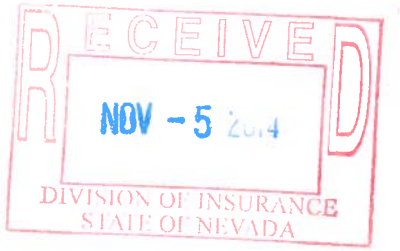
Sincerely,

Cynthia Laubacher

CYTNHIA M. LAUBACHER
Senior Director, State Affairs

PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

November 5, 2014




Submitted via email to: aplain@doi.nv.gov

The Honorable Scott J. Kipper
Commissioner
Department of Business and Industry
Nevada Division of Insurance
1818 E. College Parkway
Suite 103
Carson City, NV 89706

Re: LCB File No. R074-14 – Prescription Drug Formularies

Dear Commissioner Kipper:

The Pharmaceutical Care Management Association (PCMA) is submitting the following comments to express our concern with the proposed prescription drug formulary regulation (LCB File No. R074-14). PCMA is the national trade association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 216 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D. PCMA believes the proposed regulation is unnecessary because current law already addresses the issue of protecting patients from losing coverage of a drug if it is removed from a plan's formulary during the plan year.

Prescription drug formularies are the foundation of tools utilized by plan sponsors, including the state of Nevada, to manage ever-increasing prescription drug costs. Formularies are designed to take into consideration medical, scientific, and cost-effectiveness data in order to provide the best value to patients and employers. Existing Nevada law already provides protection for patients regarding coverage of their prescription drugs. Specifically, Nev. Rev. Stat. Ann. § 689A.04045 (Individual Health Insurance) states:

> 1. Except as otherwise provided in this section, a policy of health insurance which provides coverage for prescription drugs must not limit or exclude coverage for a drug if the drug:
> (a) Had previously been approved for coverage by the insurer for a medical condition of an insured and the insured's provider of health care determines, after conducting a reasonable investigation, that none of the drugs which are otherwise currently approved for coverage are medically appropriate for the insured; and
> (b) Is appropriately prescribed and considered safe and effective for treating the medical condition of the insured.
> 2. The provisions of subsection 1 do not:
> (a) Apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the Food and Drug Administration;
> (b) Prohibit:
> (1) The insurer from charging a deductible, copayment or coinsurance for the provision of benefits for prescription drugs to the insured or from establishing, by contract, limitations on

the maximum coverage for prescription drugs;

(2) A provider of health care from prescribing another drug covered by the policy that is medically appropriate for the insured; or

(3) The substitution of another drug pursuant to NRS 639.23286 or 639.2583 to 639.2597, inclusive; or

(c) Require any coverage for a drug after the term of the policy.

3. Any provision of a policy subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after October 1, 2001, which is in conflict with this section is void.[1]

This current law already accomplishes in a cleaner and more streamlined manner what the proposed regulation is attempting to do. Therefore, additional rules on this issue are unnecessary because health insurers are already restricted in Nevada from limiting or excluding coverage of drugs on a formulary. The proposed regulation only creates confusion and needless administrative burdens.

Additionally, the proposed regulation as drafted prohibits the removal of brand drugs from the formulary unless certain conditions are met. This prohibition would prevent a health plan or PBM from removing a brand drug from the formulary and replacing it with another brand drug that a PBM's Pharmacy and Therapeutics (P&T) Committee may have recently reviewed and found to be more effective and less expensive than the drug currently on the formulary. PBMs rely on P&T Committees staffed by independent doctors, nurses, pharmacists, and academics who specialize in specific fields of medicine to develop evidence-based guidelines that are used in drug management programs. These guidelines are based on the latest clinical literature, standards of practice, expert consultation, and outcomes data. The P&T Committee takes on the complex task of evaluating thousands of competing drugs in terms of safety, cost, and clinical efficacy in order to provide recommendations to health plans and employers regarding formulary placement and coverage. The proposed regulation forces employers and plan sponsors to keep potentially less effective, more expensive drugs on their formularies until the end of the policy year. Brand manufacturers stand to benefit significantly from this proposed regulation while Nevada patients will unfairly bear the weight of the cost.

We believe this proposed regulation is unnecessary given current Nevada law as stated above. We are concerned that it will limit the appropriate functions of formularies and increase health care costs, while providing no additional improvement in patient care since there are already protections in place in Nevada. We appreciate your consideration of our comments. If you should have any questions, please do not hesitate to contact me.

Sincerely,

Barbara A. Levy
Vice President and General Counsel

[1] *See also* Nev. Rev. Stat. Ann. §§ 689B.0368 (Group and Blanket Health Insurance), 689C.168 (Health Insurance for Small Employers), 695A.184 (Fraternal Benefit Societies), 695B.1905 (Nonprofit Corporations for Hospital, Medical and Dental Service), 695C.1734 (HMOs), 695F.156 (Prepaid Limited Health Organizations), 695G.166 (Managed Care) (2014).

PhRMA
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November 5, 2014



The Honorable Scott Kipper, Commissioner
Nevada Division of Insurance
1818 East College Parkway, Suite 103
Carson City, Nevada 89706

Re: Proposed Amendment to LCB File Number R074-14, Prescription Drug Formularies

Dear Commissioner Kipper,

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the Nevada Division of Insurance Proposed Regulation of the Commissioner LCB File Number R074-14 which seeks to prohibit certain health insurers that provide coverage for prescription drugs from making changes to the formulary after its approval by the Commissioner of Insurance. As we expressed in an earlier support statement, this regulation provides crucial protections to patients by helping to ensure that a plan cannot remove a drug from the formulary or impose greater cost-sharing on a drug than was set forth in the formulary made available at open enrollment, except for in specified circumstances.

PhRMA is a voluntary, non-profit organization representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA members are committed to finding tomorrow's cures and treatments for some of the most serious diseases. New medicines are an integral part of the healthcare system, providing doctors and their patients with safe and effective treatment options, extending and improving quality of life. PhRMA companies spent an estimated $51 billion in 2013 to discover and develop new medicines.

PhRMA applauds the Commissioner of Insurance's clear recognition of the importance of continuity of care and the negative effect that mid-year formulary changes can have on patients undergoing a course of treatment. The proposed regulation would prohibit certain health insurers from removing a prescription drug from the formulary or moving a prescription drug to a tier with a larger deductible, copayment, or coinsurance after the formulary is approved by the Commissioner except for in specified circumstances. We thank the Division of Insurance for including this important patient protection in regulation.

PhRMA respectfully requests the Division amend the rule by changing "generic drug alternative" in paragraph 5 in Sections 1 and 3 to "generic therapeutic equivalent" to be consistent with the Orange Book. Additionally, PhRMA requests striking paragraphs 6(a) and 6(b) in Section 1 and 3 which reference biosimilar and bioequivalent drugs. Biosimilars and interchangeable biologics will never be considered generic therapeutic equivalent. Due to the complex structure of biologics, biosimilars must be shown to the "highly similar to" but not the "same as" an

innovator biologic in terms of structural characteristics. It is not appropriate to define biosimilars and interchangeable biologics as generic therapeutic equivalent. Doing so may confuse providers, pharmacists, and patients. With that in mind, we respectfully oppose the inclusion of this language and request the Division remove paragraphs 6(a) and 6(b) from both sections of the rule to limit confusion and ensure safety.

This rule is an important step towards ensuring Nevada enrollees have access to affordable, medically necessary drugs through their insurers. We thank you in advance for considering our recommendations. Please let us know if you need additional information.

Sincerely,

Marissa Watkins

Marissa Watkins
Director
PhRMA State Advocacy

Anthem

9133 W Russell Road
Las Vegas, NV 89148



**VIA ELECTRONIC MAIL ONLY**

November 7, 2014~~November 5, 2014~~

Adam Plain
Insurance Regulation Liaison
Department of Business and Industry
Division of Insurance
1818 East College Parkway, Suite 103
Carson City, NV 89706
Aplain@doi.nv.gov

**RE: LCB File No. R074-14: Prescription Drug Formularies Proposed Rule - Oppose**

Dear Mr. Plain

On behalf of Anthem Blue Cross and Blue Shield of Nevada, I must write in opposition to the recent proposed rule regulating the development of our health plan formularies (LCB File No. R074-14). Anthem Blue Cross and Blue Shield of Nevada (Anthem) is one of the state's largest health benefits companies serving more than one-quarter of a million Nevadans. Our membership includes enrollees in the individual and group markets and combined with our Amerigroup membership family we are proud to be the State's largest partner in serving low-income and high-risk members throughout the State.

At a time when the shared goals of issuers and the state government should be primarily focused on the implementation of health care reform and improving access to health care coverage for all Nevadans, we believe this proposed regulation serves as an unwarranted distraction for the following reasons:

**Creates New Regulatory Burdens Leading to Costly Consumer Consequences**

At the federal level, our nationally-branded WellPoint subsidiary has sought public policy solutions that seek to mitigate the relentless trend of increasingly rising drug prices. Working alongside various industry and government partners we have pushed for greater transparency in the Federal Food and Drug Administration's (FDA) new Breakthrough Therapy Designation and we have sought solutions for state Medicaid agencies to ensure proper coverage reimbursement. Requiring Anthem and other health plans to make changes to their formularies on only an annual basis would prohibit consumers from receiving potentially needed medications as they become available while severely restricting our ability to provide enhanced medical management of prescription drug formularies in a cost effective and consumer focused way. From a cost perspective, these types of misguided regulatory solutions simply disguise the true consumer cost by shifting the cost of the coverage of these drugs to beneficiaries.

As an example, while the stated goal of this regulation generally prohibits certain insurers from: (1) removing a drug from the formulary; or (2) reclassifying the drug in the formulary to make a different deductible, copayment or coinsurance amount applicable to the drug, we note that the end result of these proposed changes will not successfully shield consumers from the problem of high cost drugs. Even if initial costs to the member were shielded for chronic higher-tiered specialty drug users, members will subsequently experience greater costs for their health care coverage in the form of higher premiums and

Anthem

copayments due to the increased cost and complexity in providing for medical and outpatient prescription drug benefits.

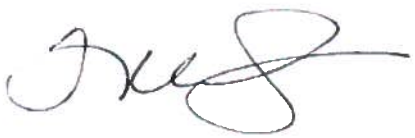
**Needlessly Usurps Existing Health Plan Policies and Established Federal Protections**

Most importantly, by attempting to clarify the conditions under which Anthem and other health plans may remove drugs from their formulary, the department fails to consider existing health plan policies regarding formulary developments which are fully intended to pro-actively limit the costs incurred by the consumer. One such circumstance occurs when generic equivalents are introduced into the market. When such generics enter the market, we agree with the recent modifications to the regulations allowing health plans to move these drugs to formularies with higher cost sharing. However, per current plan policy, plans should also be allowed the option to remove the more expensive brand name drug from the formulary in an effort to make the more cost effective generic available to members as coverage of both the brand and the generic is unnecessary since the active ingredients (and efficacy) of the drugs are comparable . In these instances the brand name drug is being replaced with a generic equivalent (including biosimilars and bioequivalent drugs). Anthem Blue Cross and Blue Shield plans have established a very detailed communication strategy to notify our members of this benefit change on the formulary alerting our members when corresponding generics are now an available alternative. Continuing to allow health plans to exercise this reasonable plan design option saves costs while ensuring continuity of care is provided to the member.

Additionally, many of these regulations are duplicative as the Affordable Care Act (ACA) establishes specific out-of-pocket (OOP) limits which already provide a level of cost protection for tiered pharmacy drugs. These limits - $6,400 for individuals and $12,800 for families in 2014 - apply to the combined total, prescription and medical out-of-pocket costs that members would have to pay under a health insurance plan.

In conclusion, as a solutions-focused health organization we continue to engage policymakers in seeking creative solutions that ensure greater pharmaceutical manufacturer transparency in light of unjustifiable trends in drug prices so that payers (including both the government and issuers) and consumers can more accurately forecast and understand the true drivers of recent drug costs. While we would welcome more discussion on the topic of drug costs, we believe the present proposed regulatory solution is both misplaced and burdensome, failing to account for the necessary detailed nuances of health plan formulary development. As such we must oppose these proposed regulations as issued.

Sincerely,



Tracey Woods
Senior Director, Government Relations

**Insurance Idea May Help Chronically Ill Nevadans**
By Linda Lott
Reno Gazette-Journal
November 11, 2014

Some Nevada health insurers have begun to implement new pricing practices that are putting the cost of medication beyond reach for vulnerable patient populations, including those living with chronic and life-threatening conditions such as multiple sclerosis, arthritis, cancer, lupus, HIV/AIDS, neuropathy and many others.

Currently, Nevada insurers are allowed to make midyear changes to their prescription drug formularies, including removing certain drugs from their formulary altogether, or moving medications to pricing tiers with larger deductibles, copayments or coinsurance. These arbitrary changes often mean that Nevada patients and their families are blindsided by hundreds or thousands of dollars in additional out-of-pocket costs every month.

Managing MS or any other chronic condition is an ongoing process, beginning with the very first symptom and continuing throughout the course of the disease. Patients and their physicians work together to find the best course of treatment for that individual patient. Doctors often prescribe multiple medications for patients living with chronic conditions. When insurers make changes to their formularies to make drugs unaffordable to patients, those patients often undertreat their conditions, or stop treating them altogether, which can jeopardize overall patient health.

For patients with chronic conditions, symptoms can be so severe that even simple day-to-day tasks can be difficult or impossible to carry out. Simple movements like getting out of bed, walking, and carrying bags can be problematic. For MS patients, overwhelming fatigue, weakness and balance problems make getting around dangerous. High out-of-pocket costs — particularly those that a patient was unable to plan for — compound health complications and force patients between taking life-sustaining medication and providing for their families.

Many patients select their insurance plan based on the coverage of specific medications, only to have the rug pulled from under them when insurers make midyear formulary changes.

Increases in patient out-of-pocket costs not only jeopardize the health of those patients directly affected, but also threaten the long-term economic viability of the state. Arbitrary insurance formulary changes lead to worsening health of patients, and declining health leads to unnecessary hospitals visits, emergency care and loss of employee productivity — and all Nevada taxpayers help foot the bill.

Fortunately for Nevada patients, some help may soon be on the way. The Nevada Insurance Commissioner on Wednesday Nov. 12 will consider a proposed regulation (R074-14) that would prohibit insurers from removing a prescription medication from a formulary or moving it to a tier with a larger patient cost burden after the formulary has been approved by the commissioner, except under very specific circumstances.

Changes in health plan requirements should mirror the annual enrollment cycle in order to ensure a patient's access to therapies and uninterrupted access to care. This common-sense step ensures that patients are not subjected to potentially dangerous midyear coverage changes while also allowing insurers to continue to manage costs.

The National Multiple Sclerosis Society along with dozens of local patient organizations urge the Nevada Insurance Commissioner to stand with patients living with chronic disabling, and life-threatening diseases and enact the proposed regulation. Ensuring continuity of care for vulnerable patient populations is an important step to help keep Nevadans healthy.

*Linda Lott is the Nevada Director for the National Multiple Sclerosis Society in Reno.*

http://www.rgj.com/story/opinion/columnists/2014/11/11/insurance-idea-may-help-chronically-nevadans/18884251