2025 HOUSE INDUSTRY, BUSINESS AND LABOR

HB 1216

2025 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Room JW327C, State Capitol

HB1216
1/27/2025

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; and to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans.

2:31 p.m. Chairman Warrey opened the meeting.

Members Present: Chairman Warrey, Vice Chairman Ostlie, Vice Chairman Johnson, Representatives Bahl, Brown, Christy, Finley-DeVille, Grindberg, Kasper, Koppelman, D. Ruby, Schatz, Schauer, Vollmer

Discussion Topics:

- Affordable medication
- Pharmaceutical profits
- Cost sharing assistance
- Coupons, discount cards
- Co-pay accumulators
- Bleeding disorders
- Payment not being tracked
- Out of pocket maximum

2:31 p.m. Representative Karen Karls, District 35, Bismarck ND, introduced, testified and submitted testimony #31852.

2:36 p.m. Karen Cossett, Bismarck, ND, testified in favor.

2:44 p.m. Emily Quellette. Executive Director, Bleeding Disorders Alliance of ND, testified in favor and submitted testimony #31451 and #31949

2:50 p.m. Lucy Laube, Government Relations Manager, National Psoriasis Foundation, testified in favor and submitted testimony #31799.

2:58 p.m. Bill Robie, Senior Director, State Government Relations, National Bleeding Disorders Foundation, testified in favor and submitted testimony #31312.

3:09 p.m. Pam Thompson, Development Director, Cystic Fibrosis Association of ND, testified in favor and submitted testimony #31743.

3:14 p.m. Alexander Kelsch, Lobbyist/Attorney, Kelsch Ruff Kranda Nagle & Ludwig representing Americas Health Insurance Plans (AHIP) testified in favor and submitted testimony #31694.

3:32 p.m. Megan Hruby, Vice President, Public Policy and Government Affairs, Blue Cross and Blue Shield of North Dakota, submitted testimony in opposition #31947.

3:47 p.m. Rebecca Fricke, Executive Director, NDPERS, testified as neutral and submitted testimony #31303.

3:55 p.m. Chrystal Bartuska, Division Director Life & Health, ND Insurance Department, testified as neutral.

Additional written testimony:
Nick Telesco, Specialists, State Advocacy, Dakota Oncology Society and Association for Clinical Oncology, submitted testimony in favor #30320. (1/21/25 original hearing testimony, postponed to 1/27/25)
Emily Stauffer, Associate Director of State Policy, EveryLife Foundation for Rare Diseases, submitted testimony in favor #31366
Eniola A. Soetan, Volunteer, American Cancer Society Cancer Action Network, submitted testimony in favor #31377.
Bobbie Will, Policy and Advocacy Manager, Susan G. Komen, submitted testimony in favor #31536.
Ben W. Hanson, Government Relations Director, American Cancer Society, Cancer Action Network, submitted testimony in favor #31782, #37015, and #37017.
Marcia Julson, Minot, ND, submitted testimony in favor #31573.
Michelle Mack, Pharmaceutical Care Management Association (PCMA), submitted testimony in favor #31612.
Emily McGann, Senior Director, State Advocacy, Pharmaceutical Research and Manufacturers of America, submitted testimony in favor #31686.
Sam Miller, Advocacy Associate, National Infusion Center Association, submitted testimony in favor #31726 and #31729.
Melissa N. Horn, State Government Affairs Director, Arthritis Foundation, submitted testimony in favor #31841.

3:55 p.m. Chairman Warrey closed the hearing.

Diane Lillis, Committee Clerk

ASCO®
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

January 20, 2025

Representative Jonathan Warrey, Chair
House Committee on Industry, Business, and Labor
600 East Boulevard Avenue
Room 327C
Bismarck, ND 58505

Dear Chair Warrey and Members of the House Committee on Industry, Business, and Labor,

The Dakota Oncology Society and Association for Clinical Oncology (ASCO) are pleased to support **HB 1216**, which would take steps to protect patients with cancer in North Dakota from co-pay accumulator programs.

The Dakota Oncology Society is a professional society representing healthcare professionals in North Dakota and South Dakota who specialize in oncology. ASCO is the world's leading professional society representing physicians who care for people with cancer. With over 50,000 members, our core mission is to ensure that cancer patients have meaningful access to high quality, equitable cancer care.

The Dakota Oncology Society and ASCO are committed to supporting policies that reduce cost while preserving quality of cancer care; however, it is critical that such policies be developed and implemented in a way that does not undermine patient access. Co-pay accumulator programs target specialty drugs for which manufacturers often provide co-pay assistance. With a co-pay accumulator program in place, a manufacturer's assistance no longer applies toward a patient's co-pay or out-of-pocket maximum. This policy means patients will experience increased out-of-pocket costs and take longer to reach required deductibles. By prohibiting these funds from counting toward patient premiums and deductibles, co-pay accumulators negate the intended benefit of patient assistance programs and remove a safety net for patients who need expensive specialty medications but cannot afford them.

Co-pay accumulator programs lack transparency and are often implemented without a patient's knowledge or full understanding of their new "benefit." Far from being beneficial, co-pay accumulator programs increase the financial burden for patients, many of whom are facing life-threatening illness. The impact is especially hard on low-income populations. Increasing patient cost can contribute to medical bankruptcy and cause patients to discontinue care, seek non-medical alternatives—or forego treatment altogether. The result is poorer health outcomes and greater cost to the system.

ASCO
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

The Dakota Oncology Society and ASCO are encouraged by the steps HB 1216 takes toward eliminating co-pay accumulator programs in North Dakota, and we strongly urge the committee to pass the measure. For a more detailed understanding of our policy recommendations on this issue, we invite you to read the ASCO Policy Brief on Co-Pay Accumulators by our affiliate, the American Society of Clinical Oncology. Please contact Nick Telesco at Nicholas.Telesco@asco.org if you have any questions or if we can be of assistance.

Sincerely,

Matthew Tinguely, MD
President
Dakota Oncology Society

Eric P. Winer, MD, FASCO
Chair of the Board
Association for Clinical Oncology

TESTIMONY OF REBECCA FRICKE

House Bill 1216 – Out-of-Pocket Expenses for Prescription Drugs

Good afternoon, Mr. Chair and members of the committee. My name is Rebecca Fricke and I am the Executive Director of the North Dakota Public Employees Retirement System, or NDPERS. I appreciate the committee taking the time to analyze House Bill 1216, which limits the maximum amount that an enrollee can be charged for prescription drugs. I am here today on behalf of the NDPERS Board to provide information in a neutral capacity so the policy makers are able to make an informed decision regarding the bill.

House Bill 1216 requires that when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement for a prescription drug under a health benefit plan, that it must include any amount paid by the enrollee, or on behalf of the enrollee by another person. The plan may not vary the out-of-pocket maximum or cost-sharing requirement, or otherwise design benefits in a manner that considers the availability of a cost-sharing assistance program for a prescription drug and stipulates that high-deductible health plans that qualify for health savings account are exempt from this cost-share limit until a member reaches their minimum deductible.

Our consultant estimates that the bill would have a financial impact on the NDPERS health insurance plan and estimates a 1.1% increase in premium, or $8,697,000, in the 2025-2027 biennium. The main driver of this additional premium is that under our current grandfathered health plan, copayments do not go towards meeting out-of-pocket maximums and this bill would require these copayments to go towards meeting the out-of-pocket maximum. The majority of NDPERS members participate in this plan.

House Bill 1216 was a bill introduced during the interim, with the analysis provided to the Employee Benefits Programs Committee, which gave the bill a favorable recommendation. The consultant analysis provided to the committee is included as an attachment to the end of my testimony (this was bill draft 68 during the interim).

Mr. Chair, I appreciate the committee taking the time to learn more about the impact this bill will have to our state. This concludes my testimony, and I'd be happy to answer any questions the committee may have.

Deloitte Consulting LLP
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USA

Tel: 612 397 4000

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Memo

Date: June 7, 2024

To: Rebecca Fricke - Executive Director, North Dakota Public Employees Retirement System

Representative Austen Schauer - Chair, Legislative Employee Benefits Programs Committee, North Dakota State Government

From: Tim Egan, Dan Plante, Ford Edgerton, and Karno Sarkar - Deloitte Consulting LLP

Subject: **FINANCIAL REVIEW OF PROPOSED BILL 25.0068.01000**

Deloitte Consulting LLP (Deloitte [i]) was engaged to review the proposed legislation and the potential financial impact to the Uniform Group Insurance Program (Program) administered by the North Dakota Public Employees Retirement System (NDPERS), as well as other considerations that may contribute to the evaluation of the legislation.

The information included in the review relies on data provided by NDPERS, as well as publicly available data and industry studies. From the data provided by NDPERS, some of these data sources were developed by NDPERS, while others were prepared or created by third parties and delivered to NDPERS.

As part of the review, all data was reviewed for reasonableness, but an audit was not performed on the data. To the extent the data contains errors or anomalies that were unknown at the time the data was provided, the analysis may be affected by those issues.

OVERVIEW OF PROPOSED BILL

The Bill creates and enacts a new section to chapter 26.1-36 of the North Dakota Century Code relating to out-of-pocket expenses for health care services. The legislation does the following:

- Defines "cost-sharing", "enrollee", "health benefit plan", and "prescription drug"
- Regulates that an insurer cannot offer a prescription drug plan unless all costs paid by a member or on behalf of a member accrue towards a member's out-of-pocket maximum calculations. This includes any amount paid by any cost-sharing assistance program
- Stipulates that high-deductible health plans that qualify for health savings accounts are exempt from this cost-share limit until a member reaches their minimum deductible

ESTIMATED FINANCIAL IMPACT

Based on the analysis, it is anticipated the proposed legislation will have a financial impact on the Uniform Group Insurance Program. It is estimated the financial impact of the proposed legislation on the Uniform Group Insurance Program is approximately $8,697,000 in the 2025-2027 biennium ending 6/30/2027.

The current health plans offered by the uniform group insurance program include a "grandfathered" health plan (PPO/Basic Grandfathered Plan) and two "non-grandfathered" health plans (PPO/Basic Non-Grandfathered Plan and High Deductible Health Plan (HDHP). A health insurance plan earns a "grandfathered" status under the Patient Protection and Affordable Care Act (PPACA) if it retains the plan provisions that existed at the time of PPACA's enactment in 2010. Consequently, "grandfathered" plans may not include certain plan provisions or consumer protections required by the PPACA for plans enacted or amended post-2010.

In the PPO/Basic Grandfathered Plan, an enrollee's pharmacy copayment currently does not accumulate towards their out-of-pocket maximum. The proposed Bill, however, seeks to revise this aspect, requiring that copayments count towards an enrollee's out-of-pocket maximum. It is anticipated this amendment would lead more enrollees to reach their out-of-pocket maximum, thus shifting any additional claim liability to the Uniform Group Insurance Program, which can lead to higher costs.

A majority of the active and pre-Medicare membership resides in the PPO/Basic Grandfathered plan and could be impacted by this change. The non-grandfathered plans already include copayments in the out-of-pocket maximum; as a result, there would be no anticipated change or financial impact to those plans.

The financial impact estimate is based on the expected change to the percentage of prescription drug claims paid by enrollees under the current plan design that does not include copayments in the out-of-pocket maximum and the proposed design (per the proposed Bill) that would include copayments in the out-of-pocket maximum.

The development of the estimated claims impact utilized an internal Medical Rate Model, which includes medical and pharmacy benefit designs and is based on over 40 million active/non-Medicare retiree claims. The Medical Rate Model functions as a claims repayment model, applying detailed input plan provisions against the claims record database, effectively repricing the claims, and producing the expected plan claim payments versus allowed charges.

As a result of the modeling, it is estimated the plan design changes required as a result of the proposed Bill would produce a 1.1% increase to the expected total costs paid by the Uniform Group Insurance Program. This anticipated change to the expected claims costs was applied to the estimated biennium claims cost for actives and pre-Medicare retirees enrolled in the PPO/Basic Grandfathered plan, as developed during the 2022 biennial renewal process and trended to the 2025-2027 biennium.

It is estimated the financial impact of the proposed legislation on the Uniform Group Insurance Program is approximately $8,697,000 in the 2025-2027 biennium ending 6/30/2027, assuming a 9.4% annual prescription drug trend.

OTHER CONSIDERATIONS

The proposed Bill defines "cost sharing" as any coinsurance, copayment, or deductible under the policy. There may be some payments that would meet the definition that are excluded from the out-of-pocket accumulation. Examples of such are:

- costs for a service or supply furnished by a Preferred Care Provider in excess of such provider's negotiated charge for that service or supply;
- costs related to not pursuing required prior authorization;
- costs for services and supplies determined to be not medically necessary, as determined by the Claims Administrator, for the diagnosis, care, or treatment of the disease or injury

involved. This applies even if they are prescribed, recommended, or approved by the person's attending physician or dentist;

- costs for care, treatment, services, or supplies that are not prescribed, recommended, or approved by the person's attending physician or dentist;

- costs to the extent they are not reasonable charges, as determined by the Claims Administrator

Since the definition of "cost sharing" includes the term "under a health benefit plan" it is assumed that member liabilities for non-covered services as described above would not be required to be included in the out-of-pocket accumulation, and therefore would not constitute a change or result in additional financial impact.

In general, changes to plan design provisions for grandfathered health plans results in the loss of grandfathered status. Since the proposed change increases the value of the PPO/Basic Grandfathered Plan, it would not forfeit its grandfathered status.

Another factor to consider when assessing the proposed Bill's financial impact is the role of cost-sharing assistance programs. A Prescription Drug Copayment Assistance Program is a type of patient assistance program designed to help patients afford the out-of-pocket costs associated with their prescription medications. These programs are typically funded by pharmaceutical companies or non-profit organizations. Examples of these assistance programs include GoodRx, SaveOn, WellRx, among others.

The estimated financial impact did include an estimate of expenses covered by copayment assistance programs, as their management falls outside the purview of the Program. According to the proposed legislation, costs absorbed by cost-sharing assistance programs will also contribute towards a member's prescription drug out-of-pocket maximum. Consequently, a member might experience reduced costs at the point of service when filling a prescription. However, this reduction would not affect the costs incurred by the Program.

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NATIONAL
BLEEDING DISORDERS
FOUNDATION
Formerly NHF

Innovate | Educate | Advocate

January 23, 2025

North Dakota House Industry, Business, and Labor Committee

RE: Committee Hearing on HB 1413

Dear Chairman Warrey and members of the Committee,

The National Bleeding Disorders Foundation (NBDF) is a national non-profit organization that represents individuals with bleeding disorders across the United States. Our mission is to ensure that individuals affected by hemophilia and other inherited bleeding disorders have timely access to quality medical care, therapies, and services, regardless of financial circumstances or place of residence. Please accept these comments in support of HB 1216 for the hearing record.

About Bleeding Disorders

Hemophilia is a rare, genetic bleeding disorder affecting about 20,000 Americans that impairs the ability of blood to clot properly. Without treatment, people with hemophilia bleed internally, sometimes due to trauma, but other times simply as a result of everyday activities. This bleeding can lead to severe joint damage and permanent disability, or even – with respect to bleeds in the head, throat, or abdomen – death. Related conditions include von Willebrand disease (VWD), another inherited bleeding disorder, which is estimated to affect more than three million Americans.

Patients with bleeding disorders have complex, lifelong medical needs. They depend on prescription medications (clotting factor or other new treatments) to treat or avoid painful bleeding episodes that can lead to advanced medical problems. Current treatment and care are highly effective and allow individuals to lead healthy and productive lives. However, this treatment is also extremely expensive, costing anywhere from $250,000 to $1 million or more annually, depending on the severity of the disorder and whether complications such as an inhibitor are present.

Importance of Financial Assistance to Patients

Many individuals with bleeding disorders rely on patient assistance programs to ensure access to their life-saving specialty drugs. And because patients with bleeding disorders require ongoing medication therapy for the course of their lifetimes, many such patients face the prospect of hitting their out-of-pocket maximum each and every year (in 2026, this will be $10,150 for an individual, or $20,300 for a family).[1] Copayment assistance programs play an essential role in mitigating this weighty financial burden – and allow patients to remain adherent to their prescribed treatment regimen, preserving their long-term health and thereby avoiding medical complications that could increase their overall health care spending.

Patients with bleeding disorders cannot select alternative treatments: no generic drugs exist for hemophilia or related conditions. The vast majority of copayment assistance programs are for drugs without generic alternatives. A recent University of Southern California Schaeffer Center analysis found that 71 out of 90 high-expenditure brand drugs that offered coupons had no generic equivalent. The analysis concludes, "these results suggest that most copay coupons are not affecting generic substitution, and many may help patients afford therapies without good alternatives. As such, the copay coupon landscape seems more nuanced, and proposals to restrict coupons should ensure that patients who currently rely on them are not harmed."[2]

In addition, all manufacturers of hemophilia specialty biologics offer copayment assistance programs; as a result, assistance for these products does not influence patients to use one product over another. To use the U.S. Department of Health and Human Services' own formulation from the federal 2021 Notice of Benefit Payment and Parameters (NBPP), hemophilia copay assistance programs do not "disincentivize a lower cost alternative" nor do they "distort the market."[3]

Copay Accumulator Adjustment Programs

Copay accumulator adjustment programs (CAAP) limit the utility of copayment assistance programs to consumers, by excluding the financial assistance from the calculation of a person's deductible and annual out-of-pocket maximum.

Consumers have little choice when it comes to evaluating health plans in advance for the existence of a CAAP. There is a distressing lack of transparency around plan implementation of CAAPs. Typically, language allowing a plan to implement a CAAP is buried deep in the contract, which can be difficult or impossible to find if you only have access to the marketing

materials on a health plan's web site. Manufacturers also are typically unaware of whether a patient's health plan has adopted an accumulator adjustment program. Moreover, individuals covered by a self-funded large group plan may find that their plan changes its policy on copay assistance midway through the plan year (this is problematic in its own right; it would also be unknown to the manufacturer).

Conclusion

The use of CAAPs dramatically increases patient out-of-pocket costs and threatens adherence to treatment for vulnerable individuals affected by serious health conditions. People who live with chronic conditions like bleeding disorders rely on access to quality care, and to accessible and affordable coverage to pay for that care. CAAPs place those patients at risk of being unable to pay for their life saving medication. HB 1216 places necessary and appropriate restrictions on the use of CAAPs by requiring insurers to count all contributions by or on behalf of an insured individual toward their annual cost-sharing requirement.

Thank you for considering our comments and making them part of the record. If you have any additional questions, or need any additional information, please contact Nathan Schaefer, NBDF Senior Vice President for Public Policy and Access (nschaefer@bleeding.org).

Sincerely,

Nathan Schaefer

[1] Since bleeding disorders are genetic conditions, there are many families that include more than one affected individual. These families may thus be subject to the family OOP maximum year after year – an unsustainable financial burden for almost any family. See, e.g., Jake Zuckerman, "A New Battle Between Insurers and Big Pharma is Costing Sick People Thousands," Ohio Capital Journal (Feb. 13, 2020), https://ohiocapitaljournal.com/2020/02/13/a-new-battle-between-insurers- and-big-pharma-is-costing-sick-people-thousands/.

[2] Van Nuys, et al. "A Perspective on Prescription Drug Copayment Coupons." USC Leonard D. Schaeffer Center for Health Policy and Economics (emphasis added), February 2018. Available online at: https://healthpolicy.usc.edu/wp-content/uploads/2018/02/2018.02_Prescription20Copay20Coupons20White20Paper_Final-2.pdf.

[3] 84 Fed. Reg. 17545.

January 24, 2025

North Dakota Legislative Branch
ATTN: House Industry, Business, and Labor Committee
600 E Boulevard Ave
Bismarck, ND 58505

Re: HB 1216 Relating to Out-of-Cost Expenses for Prescription Drugs

On behalf of the EveryLife Foundation for Rare Diseases, we are pleased to submit testimony in support of HB 1216. The EveryLife Foundation is a nonprofit, nonpartisan organization dedicated to empowering the rare disease patient community to advocate for impactful, science-driven legislation and policy that advances the equitable development of and access to lifesaving diagnoses, treatments, and cures.

It is estimated that over 30 million Americans live with one or more rare diseases that often result in burdensome medical, indirect, and non-medical expenses. Patients and families must navigate how to manage expenses from multiple inpatient and outpatient encounters, costs for prescription therapies and medical devices, and the support services that are critical for managing their health and well-being.

While 95% of rare diseases do not yet have an FDA-approved treatment, for those patients who do have an available therapy, cost-sharing assistance from drug manufacturers and patient assistance programs is an important factor in the ability to access life-alerting and life-saving treatments. Unfortunately, insurance companies are increasingly employing copay adjustment programs that prevent cost-sharing assistance from being applied to a patient's deductible or out-of-pocket maximum, removing the lifeline of cost-sharing assistance programs. HB 1216 would prevent insurers from using these programs to take advantage of North Dakota residents.

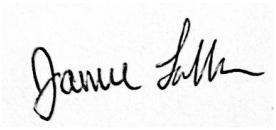
While copay adjustment programs can reduce costs for insurance companies, they leave patients with unexpected and unaffordable costs once their copay assistance is exhausted. In 2022, the EveryLife Foundation published The National Economic Burden of Rare Diseases in the United States, a study that examined the comprehensive economic impact of a subset of 379 rare diseases. The study found that the total economic impact of rare diseases in the US in 2019 was $997 billion; 60% of those costs were indirect and non-medical costs shouldered directly by families and society. Of the direct costs, inpatient care was the top driver of medical costs (~15%) while prescription medication was responsible for about 11% of medical costs.[1] With the proliferation of high deductible health plans, copay adjustment programs result in higher out-of-pocket costs for the frequent expert outpatient care that rare disease patients require as it takes longer for patients to satisfy the deductible and out-of-pocket maximum requirements.

[1] EveryLife Foundation for Rare Diseases. April 2022. The National Economic Burden of Rare Disease in the United States in 2019.

Copay adjustment programs eat into the already tight budget patients have, forcing some patients to take harmful actions, such as medicine rationing and prescription abandonment. An analysis by IQVIA showed that when patient costs reach $250, over 70% of new patients walk away from the pharmacy empty-handed, highlighting the direct connection between the rise in out-of-pocket costs and prescription abandonment.[2] Prescription abandonment is not an option for rare disease patients who are forced to incur considerable financial strain to maintain their prescription medicine costs.

Lowering the costs of health care is an important goal; however, insurance companies that use copay adjustment programs simply shift costs to patients while ultimately collecting up to double the amount of the patient's out-of-pocket requirements. Further exacerbating the tremendous out-of-pocket financial load families living with rare diseases are expected to bear.

Thank you again for the opportunity to testify in support of HB 1216. We are excited at the prospect of North Dakota joining the other states that have enacted similar legislation to protect patient access to treatments by preventing copay adjustment programs. We readily support the bill sponsors for taking a lead on this issue to ensure that all North Dakota residents with a rare disease can maintain access to affordable, life-sustaining medical care.



Jamie Sullivan
Vice President of Policy
EveryLife Foundation for Rare Diseases

Emily Stauffer
Associate Director of State Policy
EveryLife Foundation for Rare Diseases

CC:

Michael Pearlmutter, Chief Executive Officer, EveryLife Foundation for Rare Diseases
Annie Kennedy, Chief of Policy, Advocacy and Patient Engagement, EveryLife Foundation for Rare Diseases
Vicki Seyfert-Margolis, Chair, Board of Directors, EveryLife Foundation for Rare Diseases

[2] IQVIA. May 2019. Medicine Use and Spending in the US; A Review of 2018 outlook to 2023.

Chairman Warrey, Vice Chairman Ostile, and Members of the Committee,

My name is Eniola Soetan, and I am a student at Dickinson State University as well as a volunteer with American Cancer Society Cancer Action Network. I am here to express my support for HB 1216.

As someone who has had to use my fair share of health care services, I know very well the burden that this can place on individuals, families, and entire communities at large. On top of having to deal with the physical, mental, and emotional stresses that come with living with an injury or illness that requires treatment, figuring out how to make the finances work adds another monumental layer of strain to an already very difficult situation.

Copay assistance programs are a very important facet of making sure that healthcare and treatment are accessible to those who need it. In many cases, copay assistance programs can be the difference between individuals achieving a functionable quality of life, or facing progressively worse prognosis leading to death.

Unfortunately, the advent of copay accumulator programs has undermined the lifesaving efforts of copay assistance. When copay assistance does not go towards a deductible, this functionally eliminates any form of assistance to the individuals and families who need it, while also creating a system in which the insurance companies essentially get paid twice.

Many potentially fatal diseases such as certain cancers and genetic disorders are now able to be treated thanks to the help of medical breakthroughs that help to keep people alive. Unfortunately, a lot of these medications are also extremely expensive.

Consider a family that has a child with type 2 spinal muscular atrophy for example, a disease that results in low muscle tone, muscle weakness, inability or difficulty to stand, walk, or sit upright without support, and weak respiratory muscles. This disease also leaves diagnosed individuals with a life expectancy of around 30 years or so[3]. Just to be able to perform simple daily life tasks, children with this disease will require assistive devices such as braces, orthotics, and

wheelchairs, physical therapy or occupational therapy services, feeding tubes, and ventilators. If in a household with multiple guardians, one guardian will have to stay at home full time with the affected child, likely foregoing a source of income, and the child will also require some sort of in-home nurse or caretaker. In a single guardian household, this dilemma becomes even more complicated. Drugs that have been found to have a profound impact on the development of the disease have become available, but having a child with this disease is already an incredible financial demand on a family even without looking into these new drugs that have costs into the millions[2], with no guarantee that all of the necessary medical needs will have approved insurance claims.

Imagine a family who has been given a second shot at life with their child thanks to financial assistance with life-changing medication. Now imagine telling that same family that the assistance they received would not be going towards their deductible, that even though they qualified for assistance, they would still have to find a way to shell out more money in order to meet their deductible amidst extremely trying circumstances.

In adults, we often see individuals foregoing treatment all together due to an inability to afford it. According to the Kaiser Family Foundation, in 2023, 25% of US adults skipped or postponed treatment due to costs[3]. With many diseases, delayed treatment or lack of treatment worsens the prognosis of the disease quite drastically, eventually putting individuals in situations where they can hardly function on a day to day basis, let alone go to work to make some money. Diabetes can go from something easily manageable with regular insulin shots to a situation that becomes life threatening where amputations may be required. Cancer goes from an easily caught and treatable disease to a tragic and uncontrollable metastasis, all due to differences in treatment, and differences in the ability to access said treatment.

Copay assistance programs help to bridge the gap between individuals and the treatment they require so that you do not have to be rich or put yourself into insurmountable debt to be able to save yourself or a loved one's life. As someone who has lost a grandma to diabetes because of inadequate access to medication, and my own mom to cancer when I was 10 years old, this chance at life is a gift that I cannot imagine being ripped away from anyone.

In order to support and build on the great work of copay assistance programs, to improve healthcare accessibility, and ultimately to give as many people as possible a chance at life, and a high quality of life, I strongly urge the committee to give this bill a do pass recommendation.

Sincerely,
Eniola Soetan
eniola.soetan@dickinsonstate.edu

[1]- https://my.clevelandclinic.org/health/diseases/14505-spinal-muscular-atrophy-sma

[2] - https://www.drugs.com/medical-answers/zolgensma-expensive-3552644/

[3]-https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/#:~:text=The%20cost%20of%20care%20can,28%25%20vs.%2021%25).

BDAND
Bleeding Disorders Alliance of North Dakota

"When a bandage is not enough, we're here."

Emily Ouellette
HB 1216 Testimony
ND House Industry, Business, and Labor Committee Hearing
Jan 27, 2025

Thank you, Chairman Warrey and the Committee, for hearing our testimony, and thank you to Representative Karls for once again working to protect North Dakota patients' access to lifesaving drugs with HB 1216.

My name is Emily Ouellette. I speak for the community I serve professionally as Executive Director of the Bleeding Disorders Alliance of North Dakota. I also have a personal connection. My husband and nephew, who grew up in Devils Lake, have severe hemophilia.

Hemophiliacs need specialty medicine that they self-infuse 1-3 times per week at home, costing $350,000 to $1,000,000 per year. There are no generic options. This medicine prevents internal bleeds. When patients get their medicine in January, they often reach their deductible immediately. Can you imagine needing to pay your full deductible in one payment at the beginning of the year every January to receive medicine that allows you to safely work or go to school? It is important that our patients access their medicine without financial barriers, so organizations like ours as well as some manufacturers offer financial assistance.

Recently, insurance companies have implemented Copay Accumulator programs where they accept the patient assistance money, but don't count it toward the patient's deductible. Think of it this way, a college student has a $10,000 tuition bill and a $5000 scholarship. The University accepts the $5000 scholarship, but still makes you pay the full $10,000 bill, you know so the student has "skin in the game". The school receives $15,000. Is that fair? This is happening to patients all over the US. It needs to stop. With these programs, hardworking families struggle to access their medication. They take out loans or ration doses and risk permanent joint damage.

Currently, 1 out of 3 health insurance plans in North Dakota have a copay accumulator program in place. I hope you will pass this bill to prevent all insurance companies from harmfully surprising North Dakota patients. We can join the 21 states who have passed legislation to ensure patients can utilize copay assistance programs as they were intended.

Access to medication allows people like my husband to continue being a contributing member of society, raising a family, and holding a job. It allows my 12 year old nephew to stay in school and be able to participate in Tae Kwan Do. The treatments are available. They cost a lot, but these patients are well worth the cost. The system is broken - high drug costs and various

other practices make it difficult for patients to navigate their health care. This is making it even harder.

Health plans will tell you patients are driven to high cost name brand drugs. Patients with bleeding disorders do not have a generic option. They will tell you we have no skin in the game, no personal costs - we still pay our premiums, multiple doctor visits, lab work, and ancillary supply costs. Health plans still determine their formulary, and patients must still go through the utilization processes they've put in place. I know North Dakota takes pride in being a business-friendly state and some may be concerned about costs to employers. Employers will lose employees if they cannot stay healthy.

Copay assistance doesn't only provide financial relief, it improves adherence, leading to better clinical outcomes. I hope you will protect North Dakota patients in the rare disease community by supporting HB 1216. We want all payments to count, made BY the patient or on BEHALF of the patient.

Thank you.

*AIDS Institute Study – https://aidsinstitute.net/documents/TAI-2024-Report-2.27.pdf

*Global Healthy Living Foundation - https://ghlf.org/copay-assistance-protection/

HB 1216
House Industry, Business and Labor Committee
January 27, 2025

Good afternoon, Chair Warrey, and Members of the House Industry, Business and Labor Committee,

My name is Bobbie Will, the ND, MT, SD, and WY State Policy and Advocacy Manager for Susan G. Komen. I live in Representative Karls District 35 and am thankful she is sponsoring this important piece of legislation. I am before you on behalf of breast cancer patients in North Dakota to urge your **support of HB 1216**, which relates to out-of-pocket expenses for prescription drug maximums and cost-sharing requirements.

Health insurers have instituted "copay accumulator adjustment programs" which prevent payments made by copay assistance from drug manufacturers and nonprofits from counting toward a patient's cost-sharing requirements. HB 1216 will help breast cancer patients in North Dakota continue to access the treatments they need by ensuring all expenses made by or on behalf of a patient count toward their cost-sharing requirements.

According to a recent study of claims data, a vast majority of copay assistance is used for treatments that do not have a generic alternative.[1] Unfortunately, many patients are not aware that the copay assistance is not counted toward their deductible or out-of-pocket maximum until they have to pay hundreds to thousands of dollars out of pocket to continue their treatments.

A breast cancer patient should not be forced to abandon their treatment or skip doses due to costs. Studies have shown that patients are far more likely to abandon their treatment when out-of-pocket costs exceed $100.[2] Unfortunately, we hear from patients who have been forced to stop using their medications due to the high out-of-pocket costs that end up having an

[1] IQVIA. An Evaluation of Co-Pay Card Utilization in Brands after Generic Competitor Launch. https://www.iqvia.com/locations/united-states/library/fact-sheets/evaluation-of-co-pay-card-utilization
Accumulator
[2] Gleason PP, Starner CI, Gunderson BW, Schafer JA, Sarran HS. Association of prescription abandonment with cost share for high-cost specialty pharmacy medications. J Manag Care Pharm. 2009;15(8):648-658. doi:10.18553/jmcp.2009.15.8.648

increase in negative health outcomes and hospital visits- ultimately resulting in increases to overall health care costs.

As committed partners in the fight against breast cancer, we know how deeply important it is for North Dakota breast cancer patients to not be punished for using copay assistance to help them afford the necessary treatments they need. As such, we support HB 1216 and urge you to pass this critical legislation.

Bobbie Will
bwill@komen.org
701-202-5840

I am writing as a concerned citizen and as a patient of a deadly disease.

My name is Marcia Julson and I have lived my whole life with cystic fibrosis (CF). It is an incurable genetic disease. When I was born, the life expectancy was very low. Through research and advancements in medications and therapies, I have defied the odds many times over. I will be 52 years old in 2 weeks.

Every day I am alive, I take numerous medications and do breathing treatments just to stay as healthy as I can. Some of my medications cost thousands of dollars each month. I do have two co-pay cards that help immensely with the costs, but there is still a huge financial burden on patients like myself.

Please find it in your hearts to pass HB 1216 to help those of us who need to use co-pay cards.

Thank you.

Marcia Julson
2017 3rd St NW
Minot, ND 58703

January 26, 2024

The Honorable Jonathan Warrey, Chair House Industry, Business and Labor Committee
The Honorable Jorin Johnson, Vice Chair House Industry, Business and Labor Committee
The Honorable Mitch Ostlie, Vice Chair House Industry, Business and Labor Committee
North Dakota House Industry, Business and Labor Committee
North Dakota State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: **HB 1216 – Relating to Out-of-Pocket Expenses for Prescription Drugs**
PCMA Testimony in Opposition to HB 1216

Dear Chair Warrey, Vice Chairs Johnson and Ostlie, and Members of the Committee:

My name is Michelle Mack, and I represent the Pharmaceutical Care Management Association, commonly referred to as PCMA. PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 275 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs

PCMA appreciates the opportunity to provide testimony on HB 1216, a bill that would require insurers to count any amount paid by enrollees (directly or on their behalf) toward an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement under the policy. PCMA respectfully opposes HB 1216.

I want to emphasize at the outset that **PCMA does *not* oppose true means-tested patient assistance programs that help individuals afford their prescription drugs.** There is an important difference between means-tested patient assistance programs and copay coupons, which are targeted to individuals with health insurance.

The unfettered price increases of prescription drugs put patients at risk and health plan sponsors in the difficult position of either having to cut benefits or increase premiums, copays, and deductibles. While health plans pay the vast amount of their members' prescription drug costs, drug manufacturers' price increases have forced health plans to create new benefit designs that keep monthly premiums as low as possible—but require some members to shoulder more of the cost before their deductible is met.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

A recent financial review by Deloitte Consulting LLP of this bill language for the North Dakota Public Employees Retirement System **estimated the financial impact of over $8.6 million**[1] in the 2025-2027 biennium.

Drug manufacturers encourage patients to disregard formularies and lower cost alternatives by offering "coupons" to help the patient cover that higher cost. This ultimately steers patients away from cheaper alternatives and towards more expensive brand drugs (with higher cost sharing obligations), completely undermining the formulary offered by a plan sponsor.

Here are the facts when it comes to manufacturer coupons:

- The median annual list price of new brand name drugs rose from **$2,000 in 2008** to **$180,000 in 2021**.[2]
- The prices for drugs with manufacturer coupons **increase faster (12-13% per year)** compared to non-couponed drugs (7-8% per year).[3]
- **Banning coupons** would **lower prescription drug costs** by an **estimated $1.155 billion** per year.[4]
- In the Massachusetts commercial market, **coupons increased costs by $3 million** per drug.[5]
- If Medicare's ban on coupons were not enforced, costs to the program would **increase $48 billion** over 2021 - 2030.**[6]**
- **88% of brand drugs** with manufacturer coupons **have lower-cost generics or brand alternatives**, indicating that coupons aim to drive business to the brand name drugs.[7]

By definition, copay coupons target only those who already have prescription drug coverage (i.e., those who pay copays). Copay coupons are not means-tested or designed to help the poor or uninsured. Considered illegal kickbacks in federal health programs, copay coupons are still permitted in the commercial market.

Supporters of coupons say that they decrease costs for patients. While they can decrease an individual patient's cost at the pharmacy counter, they do not reduce ***actual*** costs. **Coupons are temporary—the individual patient likely pays more when the coupon**

[1] Financial Review of Proposed Bill 25.0068.01000. Deloitte. June 27, 2024.
[2] Trends in Prescription Drug Launch Prices, 2008–2021. Rome, Egilman, and Kesselheim. JAMA Network. 2022.
[3] When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization. Leemore Dafny, Christopher Ody, and Matt Schmitt. American Economic Journal: Economic Policy 2017, 9(2): 91–123.
[4] Eliminating Prescription Drug Copay Coupons. Dafny, Ody, and Schmitt. 1% Steps for Health Care Reform.
[5] Prescription Drug Coupon Study: Report to the Massachusetts Legislature. Commonwealth of Massachusetts. July 2020.
[6] Drug Manufacturer Coupons Raise Costs in Medicare Part D, Hurting Vulnerable Beneficiaries. Visante (for PCMA). May 2020.
[7] A Perspective on Prescription Drug Copayment Coupons. Karen Van Nuys, Geoffrey Joyce, Rocio Ribero, and Dana Goldman. USC Schaeffer Center for Health Policy& Economics. 2018

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goes away, instead of being started on the formulary drug from the start. It is the manufacturer who benefits by forcing the plan (indirectly the patient) to pay for the more expensive drug.

If drug companies are concerned about patients accessing medications, they should simply lower their prices, yet drug makers have determined that it is more profitable to increase copay assistance rather than just making their medications more affordable. The simplest, most effective way to reduce patient costs on drugs is for manufacturers to drop the price of the drug.

Copay accumulator programs are health plan programs designed to thwart drug manufacturers' efforts to force employers, unions, and public programs to pay for expensive, unnecessary brand medications through the use of copay coupons. Accumulators typically disallow the counting of the manufacturer's coupon towards the patient's out-of-pocket maximum and deductible because the patient hasn't actually incurred the cost. This ensures that the patient has the incentive to use the plan formulary to get to the lowest net cost and that the plan functions as it was designed.

It is for these problematic provisions noted above that we must respectfully oppose HB 1216.

Thank you for your time and consideration. Please contact me should you have any questions or concerns.

Sincerely,

Michelle Mack
Senior Director, State Affairs
Phone: (202) 579-3190
Email: mmack@pcmanet.org

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STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Support of North Dakota House Bill 1216
Patient Assistance
January 27, 2025

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) supports North Dakota House Bill (HB) 1216, which will help patients better access their medicines by prohibiting new tactics in pharmacy benefit designs by insurers that deny patients the benefit of patient assistance.

Spending on medicines is growing at the slowest rate in years. Average net prices for protected brand medicines grew 3.0% in 2023, below the rate of inflation for the fifth year in a row. Looking ahead, average net price growth is projected to be -1 to -4% per year through 2028.[1] Unfortunately, it doesn't feel that way for patients because health insurers are increasingly using deductibles and coinsurance, which results in patients paying the full list price for their medicines, not the discounted price paid by the insurer or pharmacy benefit manager (PBM). This higher cost sharing can impact patients' ability to adhere to their prescribed treatment, which can be devastating for patients with chronic conditions who rely on medicines to keep their symptoms in check. Moreover, new tactics implemented by insurers, PBMs, and third-party vendors to exploit patient assistance threaten to make it harder or even impossible for patients to get important treatments for chronic illnesses such as asthma, diabetes, HIV, arthritis, hemophilia, and others. By closing policy loopholes that allow accumulator adjustment programs (AAPs), maximizers, and alternative funding programs (AFPs) to get in the way of patients and their medicines, HB 1216 will protect patients' access to their medicines.

HB 1216 would help prohibit health insurance carriers from implementing AAPs that unfairly increase cost-sharing burdens on patients by refusing to count third-party assistance toward patients' cost-sharing contributions.

To help patients better afford and stay adherent to their medicine, many third-party entities, including pharmaceutical manufacturers, offer cost-sharing assistance. Historically, commercial health insurance plans have counted this cost-sharing towards a patient's deductible and maximum out-of-pocket limit, providing relief from high cost-sharing and making it easier for patients to get their medicines. Unfortunately, health insurance carriers and PBMs are increasingly adopting policies, often referred to as AAPs, that block manufacturer cost-sharing assistance from counting towards patient cost-sharing requirements.

When health plans implement such programs, they can substantially increase patients' out-of-pocket costs, financial burdens, and health risks. Many patients who have benefited from cost-sharing assistance to afford their medicines have no idea that health insurers and PBMs are no longer counting cost-sharing assistance toward their annual out-of-pocket limits. As a result, patients may face thousands of dollars in

[1] IQVIA, "The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028," May 7, 2024. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024

surprise out-of-pocket costs for their prescription medicines because manufacturer cost-sharing assistance isn't counted as if paid by patients themselves. Surprise out-of-pocket costs are a significant problem for patients—44% of Americans say they could not cover emergency expenses costing $400 or more without selling something or borrowing money.[2]

Patients subject to these cost-sharing surprises have a significantly greater risk of treatment discontinuation and lower refill adherence. In many cases, patients leave the pharmacy empty-handed as a result. One recent study found that implementing AAPs for specialty autoimmune medicines was correlated with reductions in medication adherence among high deductible health plan enrollees. The research included patients subject to a deductible for their medicines and those not subject to a pharmacy deductible. Those patients subject to a deductible had four times higher treatment discontinuation and 12% lower refill adherence after implementing accumulators than patients in a plan that was not subject to a pharmacy deductible.[3]

Health plans claim that AAPs help prevent cost-sharing assistance from driving patients towards a more expensive branded drug when a generic equivalent is available. However, the influence of manufacturer assistance in allegedly undermining formularies and other utilization management methods that promote the use of low-cost therapies is overstated. In fact, cost-sharing assistance is most commonly used for medicines without a generic equivalent. In 2021-2022, cost-sharing assistance for a brand medicine where a generic equivalent was available accounted for less than one percent of all commercial market medicine claims.[4] Another study found that among the most utilized drugs by spending, a majority of brand drugs with manufacturer assistance had no generic substitute.[5]

HB 1216 would help prevent health insurers from implementing copay maximizer programs that inflate patients' cost-sharing to deplete cost-sharing assistance available to the patient.

As more states have passed laws to ban AAPs, insurers and PBMs have started implementing new programs, called copay maximizer programs, so they can continue to profit from cost-sharing assistance meant for patients. To implement a copay maximizer, plans and PBMs do two things: (1) use a loophole under the Affordable Care Act (ACA) (referred to as "the EHB (essential health benefits) loophole") to target and designate specific medicines with available manufacturer cost-sharing assistance as "non-essential health benefits" so that the ACA cost-sharing limitations do not apply, and (2) increase individual patient cost sharing obligations to exhaust the full value of the manufacturer-provided cost-sharing assistance available for those medicines.

By focusing on medicines with available cost-sharing assistance programs, these copay maximizer programs affect certain patients based solely on their medical condition or need for a specific medicine. This targeting of certain medicines—and thus certain patients—is concerning and could run afoul of federal nondiscrimination requirements. Copay maximizers can also result in patients paying more for other care because payments for drugs are excluded as EHBs, meaning these expenditures don't count toward the out-of-pocket maximum, which might otherwise be reached if the payments for the drugs were counted. In some cases, copay maximizers may even result in patients being denied coverage at the pharmacy as a lever to force enrollment in the maximizer program.

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[2] Report on Economic Well-Being of U.S. Households in 2015. The Federal Reserve Board Report. May 2016.
[3] PhRMA Catalyst Blog. Guest post: Copay accumulator adjustment programs lead to four times higher treatment discontinuation for patients with high deductible. February 21, 2019.
https://catalyst.phrma.org/guest-post-copay-accumulator-adjustment-programs-lead-to-four-times-higher-treatment-discontinuation-for-patients-with-high-deductibles.
[4] IQVIA analysis for PhRMA. 2023.
[5] Van Nuys, K, et al. USC Schaeffer. A perspective on prescription drug copayment coupons. 2018.
https://healthpolicy.usc.edu/wp- content/uploads/2018/02/2018.02_Prescription20Copay20Coupons20White20Paper_Final-2.pdf.

Policymakers should stop health insurers and PBMs from using copay maximizers and similar programs so that patient assistance benefits patients as intended, not middlemen.

Finally, HB 1216 would help stop the unethical practice of AFPs, which deplete funds meant for uninsured patients and harm patients taking specialty medicines.

Alternative funding programs use questionable means to allow commercially insured patients, who otherwise may not be eligible for manufacturer patient assistance or charitable programs meant for uninsured or underinsured patients, to access these funds.

To implement an AFP, an alternative funding vendor or PBM convinces an employer to drop coverage for some or all specialty drugs from a plan. Patients prescribed these drugs are then directed to the AFP vendor who enrolls them in a manufacturer patient assistance programs or other charities or foundations meant to assist uninsured or underinsured patients. Patients must provide personal financial details and sometimes sign a power of attorney so the vendor can enroll them in a patient assistance program. The AFP vendor may disguise the insured patient as "uninsured" so that they can qualify for these patient assistance programs. If the patient refuses to enroll in an AFP, they will be required to pay the entire cost of their prescription drug.

AFPs deplete funds meant for patients in need and harm patients with chronic and sometimes life-threatening diseases. AFPs exist only for specialty drugs and thus disproportionately target individuals living with chronic and rare conditions who rely on these life-saving medications. AFPs leave patients with almost no choice—provide personal financial details, sign a power of attorney, permit the AFP to enroll them in a patient assistance or charitable program, or pay for the entire cost of their prescription drug. Patients can face treatment delays while the AFP vendor initiates the application process and searches for funding. They may also be encouraged to use the product with a more favorable assistance program rather than the medication prescribed by their doctor, which puts them at risk of poorer health outcomes.

We encourage North Dakota policymakers to protect patients and enable them to better afford their medicines by prohibiting the administration of benefit designs and policies—including AAPs, maximizers, and AFPs—that exploit patient assistance and ultimately put patient's access to medicines at risk.

PhRMA is committed to promoting policies that protect North Dakota patients and enable them to better afford their medicines. PhRMA respectfully supports the passage of HB 1216, which offers patient-centered solutions that will help patients pay less for their medicines.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

House Bill 1216
North Dakota House Committee on Industry, Business, and Labor
January 21, 2025
AHIP Testimony

Thank you for the opportunity to speak before you today. My name is Alex Kelsch, and I am testifying today on behalf of America's Health Insurance Plans (AHIP).[1]

AHIP respectfully opposes HB 1216 because it restricts health plans' ability to hold down drugs costs.

Everyone should be able to get the medications they need at a cost they can afford. However, drug prices continue to rise out of control, and pharmacy costs now represent over 24 cents[2] out of every dollar of premium spent on health care.

Unfortunately, HB 1216 does nothing to control the soaring prices of prescription drugs for patients. Instead, it would financially reward drug manufactures for steering patients towards more expensive brand-name drugs.

Drug manufacturers intentionally use copay coupons to keep drug prices high.

Drug manufacturers acknowledge their drugs are unaffordable for patients. But rather than simply lowering their prices, they offer copay coupons to hide the actual cost of those drugs.

Drug manufacturers offer these promotions only to very specific patients for a very short period of time. Once a patient hits their deductible, drug manufacturers discontinue the patient's coupons – which hides the underlying prices from patients, enticing them to continue with the most expensive drug, when there are less expensive drugs available.

It is important to note, the federal government considers copay coupons to be an illegal kickback if used by an enrollee in Medicare or Medicaid because they induce a patient to use a specific drug[3].

In the commercial market, coupons are often offered only for a limited time – once the patient hits their deductible, drugmakers discontinue the patient's assistance.

These promotions are used to increase sales, raising costs for everyone.

There are multiple studies by the U.S. House Oversight Committee[4], Harvard[5], the Congressional

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[1] AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone.
[2] *Where Does Your Health Care Dollar Go?* America's Health Insurance Plans. October 2024. https://www.ahip.org/health-care-dollar/
[3] *See 42* U.S.C § 1320a-7b; *Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons*. Department of Health and Human Services, Office of the Inspector General. September 2014. Available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf.
[4] U.S. House Committee on Oversight and Reform; Drug Pricing Investigation, Majority Staff Report. December 10, 2021. https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf
[5] Dafny, et. al. When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization. American Economic Journal: Economic Policy 9, no. 2 (May 2017): 91–123. https://www.hbs.edu/ris/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf

Research Service[6], and others, that found that drug manufacturers uses patient assistance programs as a sales tool – focusing on their rates of return, encouraging patients to stay on branded drugs after a generic is introduced, and subsidizing third-party foundations to drive sales and attract patients who otherwise might not have used the high-priced drug.

Purchasers of health care use guardrails to hold drug manufacturers accountable for pricing schemes.

Employers and purchases of health care have worked hard to develop programs to hold drug companies accountable, to shed light on these pricing schemes, and keep costs low for North Dakotans.

The Centers for Medicare & Medicaid Services (CMS) agrees that these programs are important to protect taxpayers. In addition to deeming coupons illegal kickbacks in federal programs, CMS explicitly allowed such programs to continue in the Exchange Marketplaces.[7]

Legislation banning these programs by requiring health plans to count all third-party payments towards an enrollee's cost sharing obligations will eliminate incentives for drug companies to lower prices. As a result, drug companies will make more money while North Dakota families and businesses continue to foot the bill through higher premiums, higher out-of-pocket expenses, and higher federal insurance subsidies.

The legislature should focus on solutions that forbid market manipulation.

Instead of taking away the few tools that health plans have to lower drug spending, we recommend that North Dakota legislators focus on fixing the market distortion caused by pricing schemes, including copay coupons.

AHIP stands ready to work together with policymakers on real solutions to ensure every patient has access to the high-quality drugs that they need and improve health care affordability.

[6] Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs). Congressional Research Service. June 15, 2017. https://crsreports.congress.gov/product/pdf/R/R44264/5.
[7] *Notice of Benefit and Payment Parameters for 2021*. Centers for Medicare & Medicaid Services. June 13, 2020. https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-10045.pdf.

NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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North Dakota State Assembly
House Industry, Business and Labor Committee
600 East Boulevard Avenue
Bismarck, ND 58505

January 27, 2025

Re: Support for HB1216

Dear Committee Members:

On behalf of the infusion providers we represent in your state, thank you for your service and commitment to the people of North Dakota. As a nonprofit trade association that provides a national voice for non-hospital, community-based infusion providers; we ask that you please support HB 1216.

The National Infusion Center Association (NICA) is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of infused and injectable medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in high-quality, non-hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in quality of care and safety across care settings, and enable care delivery in the highest-quality, lowest-cost setting.

When dealing with complex diseases, conventional drugs are not always effective, and infusions are often the only hope for patients suffering from autoimmune diseases or other chronic illnesses. However, it can take several years for a patient to exhaust conventional treatments before starting a biologic or infusion. When patients are subjected to step therapy or "fail first" policies that require them to try and fail a medication before taking the medication their doctor prescribed, insurance companies create yet another hoop to jump through before patients can reach clinical stability.

Onerous step therapy protocols essentially allow insurers to practice medicine by dictating what medication a patient can take. Step therapy protocols, especially those that diverge from widely

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accepted clinical guidelines, can lead to prolonged under-management of debilitating conditions and unnecessary clinical risk. As I'm sure you know, it is more important than ever for patients to avoid preventable hospital visits, not only in terms of capacity but also in an effort to keep patients with pre-existing complex conditions away from potential exposure to other illnesses.

The passage of HB 1216 would put clinical decisions back in the hands of patients and their doctors, rather than insurance companies. On behalf of the providers we serve, tending to patients battling chronic conditions for the rest of their lives, we sincerely request your support for HB 1216.

Thank you for your time and consideration.

Sincerely,

Brian Nyquist, MPH
President & CEO
National Infusion Center Association

Infusion Access Foundation

North Dakota Assembly
House Industry, Business & Labor Committee
600 E. Boulevard Ave.
Bismarck, ND 58505

January 15th, 2025

Re: Support for HB 1216

Dear Committee Members,

Representing the interests of infusion therapy patients in the state, the Infusion Access Foundation extends its gratitude for your service and dedication to the people of North Dakota and strongly encourages your support for HB 1216 at the January 27th House Industry, Business and Labor Committee hearing.

The Infusion Access Foundation is a nonprofit advocacy organization dedicated to protecting access to infusions and injections. We support patients across all disease states and advocate for expanding access to the therapies that help patients live their best, healthiest lives. In conjunction with our grassroots advocacy work, we advocate for individual patients who face significant barriers to care.

Patients facing complex, rare, or chronic diseases often require infused or injectable medications when conventional therapies are ineffective. These treatments offer hope and a pathway to stability for individuals managing conditions such as autoimmune diseases, yet the journey to accessing them is often fraught with unnecessary barriers.

Step therapy, or "fail first" policies, force patients to try and fail medications before being allowed access to the treatment originally prescribed by their doctor. These policies not only delay the start of effective treatment but also subject patients to prolonged periods of suffering, preventable disease progression, and increased clinical risk. For many, this means enduring years of ineffective care before finally receiving the medication that can truly make a difference in their health and quality of life.

When insurers dictate treatment protocols, they undermine the vital decision-making process between patients and their healthcare providers. These decisions should be based on widely accepted clinical guidelines and the individual needs of each patient,

not cost-saving measures imposed by insurance companies. Step therapy policies that deviate from evidence-based practices can exacerbate patients' conditions, increase their reliance on emergency care, and ultimately raise healthcare costs.

In passing HB 1216, North Dakota can take a critical step toward putting medical decisions back where they belong: in the hands of patients and their trusted healthcare providers. This legislation would help ensure that patients receive timely, appropriate, and effective care while reducing the emotional and physical toll of unnecessary treatment delays.

On behalf of the countless patients who face chronic and complex conditions every day, we sincerely request your support for HB 1216 during the January 27th House Industry, Business and Labor Committee hearing. Thank you for your time, attention, and commitment to the well-being of North Dakota residents.

Sincerely,

Alicia Barron, LGSW
Executive Director
Infusion Access Foundation

Cystic Fibrosis Association
of North Dakota

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January 27, 2025

Representative Jonathan Warey, Chair
House Committee on Industry, Business and Labor
600 East Boulevard Avenue
Room 327 C
Bismarck, ND 58505

Dear Chairman Warrey and members of the Committee,

I am writing to you on behalf of the Cystic Fibrosis Association of North Dakota to express our strong support for **HB 1216**. This critical piece of legislation seeks to end the harmful practice of co-pay accumulators, which directly impacts the ability of individuals living with cystic fibrosis (CF) to afford life-saving medications.

The Cystic Fibrosis Association of North Dakota is dedicated to improving the lives of individuals living with cystic fibrosis, a rare and chronic genetic disease that affects the lungs, digestive system, and other organs. With no known cure, CF requires individuals to undergo frequent treatments, including daily medications, physical therapy, and sometimes hospitalizations. These treatments are vital to maintaining health and preventing life-threatening complications.

For people living with cystic fibrosis, access to medications is not just a matter of comfort—it is a matter of survival. However, co-pay accumulators are a growing barrier that many patients are facing. These programs prevent the financial assistance provided by pharmaceutical manufacturers from counting toward the patient's deductible and out-of-pocket maximum. As a result, patients are forced to pay out-of-pocket for medications that are extremely costly and with no generic equivalent.

For individuals with cystic fibrosis, who require specialized and high-cost medications, the financial burden caused by co-pay accumulators is overwhelming and devastating. Many families struggle to make ends meet and are left choosing between paying for necessary medications and basic necessities like housing or food. The consequences of not being able to afford these medications can be catastrophic, leading to deteriorating health, increased hospitalizations, and a significantly lower quality of life.

HB 1216 is a critical step in protecting the health and well-being of North Dakota residents with cystic fibrosis and other chronic conditions by ensuring that the financial assistance provided through manufacturer programs is properly applied to the patient's out-of-pocket costs. This legislation will ensure that patients are not penalized for accessing financial assistance programs and will help alleviate the financial burden that many CF families are currently facing.

On behalf of the Cystic Fibrosis Association of North Dakota, I urge you to support **HB 1216** and help ensure that North Dakotans living with cystic fibrosis have access to the medications they need to live healthier, longer lives.

Thank you for your time and consideration.

Sincerely,
Pam Thompson
Development Director
Cystic Fibrosis Association of North Dakota

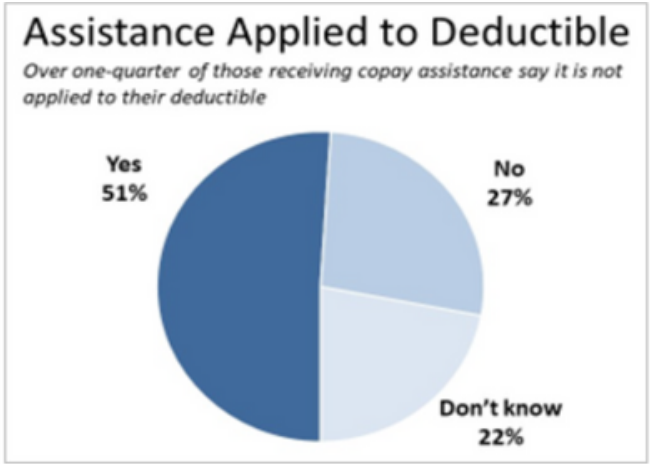
Prescription Drug Copay Assistance and Accumulator Adjustment

Many individuals with cancer and survivors of cancer have difficulty affording the cost of their prescription drugs. This is especially true for newer drugs – including cancer drugs – that do not yet have a generic equivalent. To help temper high prescription costs, many of these individuals receive copay assistance offered through manufacturer programs and charitable patient assistance programs.

Manufacturer programs and charitable patient assistance programs help many cancer patients afford their medications. A patient assistance program's financial support can give patients access to a life-saving drug that they otherwise could not afford. And many of the programs exist for drugs without generic alternatives.

Copay accumulator adjustments are a relatively new insurance practice. These programs allow the enrollee to use copay assistance, but the amount of the support does not count towards the enrollee's out-of-pocket cost obligations like meeting their deductible. Only the funds spent directly by the enrollee count, leaving patients with significant and surprise costs.

A May 2022 survey[1] conducted by the American Cancer Society Cancer Action Network (ACS CAN) explores cancer patients' and survivors' experiences and perspectives on copay assistance and found:



- Prescription drug costs are a challenge for nearly one-third of cancer patients and survivors (31%), with one-fifth having skipped or delayed taking prescribed medications due to costs.
- Those who have enrolled in copay assistance programs agree that the assistance provides access to medication through the program that they otherwise couldn't afford (83%), while some who were unable to enroll reported declining treatment (8%) or going into debt to cover their prescription drug costs (18%).
- Over a quarter (27%) of those who enrolled report that the assistance they received was not applied to their deductible or other out-of-pocket cost requirements and another 22% were unsure.
- The negative impacts of not being able to benefit from a copay assistance program are even greater among some patient populations, with over one-quarter of Black, Hispanic, and Asian cancer patients and survivors reporting they have declined treatment due to cost after finding they were unable to enroll in a copay assistance program.

ACS CAN supports legislation to restrict the use of copay accumulator adjustment programs.

1 American Cancer Society Cancer Action Network Survivor Views Survey fielded May 16-26, 2022. https://www.fightcancer.org/survivor-views.

January 27, 2025

Good afternoon House IBL Committee members,

My name is Lucy Laube. I am the State Government Relations Manager for the Western Region of The National Psoriasis Foundation and I ask for your support of HB 1216, sponsored by Representative Karls. I also am a patient living with Crohn's disease and have relied on copay assistance to afford my life-saving medication for the past 9 years.

The National Psoriasis Foundation represents roughly 8 million Americans living with psoriasis and psoriatic arthritis and who rely on high-cost specialty drugs. Many of these patients rely on copay assistance from drug manufacturers, charitable foundations and other third parties to afford the medications that they need. In fact, A 2020 National Psoriasis Foundation survey found that 70 percent of people with psoriatic disease who take a biologic reported they could not afford that medication without copay assistance.

In recent years, health insurers have begun implementing new programs called "copay accumulator adjustment programs" that do not count payments from copay assistance toward patients' deductibles and out-of-pocket maximums. This places an extreme financial burden on patients who are forced to pay out of pocket to reach their full deductibles or forego potentially life-saving treatments because they cannot afford it. In fact, studies have shown that patients are far more likely to abandon their treatment when out-of-pocket costs exceed $100. This abandonment of treatment can lead to irreversible negative health outcomes to the patients.

HB 1216 will ensure patients continue to have access to their essential medications and stay on their treatment regime prescribed by their doctor by ending the practice of Copay Accumulator Adjustment Programs and requiring health insurance plans and PBM's to apply any amount paid by the insured patient through copay assistance to the patient's cost sharing obligations. There have been similar patient-friendly copay accumulator reform bills passed in 20 states and Puerto Rico already. We encourage North Dakota to join its west coast states in passing this legislation and be the 21st state with protections.

Sincerely,

Lucy Laube

State Government Relations Manager, Western Region

Arthritis Foundation®

arthritis.org/advocacy

Representative Jonathan Warrey, Chair
Members of Industry, Business and Labor
327C Room - ND State Capitol

Re: Support for HB 1216 – Make All Copays Count

January 27, 2025

Dear Chairman Warrey and members of the Industry, Business and Labor Committee,

On behalf of more than 129,000 North Dakota residents with doctor-diagnosed arthritis, thank you for the opportunity to submit testimony in **support of HB 1216**, legislation that addresses copay accumulator policies in North Dakota to ensure that third-party patient copay assistance – a payment provided on behalf of eligible patients with chronic or terminal conditions to help them afford their prescribed medications – counts towards patients' annual out-of-pocket cost-sharing obligations.

Copay accumulator programs prevent any co-payment assistance that may be available for high-cost specialty drugs from counting towards a patient's deductible or maximum out-of-pocket expenses. Many pharmaceutical manufacturers offer co-pay cards that help cover a patient's portion of drug costs. Traditionally, pharmacy benefit managers have allowed these co-payment card payments to count toward the deductible required by a patient's health insurance plan. With an accumulator adjustment program, patients are still allowed to apply the co-payment card benefits to pay for their medications up to the full limit of the cards, but when that limit is met, the patient is required to pay their full deductible before cost-sharing protections kick in.

Currently, the state of North Dakota does not have a law to ensure that health insurers count co-payment assistance towards a patient's cost-sharing requirements. Now more than ever, it will be important for the North Dakota State Legislature to act given 1 out of 3 of marketplace insurers in the state have copay assistance diversion policies.[1]

Legislation is necessary on this issue as patients are often unaware they are enrolled in one of these programs until they go to the pharmacy counter and realize they must pay the full cost of their medication, which can lead them to abandon or delay filling their prescription. These programs can be called different names, are often marketed as a positive benefit, and are disclosed many pages into plan materials, leading to a lack of awareness about them to patients.

[1] Institute, T. A. (2024). 2024 TAI Report: Copay Accumulator Adjustment Programs. National Policy Office. Washington, DC: The Aids Institute. Retrieved from https://www.theaidsinstitute.org/copays/TAI-copay-report-2024

In a recent Arthritis Foundation survey, 37% of patients reported they had trouble affording their out-of-pocket costs. Of those, 54% say they have incurred debt or suffered financial hardship because of it. The Arthritis Foundation also surveyed in 2017 asking patients about accumulator programs and found that if patients are faced with a large, unexpected charge for a prescription drug, the top three reactions would be: abandoning or delaying their prescription fill; lengthening the time between doses; and asking their provider to switch to another drug.

HB 1216 resolves this issue by simply ensuring that when calculating a patient's overall contribution to any out-of-pocket maximum or any cost-sharing requirement, a health plan must include any amounts paid by the patient or paid on behalf of the patient by another person or third party.

Currently, 21 states, DC and Puerto Rico have enacted laws that require insurers to count third party payments, including copay assistance, towards cost-sharing limits. Further, Minnesota and Nevada have also taken regulatory steps to issue guidance to plans to remove accumulator programs.

The Arthritis Foundation thanks the committee for their consideration of HB 1216 to add North Dakota to the list of states ensuring ALL copays count and urges all committee members to support this critical legislation.

Melissa Horn
Director of State Legislative Affairs
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Washington, D.C. 20036
240.468.7464 | mhorn@arthritis.org

HB 1216 – House Industry, Business & Labor Committee – January 27, 2015

For the record, my name is Rep. Karen Karls. I represent District 35 in central Bismarck. My husband Ken was executive director of the Cystic Fibrosis Association of ND for many years.

2 ½ years ago I visited with Karen, an adult with cystic fibrosis, a hereditary, chronic disease. She told me how the miracle drug Trikafta has changed her life, but it's very expensive. She has good insurance, but the deductible is $5,000. This medication is $28,000 per month. Once she meets her deductible she is covered for the rest of the year. The drug company gave her financial assistance in the form of a $5,000 VISA card to help her afford her medication. The card was accepted, but she was later billed for the entire $5,000 because the insurer no longer counts payment by a 3rd party toward her deductible. She is here today to share her testimony and will explain in more detail. (Please note there are submitted testimonies online from people suffering from other rare diseases.)

Needless to say, medications used to treat chronic diseases like CF, hemophilia and others are extremely expensive. Why? Because the pharmaceutical company that takes on the research for this disease faces YEARS of lab testing, clinical research, and then faces the rigors of winning FDA approval. There is a comparatively small market for these medications, even though they are "miracle" drugs—there are no generic alternatives for them! Thus the extremely high costs.

To help patients better afford their medications (and stay on them) many 3rd-party entities, including the drug manufacturers, offer cost-sharing assistance such as discount coupons (AKA "copay assistance".) Historically, commercial health insurance plans have counted these coupons towards a patient's deductible and maximum out-of-pocket limit, providing relief from high cost sharing and making it easier for patients to get their medications.

Unfortunately, health insurance carriers have adopted policies, often referred to as "accumulator adjustment programs" (AKA "copay accumulators") that block manufacturer coupons from counting towards deductibles and out-of-pocket limits. This means patients could be paying thousands more at the pharmacy. Many have relied on this assistance and have no idea that their health insurer no longer counts these coupons. This can result in unpleasant surprises at the pharmacy counter where they may face thousands of dollars of unexpected costs.

If companies are willing to create a miracle drug and help patients obtain it via drug assistance programs, these should be accessible to them. We need to update our laws to prohibit insurers from this practice and enable patients to access and afford the lifesaving medications they need to manage their chronic illness. HB 1216 hopes to accomplish this.

Mr. Chairman and member of the committee, I will walk you through the bill, if you like.
Section 1 is the definition section; things to note…this bill is for prescription drugs only, specifically drugs for which there is no generic equivalent. The "meat" of Subsection 2 is on page 2, line 1 & 2: "…the health benefit plan provides for the inclusion of any amount paid by the enrollee or paid on behalf of the enrollee by another person." Section 2 deals with self-insurance plans; LC informed me that if our state PERS plan ever becomes self-insured, we will need these provisions.

I will stand for questions.

Additional Information

Patients always had the ability to use any source of funds available to pay their prescription drug deductibles, be it their bank account, a credit card, a loan, a gift from family or friends, GoFundMe campaigns, manufacturer's assistance, non-profit assistance, etc. Insurers and PBMs have recently decided they should determine which funds patients can use, and if patients use the "wrong" funds, they will simply keep the payments but not apply them to the patient's deductible or annual limit. HB 1216 prevents insurers and PBMs from making these decisions for patients and in the process, profiting off of "double dipping".

The intent of this bill is not to eliminate co-payments, but to allow a third-party to assist with the out-of-pocket maximums…to help people who suffer from chronic diseases.

Over the last few years, 21state legislatures have enacted laws protecting patients with chronic illnesses by protecting the use of drug company assistance coupons.

False: Pharma does not give these coupons to the uninsured: drug companies have patients' assistance plans for free or low-cost drugs for the uninsured. It is a needs-based program.

False claim: Federally, drug coupons are illegal under both Medicaid and Medicare: comparing Medicaid & Medicare to commercial insurance plans is not an apples-to-apples comparison. US insurance is made up of a variety of plan types (Medicare, Medicaid, Veterans Affairs, and Commercial) all of which are structured and regulated differently. HB 1216 addresses a challenge faced by many of our ND residents, which the state legislature has full authority to regulate.

Good afternoon, Chairman Warrey, Members of the House Industry, Business and Labor committee. My name is Megan Hruby and I am with Blue Cross Blue Shield of North Dakota.

I am here this afternoon to provide some important perspective on House bill 1216, the bill relating to copay coupons and accumulator programs for prescription drugs. BCBSND is opposed to HB 1216 as currently written because despite the sponsors best intentions, this bill will not lower costs for consumers in North Dakota. I believe that we share the same goal as the advocates here today, which is more affordable prescriptions, we simply disagree on the best way to get there.

I want to start by saying clearly, whether or not this bill passes or fails, the coupons will remain. Anyone who receives a coupon today, will still have a coupon regardless of what happens with the bill. There was a lot of confusion about that last Session, so let's clear that up. The coupons stay no matter what. This bill only impacts how much of the cost of the coupons is shifted from pharma to health insurers.

Unfortunately, what else will stay if this bill continues as currently written is the inflated cost the people of North Dakota are paying for specialty name-brand drugs because of manufacturers' coupon schemes.

Here is what you will hear me ask you to consider today:

1. The coupons are a targeted marketing effort meant to increase profits for drug manufacturers. These coupons are not available to everyone. They are only available to the well insured. If this bill intends to help consumers, it should require companies to offer the coupons to all who could benefit from the medications, all year long.

2. This bill does not help consumers as a whole. In the long run, it increases overall costs for everyone. If you look at the attached Harvard Magazine article, manufacturer sponsored coupons increase costs 8% or more than $1Billion in one drug class alone.

3. The entities this bill benefits most are the pharmaceutical companies. Health insurance costs in the fully insured marketplace in North Dakota are regulated by Commissioner Jon Godfread, unlike drug prices, which are set by drug manufacturers who stand to profit from this bill through maintaining higher drug costs.

The coupons are a targeted marketing effort meant to increase pharmaceutical profits.

Pharmaceutical gift cards are not a charitable effort – they are clearly targeted at commercially insured individuals for use on a specific drug purchase. If they were using the gift card for a medical procedure, would the pharmaceutical company allow it? No. They only allow the gift card to be used if the consumer purchases the name brand drug that the company manufactures. So, if you are following with me, it is a kick back, which is why it is not allowed under Medicare and Medicaid. It's illegal for pharmaceutical

companies to offer copay assistance for medications that you purchase through Medicare due to the Social Security Amendments of 1972. Included in those amendments is the Anti-Kickback Statute (AKS).

Regardless of this bill and coupons, carriers are paying the vast majority of the cost of these very expensive drugs. Speaking for BCBSND, we do it gladly. Newer drugs are improving and saving lives. Pharmaceutical spend is our fastest rising area at 20% annually, with 58% of that being on specialty drugs. Examples of these include cell and gene therapies at up to $4 million per treatment, oncology drugs ranging between $5000 and $150,000 per month and of course, GLP1 diabetic medications at over $1000 per member per month. If what the pharma companies are doing were truly altruistic, they would lower the cost of the drug rather than give out gift cards for thousands of dollars to a select population. They would also provide them to the uninsured, who arguably need them the most. But they don't. They only provide them to people who have commercial insurance because they know they can pass laws like these and recoup even more money, borne by insurance consumers via higher premiums.

This bill does not help consumers as a whole.

Pharmaceutical drug makers provide coupons for brand medications to market new drugs and encourage prescribers and patients to utilize their products. I linked to my testimony an article from Harvard Magazine entitled "How Coupons Keep Drugs Costly." In it, the authors discuss a recent study conducted by Rauner professor of business administration Leemore Dafny. Dafny and her colleagues estimated that "if you banned coupons, multiple sclerosis (MS) drug prices would be 8 percent lower, which in the U.S. means about a billion dollars less in spending"— That estimate is for MS prescriptions alone. https://www.harvardmagazine.com/2022/12/right-now-coupons-keep-drugs-costly

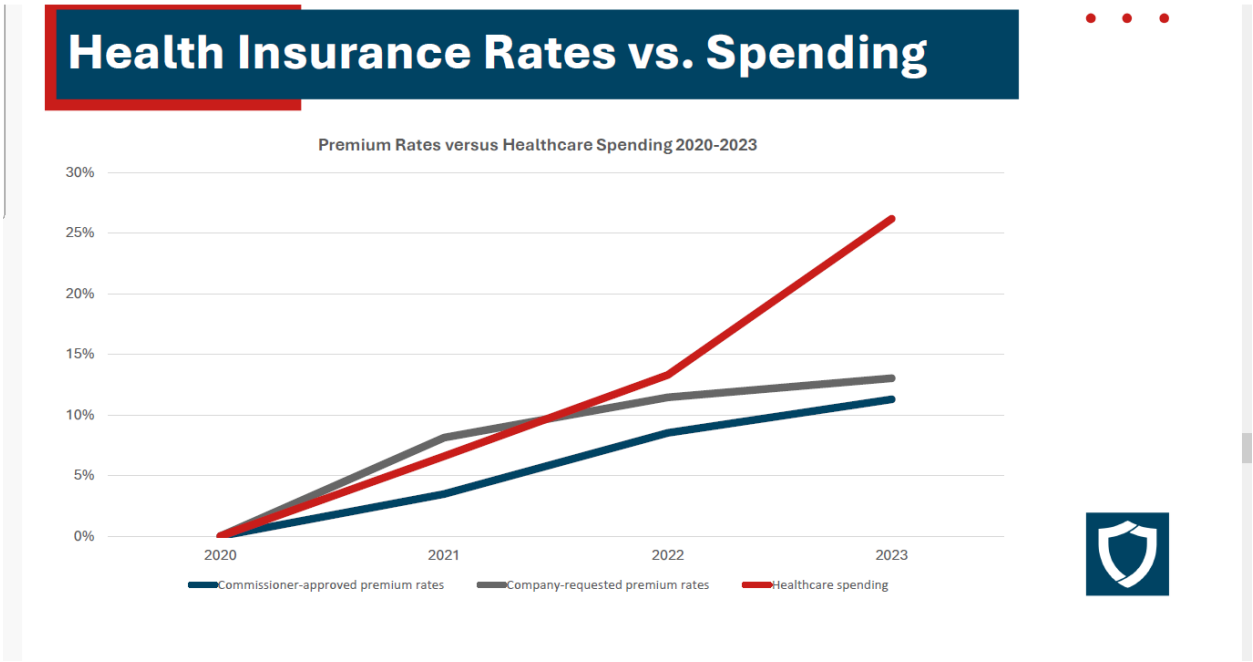
One of the arguments for this bill is that these are only for high-cost drugs with no generic. That's not true. Drug companies do offer the coupons for drugs with a generic therapeutic alternative. The Dafny study also shows that the share of brand-name prescription drug spending that included a coupon rose from 26 percent in 2007 to 90 percent in 2017. And the number of drugs with available coupons rose from about 200 in 2008 to more than 800 in 2018.

This bill is a balloon squeezer. Passing this bill will "lower" initial costs for commercially insured North Dakotans who receive a copay coupon at the expense of commercially insured North Dakotans who do not receive coupons.

The entities this bill benefits most are the pharmaceutical companies.

In the United States, there is no regulation of prescription drug pricing. Rather drug companies set their own prices. In contrast, in North Dakota, carrier premium rates are reviewed and approved by the North Dakota Insurance Department. What that means is that health insurance carriers must share two to five years of data to justify each year's premium rate. The Commissioner almost always cuts the rate we ask for, and then approves those rates. Carriers cannot charge more than the rate approved. One thing of note

is that this legislation would not apply to self-funded ERISA plans, as it has a direct tie to and impact on ERISA plan benefit administration and therefore has an "impermissible connection with" ERISA plans that has consistently been struck down by federal courts, including the U.S. Supreme Court.



I've heard the sponsors of the bill say that insurers would "pocket money from your grandma or church if they helped you pay…" I will share very clearly with you that if our members get a gift of money from their grandmother, charitable websites, their church, or the like, and use it towards their copay, BCBSND one hundred percent applies and counts it toward your deductible. Let's also be clear, Grandma isn't raising the price of her cookies to recover the costs of her gift to you nor is Grandma requiring you or BCBSND to go purchase her cookies to get the assistance. Grandma doesn't benefit monetarily.

As stated, BCBSND opposes this bill. However, BCBSND could potentially support HB 1216 with the following amendments.

1. Amend the bill to require pharmaceutical companies extend the coupons to the insured and uninsured, twelve months of the year (to ensure that folks can receive their medications whenever they need them, not just once they get a few cycles in) with an accountability measure in place to prove that the manufacturers are doing so.

2. Amend the bill to mirror the proponents' intent and ban the offering of copay coupons for brand name drugs with a biologically equivalent, generic therapeutic alternative or biosimilar drug available.

The spending on consumer coupons for prescription drugs is substantial, with figures reaching into the billions of dollars annually. Passage of this bill allows drug manufacturers to pick winners (those on their newest, brand name drugs receiving a coupon) and losers (the uninsured, those on government programs like TriCare, Medicare, and Medicaid; and those policy holders who do not receive a copay coupon but will have to pay for the increased costs.) The best and most altruistic solution would be to eliminate coupons altogether and have pharmaceutical companies lower the price of their drugs by an equivalent amount. But since that option isn't on the table, BCBSND respectfully asks for consideration of the amendments or a Do Not Pass vote.

Thank you for your consideration and I will stand for any questions.

Protect ND Patients

Yes! on HB 1216

BDAND

ALL COPAYS COUNT COALITION

Myths vs Facts

Medicine for a hemophiliac can range anywhere from $500,000-$1,000,000 annually .

Patients with rare diseases rely on Patient Assistance Programs offered by pharmaceutical companies and non-profits to meet their deductible requirements, which they often hit the first month or two of the year. These payments are not given to the patient, but directly to insurance. These are different than the coupons that you might use at a local pharmacy.

Recently, insurance companies have implemented Copay Accumulators on many health plans, and are NOT accepting this patient assistance to count toward patients' deductibles.

Think of it this way: You are a college student with a $10,000 tuition bill and have a $5000 scholarship. The University accepts the $5000, but still makes you pay the full $10,000 bill (thus receiving $15,000 instead of $10,000) because you personally didn't pay it. Is that fair?

This is happening to patients all over the US, including North Dakota. Health plans will tell you patients are driven to high cost name brand drugs. **Patients with bleeding disorders do not have a generic option**. They will tell you we have no skin in the game, no personal costs -we still pay our premiums, multiple doctor visits, lab work, and ancillary supply costs.

To date, 21 states and Puerto Rico have enacted copay accumulator legislation. Help us add North Dakota to the list!

Scan this to see the full list -->

Bleeding Disorders Awareness

Facts:

- Hemophilia & von Willebrand Disease (VWD) are bleeding disorders caused by a protein deficiency required for blood to clot. Patients use products made from either human plasma or animal cells that replace proteins and control clotting.
- Many bleeding disorder patients were exposed to HIV and viral Hepatitis (B&C) prior to 1992 when all blood products were screened.
- It is estimated that 70% of all individuals with bleeding disorders who used factor products before 1987 may have been exposed to HIV and as many as 90% were exposed to Hepatitis C.
- About 20,000 people are affected by hemophilia in the U.S. and approximately 1% of the population is affected by VWD.
- Bleeding Disorders Alliance of North Dakota (BDAND) serves about 300 individuals and families who live with bleeding disorders in North Dakota and NW Minnesota.

Challenges:

- Access to insurance, discrimination issues, access to medications, co-infections.
- High annual medication cost, many with costs that exceed $500,000.
- Patients live with multiple chronic conditions and have unique care issues.

For more information about bleeding disorders, or to arrange a meeting, please contact:

Bleeding Disorders Alliance of North Dakota, Emily Ouellette, Executive Director

bdand.org director@bdand.org 701-381-0670 PO Box 548, Fargo, ND 58107

Please Support HB 1216 in North Dakota!

Patients for Prescription Access

Copay Assistance **Helps** Patients

Copay Accumulators Hurt Patients

Copay assistance provided by pharmaceutical manufacturers and nonprofit organizations provide a financial lifeline for many people living with chronic conditions who need **lifesaving** medications.

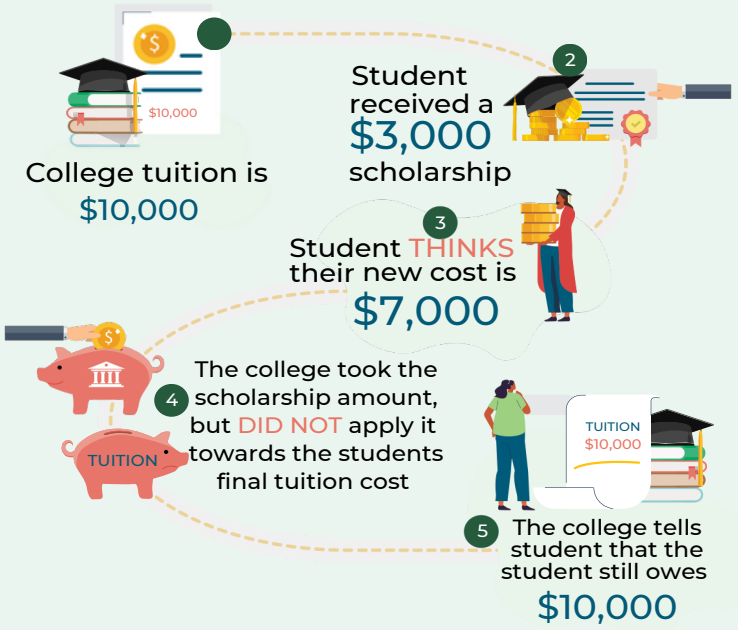
Insurers have raised deductibles, increased use of coinsurance, and added new prescription drug formulary tiers.

Insurers Double Dip While Patients are Denied Life-Essential Medications:

Many Insurers and PBMs are now utilizing copay accumulators that stop copay assistance from counting towards a patient's deductible and maximum out of pocket spending. These practices are creating significant financial and health issues for patients.

- All of the money paid through the copay assistance, which was intended to help the patient, goes directly to the health insurance company.
- Copay accumulators allow the insurance company to double dip and get paid TWICE - once from the copay assistance and then again by patients' deductibles
- This jeopardizes the health of patients and can ultimately result in the use of more expensive health care services, disability, unemployment and loss of independence.

Imagine if this same practice was applied to college tuition...



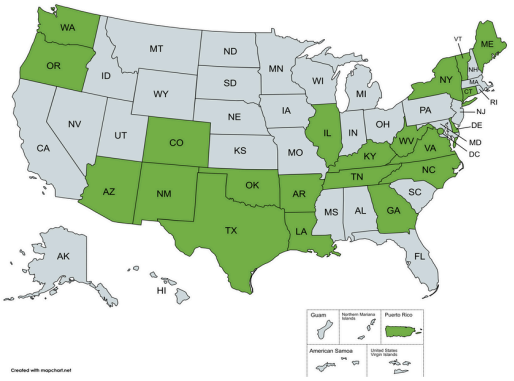
*The college receives $13,000, when the bill was only $10,000.

Call to Action

Lawmakers must pass legislation to prevent harmful and unfair copay accumulator policies, an emerging change in insurance plans.

We must "Stop the Double Dip"

As of Jan 2025, 21 states (and Puerto Rico) have enacted laws banning payer and PBM use of copay accumulator programs: AR, AZ, CO, CT, DE, GA, IL, KY, LA, ME, NC, NM, NY, OK, OR, TN, TX, VA, VT, WA, WV) DC, and Puerto Rico



Copay Accumulator Adjustors
Clearing Up the Misconceptions

Copay Accumulator Adjustment Programs are affecting a tremendous number of patients with a diverse set of health conditions – most affected are those with chronic and/or rare disorders.

- Allowing Health Plans to utilize Copay Accumulator Adjuster programs leave a lot of patients vulnerable and unable to access their medication. Patients are choosing between paying their rent/mortgage, putting food on the table, or paying for their medication.
- Bleeding Disorder patients meet their OOP maximum the first month or two of the year. They depend on Copay Assistance Programs to help them meet their deductible.

The health plans will argue this is manufacturers "gaming" the system or trying to preserve market share to drive more business to higher cost drugs.

- In this version of the bill language, the medicine either doesn't have a generic available OR if it does, the plan still has control over whether the patient can access it through their internal utilization and appeals processes.
- Bottom line is that health plans should be designed to ensure that the most medically appropriate medicine that is covered by the plan is what is approved.
- And if this "gaming the system" argument is truly the case, **why did health plans create these accumulator adjustment programs specifically in the specialty areas where there are no generic equivalents?**

There is a misconception that copay coupons allow patients to circumvent the formulary.

- Health plans still determine:
    - What is on or off formulary and what is preferred and non-preferred.
    - The utilization processes that patients and their doctors must navigate to ask for any exceptions to a preferred drug or for something that not on the formulary.
- Patients should not be penalized for correctly working through the process their plan has laid out for them, whether that is the copay and out-of-pocket costs they have to pay OR the process to gain approval to get access to a medicine that is prescribed for their condition.
- Keep in mind that copay cards are just a patch for a broken system overall; Current health plans and drug prices make it difficult for patients to obtain their medication - manufacturers and some non-profits are providing copay assistance because patients can't afford their out-of-pockets on their medicines.

Costs rise when patients don't have access to their specialty medication.

- Patients experience complications and disease progression, sending them to the Emergency Room, needing avoidable surgeries, and additional treatment they would not have needed had they had access to the medication in the first place. They often miss school and/or work. • A patient's mental health also suffers when they have to deal with complications of their disease, and navigate health plans.

Health Plans say patients have 'no skin in the game' if they rely on Copay Assistance Programs

- Patients still pay the cost of multiple doctor visits, lab work, and ancillary supplies for their infusions. Many patients also pay for physical therapy and other services to treat their bleeding disorder.

For more information, please contact:

BDAND
Bleeding Disorders Alliance of North Dakota

Emily Ouellette, Executive Director
Bleeding Disorders Alliance of North Dakota
director@bdand.org | 701-381-0670

NATIONAL BLEEDING DISORDERS FOUNDATION
Innovate | Educate | Advocate

Bill Robie, Senior Director of Government Relations
National Bleeding Disorders Foundation
brobie@bleeding.org | 212-328-3775

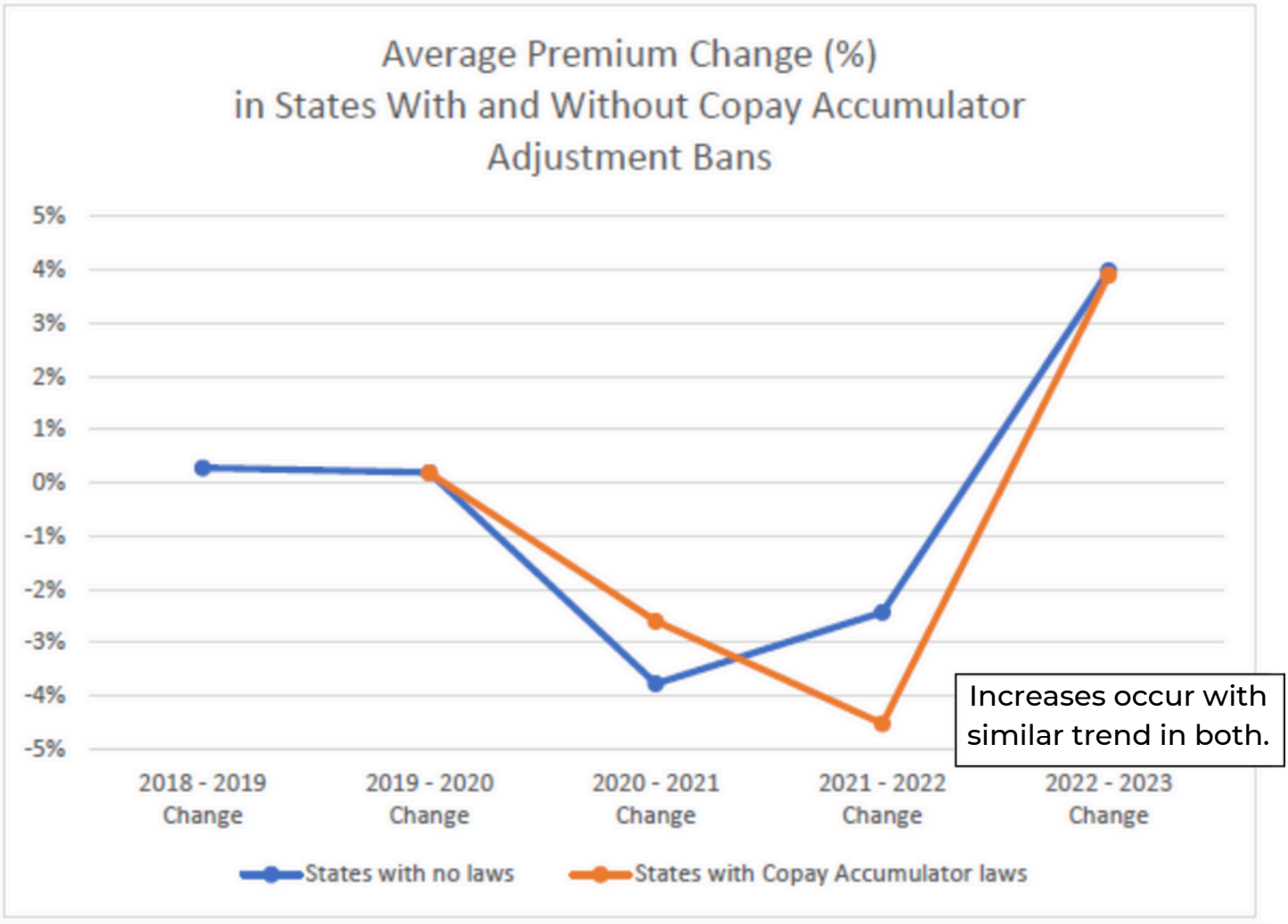
True Facts: Current data shows there is no evidence that Co-Pay Accumulator bans will increase premiums.

Previously, opponents have claimed that there will be a raise in premiums if Co-Pay Accumulator bans are passed. While it's true that healthcare premiums continue to increase, there is no evidence and correlation between passage of bans and trend.

- Fortunately, we now have data from several data sources on premiums from the 21 states and Puerto Rico that have passed Co-Pay Accumulator bans. The data doesn't substantiate those concerns. [1] See the charts and studies below.

- Global Healthy Living Foundation's analysis shows that despite what insurers and pharmacy benefit managers say, protecting patient assistance programs has not increased the cost of health insurance: https://ghlf.org/copay-assistance-protection/

- The AIDS Assistance's 2023 study shows Co-Pay Accumulator laws are not increasing average benchmark premiums in states that passed CAAP laws (at least for the first 16 of the 21w/ existing bans). And in fact, in several states average premiums declined (presumably due to better medication adherence):The-AIDS-Inst.-Copay-Assistance-Does-Not-Increase-Premiums.pdf



1] https://www.kff.org/affordable-care-act/state-indicator/marketplace-average-benchmark-premiums/?activeTab=graph&currentTimeframe=0&startTimeframe=10&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

Assumes law impacted premiums the year after it was passed.

Key:

Blue cells = States with copay accumulator adjustment bans passed between 2019 and 2022;

Orange font = Year law impacted premiums

Marketplace Average Benchmark Premiums by State Copay Assistance Accumulator Bans in Place by 2023

States	2018	2019	2020	2021	2022	2023
Arizona	$516	$471	$442	$436	$390	$410
Illinois	$486	$478	$451	$423	$418	$453
Virginia	$535	$555	$521	$479	$450	$371
West Virginia	$545	$596	$628	$654	$752	$824
Georgia	$483	$487	$463	$456	$394	$413
Arkansas	$364	$378	$365	$394	$387	$416
Connecticut	$545	$475	$570	$580	$581	$627
Kentucky	$422	$460	$471	$476	$387	$422
Louisiana	$474	$454	$500	$545	$541	$565
North Carolina	$627	$618	$558	$516	$504	$512
Oklahoma	$659	$696	$601	$554	$498	$510
Tennessee	$743	$548	$511	$466	$445	$473
Delaware	$589	$684	$548	$540	$548	$549
Maine	$588	$544	$513	$440	$427	$457
New York	$506	$569	$610	$597	$592	$627
Washington	$336	$406	$391	$388	$396	$395
Alabama	$558	$546	$553	$590	$597	$567
Alaska	$726	$702	$724	$675	$712	$762
California	$430	$439	$430	$426	$417	$432
Colorado	$470	$488	$358	$351	$358	$380
District of Columbia	$324	$393	$414	$415	$387	$428
Florida	$466	$477	$468	$457	$456	$471
Hawaii	$438	$493	$474	$478	$484	$469
Idaho	$478	$498	$520	$495	$461	$425
Indiana	$339	$339	$387	$421	$398	$397
Iowa	$713	$762	$742	$523	$502	$484
Kansas	$518	$552	$502	$491	$450	$471
Maryland	$487	$419	$397	$347	$328	$336
Massachusetts	$316	$332	$343	$363	$389	$417
Michigan	$381	$383	$360	$347	$340	$362
Minnesota	$385	$326	$309	$307	$327	$335
Mississippi	$519	$521	$487	$459	$448	$461
Missouri	$529	$499	$483	$479	$442	$473
Montana	$525	$561	$483	$471	$483	$477
Nebraska	$767	$838	$711	$699	$595	$550
Nevada	$432	$410	$374	$393	$383	$386
New Hampshire	$475	$402	$405	$357	$309	$323
New Jersey	$413	$352	$392	$405	$424	$441
New Mexico	$414	$365	$345	$339	$389	$445
North Dakota	$377	$457	$383	$493	$497	$475
Ohio	$371	$380	$375	$375	$375	$413
Oregon	$414	$443	$446	$437	$444	$462
Pennsylvania	$575	$484	$459	$455	$390	$433
Rhode Island	$311	$336	$332	$349	$361	$379
South Carolina	$520	$552	$509	$476	$444	$496
South Dakota	$521	$557	$593	$618	$601	$626
Texas	$434	$444	$432	$436	$424	$461
Utah	$550	$542	$486	$472	$456	$471
Vermont	$505	$622	$662	$669	$749	$841
Wisconsin	$569	$537	$491	$457	$429	$456
Wyoming	$865	$865	$881	$791	$762	$802

ALL COPAYS COUNT COALITION

Correcting the Record on Copay Assistance and Accumulator Adjustment Policies

MYTH

Copay assistance provided by pharmaceutical manufacturers keeps drug prices high, by incentivizing the use of high-cost treatments instead of lower cost generic equivalents.

FACT

Copay accumulator adjustment policies (CAAPs) largely target specialty medications for which there are generally no generic equivalents available. In fact, data shows that for all commercial market claims for specialty medications where copay assistance was used, only 3.4% of those claims were for a product that may have a generic alternative available.[1] If copay assistance programs were intended to drive patients away from generic alternatives, then this share would be significantly higher.

The truth is that copay assistance is a critical lifeline that helps ensure the most vulnerable patients can access their needed medications. When barriers prevent patients from accessing these medications, it ends up costing the health system more money due to complications and worsening health outcomes. Research has found that the cost of patients not receiving optimal medication therapy is over $528 billion each year in the United States.[2]

MYTH

Copay assistance enables patients to circumvent plan design and go right to the highest-cost drugs.

FACT

Patients taking specialty medications must first go through utilization management (UM) protocols imposed by their health plan, such as prior authorization and step therapy, before being granted access to the medication their doctor has prescribed. It is only *after* receiving approval for his/her medication from the health plan that patients can request copay assistance.

MYTH

If patients don't like accumulator policies, they should be better health care consumers and choose a health plan that works better for them.

FACT

When it comes to choosing a health plan, most patients do not have a choice. Plans with copay accumulators are either all that is offered, or all they can afford. For many Americans, it all comes down to the cost of the premium, and sadly, the lowest premium plans come with the highest out-of-pocket cost burden. In fact, many employers only offer high deductible health plans (HDHPs) which can require a deductible of up to $8,700 – which many patients cannot afford without assistance.

With more than 80% of commercially insured plans having copay accumulator policies, millions of Americans are insured, but left unable to exercise their health plan benefits to get the medications they need.[3]

Correcting the Record on Copay Assistance and Accumulator Adjustment Policies

MYTH

When patients are allowed to use copay assistance, they have less "skin in the game."

FACT

Patients living with chronic illnesses don't have the luxury of forgoing certain health care treatments and services. Copay assistance helps shoulder the increasingly high burden of out-of-pocket costs for needed medicines.

In recent years, **patients are being forced to pay more out of pocket than ever before.** More than half of all Americans are now in HDHPs, and the average deductible has increased 90% since 2015.[4,5] While 56% of Americans report being unable to cover an unexpected expense of over $1,000, Affordable Care Act (ACA)-compliant plans are allowed to charge $8,700 out of pocket for an individual and $17,400 for a family in 2022.[6,7] **This is not a matter of choosing smarter – it is an impossible financial situation.**

MYTH

Internal Revenue Service (IRS) guidance stands in the way of the Centers for Medicare & Medicaid Services (CMS) disallowing copay accumulator adjustor policies.

FACT

This is a misreading of the IRS guidance. **Although critics often point to 2004 IRS informal guidance as preventing CAAP bans, the guidance does no such thing.**

The IRS informal guidance itself does not address copay assistance at all. What's more, the 2004 informal guidance predated patient cost-sharing protections that were set in the ACA, prior to the emergence of accumulator adjustor policies.

The IRS has since clarified its position on the use of copay cards for enrollees on a HDHP paired with a health savings account (HSA) that wish to contribute to their HSA, stating that the enrollee is only required to meet the minimum deductible to be considered to have met their financial responsibility. **Claiming IRS rules block copay help from counting towards a patient's deductible is simply untrue and harms America's most vulnerable patients.**

To set the record straight, **CMS should require that insurers and pharmacy benefit managers (PBMs) *count all copayments made by or on behalf of an enrollee* toward that enrollee's annual deductible and out-of-pocket limit.** CMS can do this in their annual updated guidance, known as the Notice of Benefit and Payment Parameters (NBPP), which informs health insurance plan design and implementation.

REFERENCES

1 https://www.iqvia.com/locations/united-states/library/fact-sheets/evaluation-of-co-pay-card-utilization

2 https://www.sciencedaily.com/releases/2018/04/180402160613.htm?utm_source=H2Rminutes

3 https://www.ajmc.com/view/contributor-providers-and-patients-push-back-payers-push-forward-co-pay-mitigation-programs

4 https://www.hemophilia.org/sites/default/files/document/files/NHF - National Patients and Caregivers Survey on Copay Assistance %28Key Findings%29.pdf

5 https://aidsinstitute.net/documents/2021_TAI_Double-Dipping_Final-031621.pdf

6 https://www.cnbc.com/2022/01/19/56percent-of-americans-cant-cover-a-1000-emergency-expense-with-savings.html

7 https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/

Fact Sheet

IMS Health & Quintiles are now IQVIA™

AN EVALUATION OF CO-PAY CARD UTILIZATION IN BRANDS AFTER GENERIC COMPETITOR LAUNCH

Introduction

Patient savings programs, in particular co-pay card programs, continue to bear scrutiny across the industry. Co-pay card programs are patient-based programs designed by manufacturers to assist commercially insured and cash paying patients in affording their medications. Industry stakeholders are especially critical of these programs, claiming they incentivize the use of high-cost therapies – including the purchase of branded drugs over their less expensive, generic equivalents. In an effort to quantify the use of patient savings programs among brands that have lost exclusivity on their patents (LOE) and have generic equivalents in the market, IQVIA identified post-LOE brands in pharmacy claims data and measured co-pay card use within them.

Approach

IQVIA analyzed retail, pharmaceutical, patient claims-level data from 2013 through 2017 to quantify the use of co-pay card programs in brands that have lost exclusivity. Brands with at least one generic equivalent were identified as "post-LOE" in the analysis. IQVIA further categorized the post-LOE brands by those with a manufacturer co-pay offset program (i.e, brands that demonstrated at least 1% of volume adjudicated with a co-pay card while a generic was available). Claims volumes were aggregated and compared across these different market cohorts (summarized in Figure 1).

Co-pay card use is captured in the IQVIA data at a claim level using the secondary payer information present on the claim. Among commercial claims, secondary payers predominantly are attributed to co-pay card programs provided by manufacturers.

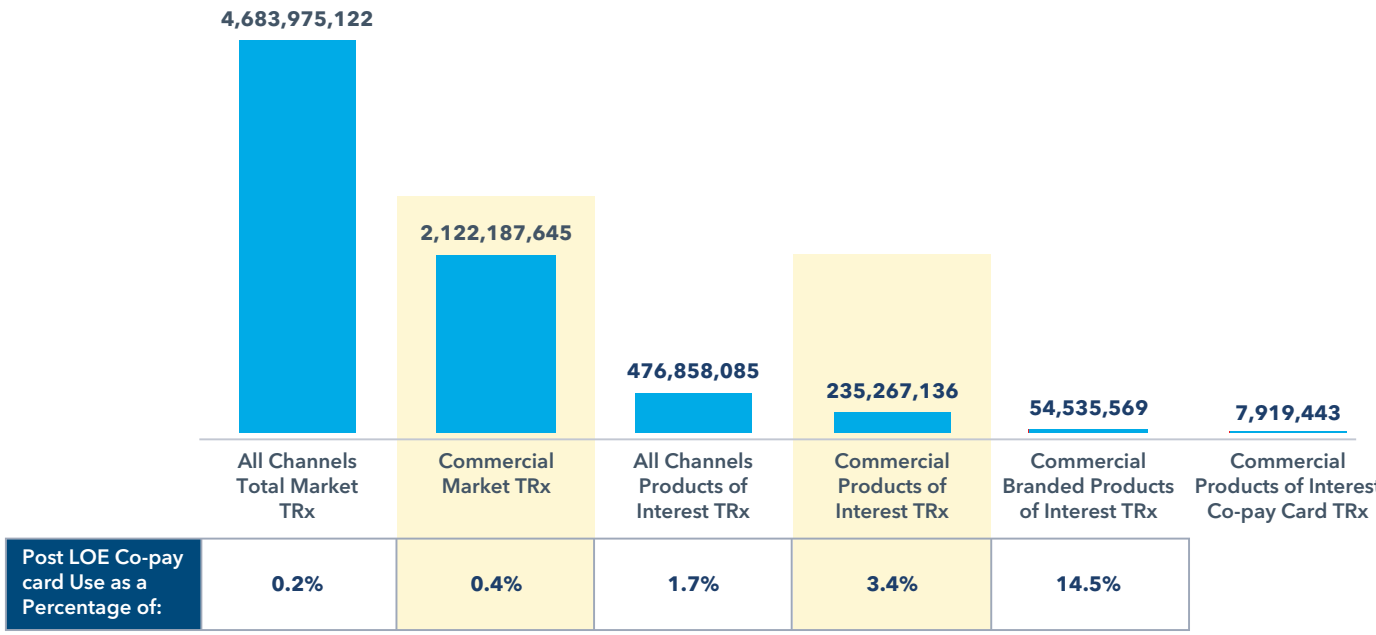
Figure 1: Market Cohort Definitions

MARKET COHORT	DESCRIPTION	B AND/OR G
All Channels Total Market TRx	Encompasses all volume across payer channels.	Brand & Generic
Commercial Market TRx	Limits to commercial volume only.	Brand & Generic
All Channels Products of Interest TRx	Flags brands with at least one generic entry and further refines by limiting to brands that had at least 1% of their volume adjudicated with a co-pay card post-LOE. The generic volume associated with these brands is also included to reflect the molecule's volume across payer channels.	Brand & Generic
Commercial Products of Interest TRx	Limits to the commercial volume for Products of Interest.	Brand & Generic
Commercial Branded Products of Interest TRx	Reflects the branded commercial volume for the products of interest.	Brand Only
Commercial Products of Interest Co-pay Card TRx	Represents the branded products of interest that were filled with a co-pay card.	Brand Only

Results:

Despite continued public attention, patient co-pay assistance program claims only make up a small proportion of commercial, prescription volume for post-LOE products with co-pay card programs. As demonstrated in Figure 2, a small subset of commercial volume is represented by post-LOE brands with evidence of a manufacturer-sponsored co-pay card programs. While co-pay cards are still being utilized by patients on brand scripts after LOE, the use is limited and only makes up 0.4% of the total commercial market volume. The total commercial volume for post-LOE products with a co-pay card program available (the brands and their generic counterparts) represent 11.1% of commercial volume. For prescriptions filled with a post-LOE brand that sponsors a patient support program, 14.5% of claims are associated with these programs.

Figure 2: Claims Volume by Market Cohort (2017)



Source: IQVIA NSP, NPA, and FIA data sets; IQVIA Analysis

Implications:

While some manufacturers may implement strategies to retain brand volume after the loss of exclusivity, manufacturer co-pay assistance programs appear to have limited use and represent only part of a brand's potential retention strategy. Formulary exclusions and automatic generic substitution at the pharmacy are effective tools for promoting generic uptake, thereby curtailing co-pay card use among post-LOE brands. Additionally, co-pay card use on branded scripts post-LOE represents a sliver of the total commercial market, making up only 0.4% of volume across all products. When narrowing in on the total commercial volume for products where manufacturer co-pay assistance is available, only 3.4% of total volume is attributable to prescriptions using these programs. If patient savings programs were having a substantial impact on generic product uptake after loss of exclusivity, one would expect to see higher utilization in the market.

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2025 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Room JW327C, State Capitol

HB1216
2/3/2025

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; and to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans.

10:55 a.m. Chairman Warrey called the meeting to order.

Members Present: Chairman Warrey, Vice Chairman Ostlie, Vice Chairman Johnson, Representatives Bahl, Brown, Christy, Finley-DeVille, Grindberg, Kasper, Koppelman, D. Ruby, Schatz, Schauer, Vollmer

Discussion Topics:

- Deductible transactions

10:55 a.m. Representative D. Ruby moved Do Not Pass.

10:55 a.m. Representative Koppelman seconded the motion.

Representatives	Vote
Representative Jonathan Warrey	Y
Representative Mitch Ostlie	N
Representative Landon Bahl	Y
Representative Collette Brown	N
Representative Josh Christy	Y
Representative Lisa Finley-DeVille	N
Representative Karen Grindberg	Y
Representative Jorin Johnson	Y
Representative Jim Kasper	N
Representative Ben Koppelman	Y
Representative Dan Ruby	Y
Representative Mike Schatz	N
Representative Austin Schauer	N
Representative Daniel R. Vollmer	Y

Motion passed 8-6-0

11:09 a.m. Representative D. Ruby will carry the bill.

11:09 a.m. Chairman Warrey closed the meeting.

Diane Lillis, Committee Clerk

Bill reconsidered on 02/05/25.

2025 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Room JW327C, State Capitol

HB1216
2/5/2025

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; and to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans.

9:02 a.m. Chairman Warrey called the meeting to order.

Members Present: Chairman Warrey, Vice Chairman Ostlie, Vice Chairman Johnson, Representatives Bahl, Brown, Christy, Finley-DeVille, Grindberg, Kasper, Koppelman, D. Ruby, Schatz, Schauer, Vollmer

Discussion Topics:

- Insurer double-dipping
- Copay assistance/accumulators
- Out-of-pocket deductible
- Expensive specialty drugs
- Gift Card
- Needs based
- Discount value

9:03 a.m. Representative Koppelman moved to reconsider the bill.

9:03 a.m. Representative Schauer seconded the motion.

Voice vote.

Motion passed.

9:04 a.m. Representative Karen Karls, District 35, Bismarck, ND, testified in favor and submitted testimony #35931.

9:16 a.m. Representative D. Ruby moved to adopt amendment LC #25.0068.01001, #35612.

9:17 a.m. Representative Kasper seconded the motion.

Voice vote.

Motion passed.

9:17 a.m. Chrystal Bartuska, Division Director Life & Health, ND Insurance Department, testified as neutral.

9:26 a.m. Chairman Warrey closed the meeting.

Diane Lillis, Committee Clerk
Bill was held over.

25.0068.01001
Title.

Prepared by the Legislative Council staff for Representative Karls
February 3, 2025

Sixty-ninth
Legislative Assembly
of North Dakota

PROPOSED AMENDMENTS TO

HOUSE BILL NO. 1216

Introduced by

Representatives Karls, Hagert, Kiefert, Wagner

Senators Boschee, Dever, Sorvaag

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; and to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 26.1-36 of the North Dakota Century Code is created and enacted as follows:

Out-of-pocket expenses - Prescription drugs.

1. As used in this section:

   a. "Cost-sharing" means any coinsurance, copayment, or deductible under a health benefit plan.

   b. "Enrollee" means an individual entitled to prescription drug coverage under a health benefit plan.

   c. "Grandfathered health plan" has the meaning stated in the Patient Protection and Affordable Care Act [Pub. L. 111-148], as amended by the Health Care and Education Reconciliation Act of 2010 [Pub. L. 111-152]. The term includes the public employees retirement system uniform group insurance program's grandfathered preferred provider organization plan.

   d. "Health benefit plan" has the same meaning as provided under section 26.1-36.3-01.

~~d.~~e. "Prescription drug" means a drug for which a prescription is required:

(1) Without a generic equivalent; or

(2) With a generic equivalent and the enrollee has obtained access to the drug through prior authorization, a step therapy protocol, or the heath care insurer's expectations and appeals process.

2. ~~To~~Except as provided under subsection 4, to the extent permitted by federal law and regulation, an insurer may not deliver, issue, execute, or renew a health benefit plan providing prescription drug coverage unless when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement for a prescription drug under the health benefit plan, the health benefit plan provides for the inclusion of any amount paid by the enrollee or paid on behalf of the enrollee by another person. The health benefit plan may not vary the out-of-pocket maximum or cost-sharing requirement, or otherwise design benefits in a manner that takes into account the availability of a cost-sharing assistance program for a prescription drug.

3. If application of this section would result in ineligibility of a health benefit plan that is a qualified high-deductible health plan to qualify as a health savings account under section 223 of the Internal Revenue Code [26 U.S.C. 223], the requirements of this section do not apply with respect to the deductible of the health benefit plan until after the enrollee has satisfied the minimum deductible under section 26 U.S.C. 223.

4. This section does not apply to a grandfathered health plan.

SECTION 2. AMENDMENT. Section 26.1-36.6-03 of the North Dakota Century Code is amended and reenacted as follows:

26.1-36.6-03. Self-insurance health plans - Requirements. (Effective through July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.

HB 1216 True Facts

HB 1216 would allow a third-party to assist with the out-of-pocket maximums to help those who suffer from rare diseases afford their specialty prescriptions.

Example: Patient A used a $5,000 gift card from the drug manufacturer to cover her out-of-pocket amount at the beginning of her healthcare policy year. The pharmacy accepted it, but later she was billed by her insurance provider for $5,000, claiming because her policy now includes a copay accumulator, they don't accept payment from a third-party. In other words, the insurer is double-dipping.

Legislation banning this practice has passed in 21 other states and our hope is that North Dakota will also stop this practice. It applies to only the prescription side of a health plan and is only for prescription drugs for which there is no generic equivalent.

Copay assistance is for people who have insurance but need help meeting their out-of-pocket deductible. The cost of the drug is already pre-set prior to patients using "assistance."

Copay Accumulator programs target specialty drugs for which manufacturers often provide copay assistance. With a copay accumulator in place, the insurance company decides that assistance no longer applies toward a patient's out-of-pocket maximum (deductible). This means patients will experience increased costs and take longer to reach required deductibles. By prohibiting these third-party funds from applying it removes a safety net for chronic disease patients who need expensive specialty drugs but cannot afford them.

This increases the financial burden for those facing life-threatening disease. It can contribute to medical bankruptcy and discontinuance of care because the insurance company refuses to apply the money they receive to the patient's out-of-pocket maximum. The result is poorer health outcomes and greater cost to the system downstream.

Many employers who contribute significantly to their employee premiums, often don't understand that these copay accumulators keep their employees and their families dealing with chronic disease from the medicines they need.

2025 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Room JW327C, State Capitol

HB1216
2/10/2025

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; and to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans.

10:19 a.m. Chairman Warrey opened the meeting.

Members Present: Chairman Warrey, Vice Chairman Ostlie, Vice Chairman Johnson, Representatives Bahl, Brown, Finley-DeVille, Grindberg, Kasper, Koppelman, D. Ruby, Schatz, Schauer, Vollmer

Member Absent: Representative Christy

Discussion Topics:

- Health care insurance grandfather plans
- Fiscal impact of the bill
- Health care plan coupons
- Treated as secondary insurance
- Brand name vs generic drugs
- Accumulator co-pay

10:21 a.m. Alex Kelsch, America's Health Insurance Plans, answered committee questions.

10:35 a.m. Megan Ruby, Blue Cross Blue Shield North Dakota, answered committee questions.

10:49 a.m. Dylan Wheeler, Sanford Health Plans, answer committee questions.

10:55 a.m. Rebecca Fricke, Executive Director of the Public Employees Retirement System, answered committee questions.

10:57 a.m. Megan Ruby, Blue Cross Blue Shield North Dakota, answered committee questions.

11:04 a.m. Ben Hansen, American Cancer Society Cancer Action Network, answered committee questions.

11:09 a.m. Chairman Warrey closed the meeting.

Diane Lillis, Committee Clerk

2025 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Room JW327C, State Capitol

HB 1216
2/12/2025

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; and to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans.

2:46 p.m. Chairman Warrey opened the meeting.

Members Present: Chairman Warrey, Vice Chairman Ostlie, Vice Chairman Johnson, Representatives Brown, Finley-DeVille, Grindberg, Kasper, Koppelman, D. Ruby, Schatz, Schauer, Vollmer

Members Absent: Representatives Bahl, Christy

Discussion Topics:

- Fiscal note
- Health plan charges
- Treated as secondary insurance
- Brand name vs generic drugs
- Physicians prescribe
- Accumulator co-pay
- Coupon spread all year
- Coupon from the manufacturer
- Co Pay assistance
- Healthcare procedures

2:48 p.m. Representative D. Ruby moved Do Not Pass as amended.

2:55 p.m. Representative Schauer seconded the motion.

Representatives	Vote
Representative Jonathan Warrey	Y
Representative Mitch Ostlie	N
Representative Landon Bahl	AB
Representative Collette Brown	N
Representative Josh Christy	AB
Representative Lisa Finley-DeVille	N
Representative Karen Grindberg	Y
Representative Jorin Johnson	N
Representative Jim Kasper	N
Representative Ben Koppelman	N
Representative Dan Ruby	Y
Representative Mike Schatz	N

Representative Austin Schauer	N
Representative Daniel R. Vollmer	Y

Motion failed 4-8-2

3:17 p.m. Chairman Warrey closed the meeting.

Diane Lillis, Committee Clerk

2025 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Room JW327C, State Capitol

HB1216
2/17/2025

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; and to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans.

3:31 p.m. Chairman Warrey opened the meeting.

Members Present: Chairman Warrey, Vice Chairman Ostlie, Vice Chairman Johnson, Representatives Bahl, Brown, Finley-DeVille, Grindberg, Kasper, Koppelman, D. Ruby, Schatz, Schauer, Vollmer

Member Absent: Representative Christy

Discussion Topics:

- Expensive biological drugs
- Copayment assistance
- 75/25 Insurance/patient
- Copay accumulator

3:41 p.m. Representative Schauer moved to amend on Page 1 line 10 add "or" between coinsurance, copayment, to take out "or deductible" and on page 2 line 13 change "person" to "individual".

3:41 p.m. Representative Kasper seconded the motion.

Voice vote.

Motion passed

3:53 p.m. Representative Schauer moved Do Pass as amended.

3:53 p.m. Representative Kasper seconded the motion.

Representatives	Vote
Representative Jonathan Warrey	Y
Representative Mitch Ostlie	Y
Representative Landon Bahl	Y
Representative Collette Brown	Y
Representative Josh Christy	AB
Representative Lisa Finley-DeVille	Y
Representative Karen Grindberg	Y
Representative Jorin Johnson	Y

Representative Jim Kasper	Y
Representative Ben Koppelman	Y
Representative Dan Ruby	N
Representative Mike Schatz	Y
Representative Austin Schauer	Y
Representative Daniel R. Vollmer	Y

Motion passed 12-1-1

3:55 p.m. Representative Koppelman will carry the bill.

3:55 p.m. Chairman Warrey closed the meeting.

Diane Lillis, Committee Clerk

25.0068.01003
Title.02000

Adopted by the Industry, Business and Labor Committee
February 17, 2025

2-17-25
JB 1 of 4

Sixty-ninth
Legislative Assembly
of North Dakota

PROPOSED AMENDMENTS TO

HOUSE BILL NO. 1216

Introduced by

Representatives Karls, Hagert, Kiefert, Wagner

Senators Boschee, Dever, Sorvaag

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; and to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans.

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   b. "Enrollee" means an individual entitled to prescription drug coverage under a health benefit plan.

   c. "Grandfathered health plan" has the meaning stated in the Patient Protection and Affordable Care Act [Pub. L. 111-148], as amended by the Health Care and Education Reconciliation Act of 2010 [Pub. L. 111-152]. The term includes the public employees retirement system uniform group insurance program's grandfathered preferred provider organization plan.

   d. "Health benefit plan" has the same meaning as provided under section 26.1-36.3-01.

~~d.~~e. "Prescription drug" means a drug for which a prescription is required:

(1) Without a generic equivalent; or

(2) With a generic equivalent and the enrollee has obtained access to the drug through prior authorization, a step therapy protocol, or the heath care insurer's expectations and appeals process.

2. ~~To~~

a. Except as provided under subsection 4, to the extent permitted by federal law and regulation, an insurer may not deliver, issue, execute, or renew a health benefit plan providing prescription drug coverage unless when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement for a prescription drug under the health benefit plan, the health benefit plan provides for the inclusion of any amount paid by the enrollee or paid on behalf of the enrollee by another ~~person~~individual.

b. The health benefit plan may not vary the out-of-pocket maximum or cost-sharing requirement, or otherwise design benefits in a manner that takes into account the availability of a cost-sharing assistance program for a prescription drug.

c. An amount paid by a cost-sharing assistance program for a prescription drug may apply to an enrollee's copayment but may not apply to the annual deductible or out-of-pocket maximum. An enrollee shall notify the insurer of any cost-sharing assistance used to reduce a copayment.

3. If application of this section would result in ineligibility of a health benefit plan that is a qualified high-deductible health plan to qualify as a health savings account under section 223 of the Internal Revenue Code [26 U.S.C. 223], the requirements of this section do not apply with respect to the deductible of the health benefit plan until after the enrollee has satisfied the minimum deductible under section 26 U.S.C. 223.

4. This section does not apply to a grandfathered health plan.

SECTION 2. AMENDMENT. Section 26.1-36.6-03 of the North Dakota Century Code is amended and reenacted as follows:

26.1-36.6-03. Self-insurance health plans - Requirements. (Effective through July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.
2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22, 26.1-36-23.1, and 26.1-36-43. Section 54-52.1-04.18 applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

Self-insurance health plans - Requirements. (Effective after July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.
2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22,

26.1-36-23.1, and 26.1-36-43. Section 1 of this Act applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

REPORT OF STANDING COMMITTEE
HB 1216

Industry, Business and Labor Committee (Rep. Warrey, Chairman) recommends **AMENDMENTS (25.0068.01003)** and when so amended, recommends **DO PASS** (12 YEAS, 1 NAY, 1 ABSENT OR EXCUSED AND NOT VOTING). HB 1216 was placed on the Sixth order on the calendar.

2025 SENATE HUMAN SERVICES

HB 1216

2025 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

HB 1216
3/10/2025
12:13 PM

Relating to out-of-pocket expenses for prescription drugs; relating to self-insurance health care plans.

12:13 p.m. Chairman Lee opened the hearing.

Members Present: Chairman Lee, Vice-Chairman Weston, Senator Van Oosting, Senator Clemens, Senator Hogan, Senator Roers.

Discussion Topics:

- Copay Accumulator Programs

12:14 p.m. Representative Karen Karls introduced the bill and submitted testimony #39895.

Additional written testimony:

Mark Hobraczk, Director of Public Policy with AiArthritis, submitted written testimony in favor #39770.

Nick Telesco, State Advocacy for Dakota Oncology Society/ASCO, submitted written testimony in favor #39607.

12:15 p.m. Chairman Lee closed the hearing.

Andrew Ficek, Committee Clerk

ASCO®
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

March 7, 2025

Senator Judy Lee, Chair
Senate Committee on Human Services
Fort Lincoln Room
600 East Boulevard Avenue
Bismarck, ND 58505

Dear Chair Lee and Members of the Senate Committee on Human Services,

The Dakota Oncology Society and Association for Clinical Oncology (ASCO) are pleased to support **HB 1216 as originally introduced**, which would take steps to protect patients with cancer in North Dakota from co-pay accumulator programs.

The Dakota Oncology Society is a professional society representing healthcare professionals in North Dakota and South Dakota who specialize in oncology. ASCO is an organization representing physicians who care for people with cancer. With over 50,000 members, our core mission is to ensure that cancer patients have meaningful access to high quality, cancer care.

The Dakota Oncology Society and ASCO are committed to supporting policies that reduce cost while preserving quality of cancer care; however, it is critical that such policies be developed and implemented in a way that does not undermine patient access. Co-pay accumulator programs target specialty drugs for which manufacturers often provide co-pay assistance. With a co-pay accumulator program in place, a manufacturer's assistance no longer applies toward a patient's co-pay or out-of-pocket maximum. This policy means patients will experience increased out-of-pocket costs and take longer to reach required deductibles. By prohibiting these funds from counting toward patient deductibles and out-of-pocket maximum, co-pay accumulators negate the intended benefit of patient assistance programs and remove a safety net for patients who need expensive specialty medications but cannot afford them.

Co-pay accumulator programs lack transparency and are often implemented without a patient's knowledge or full understanding of their new "benefit." Far from being beneficial, co-pay accumulator programs increase the financial burden for patients, many of whom are facing life-threatening illness. The impact is especially hard on low-income populations. Increasing patient cost can contribute to medical bankruptcy and cause patients to discontinue care, seek non-medical alternatives—or forego treatment altogether. The result is poorer health outcomes and greater cost to the system.

The Dakota Oncology Society and ASCO are encouraged by the steps HB 1216 takes toward eliminating co-pay accumulator programs in North Dakota, and

we strongly urge the committee to pass the measure. For a more detailed understanding of our policy recommendations on this issue, we invite you to read the ASCO Policy Brief on Co-Pay Accumulators by our affiliate, the American Society of Clinical Oncology. Please contact Nick Telesco at Nicholas.Telesco@asco.org if you have any questions or if we can be of assistance.

Sincerely,

Matthew Tinguely, MD
President
Dakota Oncology Society

Eric P. Winer, MD, FASCO
Chair of the Board
Association for Clinical Oncology

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

March 9, 2025

The Honorable Jonathan Warrey, Chair
Senate Industry, Business, and Labor Committee
North Dakota State Capitol
600 East Boulevard Avenue
Bismarck, ND 58505

RE: Support H.B. 1216 to protect patients from harmful "copay accumulator adjusters"

Dear Chairman Warrey,

The International Foundation for Autoimmune and Autoinflammatory Arthritis (AiArthritis) urges your committee to support legislation overwhelming passed by the House (H.B. 1216) that would ensure health insurers credit all sums paid by or on behalf of patients toward their annual deductibles and out-of-pocket (OOP) maximums.

Who We Are - We don't represent the patient voice, we are the patient voice

AiArthritis is a patient-led, non-profit organization (based in St. Louis) that advocates for persons with autoimmune and autoinflammatory arthritis diseases worldwide. We are a recognized leader in advancing education, advocacy, and research for those impacted by AiArthritis diseases.

As we are led by patients, we understand how important it is to be able to promptly access safe, effective, and affordable treatment. Through lived experience, we also know first-hand how health plan protocols that disrupt continuity of care often lead to negative health outcomes, comorbidities, and significantly lower rates of remission—all of which increase costs for patients, plans, and providers.

Our organization is also part of the national All-Copays Count Coalition that was formed to protect patient access to life-saving therapies and ensure all copays are properly counted towards their total OOP costs.

About AiArthritis Diseases

While they are 100 known autoimmune and autoinflammatory diseases, only about two dozen of these conditions include inflammatory arthritis as a major clinical component - some examples include as rheumatoid arthritis, psoriatic arthritis, lupus, Crohn's disease, axial spondyloarthritis (including ankylosing spondylitis), and all juvenile versions of arthritis. Inflammation resulting from these conditions affects more than just the joints, but also tissues and organs throughout the body.

AiArthritis diseases are complex and chronic conditions that require comprehensive and uninterrupted care, often for much of a patient's lifetime. Many with AiArthritis diseases rely on specialty biologics to prevent disease progression and/or disability, which are often not affordable or accessible to patients without 3d party assistance with copays, coinsurance and deductibles that can cost tens of thousands of dollars, even for patients with adequate health coverage.

What Are Copay Accumulators

Copay accumulator adjuster programs (CAAPs) are a cost-containment technique that has exploded in the last few years and are currently found in most commercial health plans. They can be hard to spot, even for insurance experts, since they are deliberately hidden in lengthy plan documents under deceptive names such as "out-of-pocket protection programs" or "specialty copay solutions".

Health plans that rely on CAAPs will *accept* 3d party assistance for a subscriber's cost-sharing obligations (from manufacturers or non-profit organizations) but then refuse to *credit* that assistance to the subscriber's annual deductible or OOP maximum limit (often with little or no advance notice).

These programs are exceptionally harmful for persons with high-cost conditions (like AiArthritis diseases) because they can force patients to pay their entire OOP maximum early in the calendar year with one of their first prescription fills. Very few individuals can pay up to $9,200 up-front (the OOP max in 2025, which is double for families) to receive medication that they rely on to maintain basic functioning. Patients confronted with such costs either discontinue and forgo regular treatment or often turn to the ER for acute care, resulting in far higher costs for <u>both</u> patients and insurers.

Health plans claim CAAPs are needed to prevent 3d party copay assistance from artificially inflating drug prices by incentivizing consumers to purchase costlier brand-name products. However, this does <u>not</u> apply for most specialty drugs that have **no FDA-approved generic alternative.**

Furthermore, this argument is contradicted by the fact that plans are not simply refusing to accept 3d party copay assistance. Instead, health plans pocket the assistance – and then "double-dip" by *again* collecting the full cost-sharing amount from the subscriber. In addition, we understand that health plans may not always apply CAAPs uniformly, but rather discriminatorily target only those with these highest cost conditions in an effort to discourage their enrollment.

According to the annual report published by The AIDS Institute, one-third of all participating insurers in the ACA Marketplace for North Dakota currently applies some form of CAAPs[1]. As a result, we strongly urge your committee to follow the lead of 21 states (including Arkansas, Oklahoma, and Texas) that have already acted to restrict them.

There was **broad bipartisan consensus** in these states that denying those with the highest-cost conditions the critical access to care provided by copay assistance is grossly harmful, unfair, and counter-productive. Furthermore, data from The AIDS Institute documented that CAAP protections **did <u>not</u> appreciably increase premiums** in the states that enacted them[2].

[1] See TAI-Grade-Sheet_North-Dakota.pdf
[2] See https://aidsinstitute.net/documents/TAI-Report-Copay-Accumulator-Adjustment-Programs-2023.pdf.

Please feel free to reach out with any questions or for additional information regarding copay accumulator protections and the harm they cause to persons with AiArthritis diseases.

Sincerely,

Mark Hobraczk, JD, MPA
Director of Public Policy
Person living with ankylosing spondylitis (an AiArthritis disease)
mark@aiarthritis.org

cc: Members of the Industry, Business, and Labor Committee

HB 1216 – Senate Human Services Committee – March10, 2025

For the record, my name is Rep. Karen Karls. I represent District 35 in central Bismarck.

My husband Ken was executive director of the Cystic Fibrosis Association of ND for many years. 2 ½ years ago I visited with Karen, an adult with cystic fibrosis, a hereditary, chronic disease. She told me how the miracle drug Trikafta has changed her life, but it's very expensive. She has good insurance, but the deductible is $5,000. This medication is $28,000 per month. Once she meets her deductible she is covered for the rest of the year. The drug company gave her financial assistance in the form of a $5,000 VISA card to help her afford her medication. The card was accepted, but she was later billed for the entire $5,000 because the insurer no longer counts payment by a 3rd party toward her deductible. She is here today to share her testimony and will explain in more detail. (Please note there are submitted testimonies online from people suffering from other rare diseases.)

Needless to say, medications used to treat chronic diseases like CF, hemophilia and others are extremely expensive. Why? Because the pharmaceutical company that takes on the research for this disease faces YEARS of lab testing, clinical research, and then faces the rigors of winning FDA approval. There is a comparatively small market for these medications, even though they are "miracle" drugs—there are no generic alternatives for them! Thus the extremely high costs.

To help patients better afford their medications (and stay on them) many 3rd-party entities, including the drug manufacturers, offer cost-sharing assistance. Historically, commercial health insurance plans have counted this assistance towards a patient's deductible and maximum out-of-pocket limit, providing relief from high cost sharing and making it easier for patients to get their medications.

Unfortunately, health insurance carriers have adopted policies, often referred to as "accumulator adjustment programs" (AKA "copay accumulators") that block manufacturer assistance from counting towards deductibles and out-of-pocket limits. This means patients could be paying thousands more at the pharmacy. Many have relied on this assistance and have no idea that their health insurer no longer counts it toward their cost-sharing obligation. This can result in unpleasant surprises at the pharmacy counter where they may face thousands of dollars of unexpected costs.

If companies are willing to create a miracle drug and help patients obtain it via drug assistance programs, these should be accessible to them. We need to update our laws to prohibit insurers from this practice and enable patients to access and afford the lifesaving medications they need to manage their chronic illness. HB 1216 hopes to accomplish this.

Madam Chair and member of the committee, I will walk you through the bill, if you like.
Section 1 is the definition section; things to note…this bill is for prescription drugs only, specifically drugs for which there is no generic equivalent. The "meat" of Subsection 2 is on page 2, line 1 & 2: "…the health benefit plan provides for the inclusion of any amount paid by the enrollee or paid on behalf of the enrollee by another person." Section 2 deals with self-insurance plans; LC informed me that if our state PERS plan ever becomes self-insured, we will need these provisions.

I will stand for questions.

2025 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

HB 1216
3/10/2025
2:40 P.M.

Relating to out-of-pocket expenses for prescription drugs; and to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans.

2:40 p.m. Chairman Lee opened the hearing.

Members Present: Chairman Lee, Vice-Chairman Weston, Senator Van Oosting, Senator Clemens, Senator Hogan, Senator Roers.

Discussion Topics:

- Plan Selection
- Duplicate Use of Funds

2:40 p.m. Karen Cossette testified in favor and submitted testimony #40153.

2:48 p.m. Ben W. Hanson, Government Relations Director with American Cancer Society Cancer Action Network, testified in favor and submitted testimony #39873, #39874, #39875, #39876, #39877 and #40094.

2:53 p.m. Emily Ouellette, Executive Director of Bleeding Disorders Alliance of North Dakota, testified in favor and submitted testimony #39791, #39792, #39793, and #39794.

3:02 p.m. Bobbie Will, Policy and Advocacy Manager for Susan G. Komen, testified in favor and submitted testimony #39715.

3:05 p.m. Megan Hruby, Blue Cross Blue Shield of ND, testified in opposition and submitted testimony #40086.

3:15 p.m. Dylan Wheeler, Head of Government Affairs Sanford Health Plan, testified in opposition and submitted testimony #39771.

3:17 p.m. Alex Kelsch, Lobbyist for Americas Health Insurance Plans, testified in opposition and submitted testimony #39880.

3:20 p.m. Rebecca Fricke, Executive Director of The North Dakota Public Employees Retirement System, testified in neutral and submitted testimony #39604.

3:31 p.m. Representative Karen Karls testified in favor.

3:37 p.m. Chairman Lee closed the hearing.

Andrew Ficek, Committee Clerk

TESTIMONY OF REBECCA FRICKE

House Bill 1216 – Out-of-Pocket Expenses for Prescription Drugs

Good morning, Madame Chair and members of the committee. My name is Rebecca Fricke and I am the Executive Director of the North Dakota Public Employees Retirement System, or NDPERS. I appreciate the committee taking the time to analyze House Bill 1216, which limits the maximum amount that an enrollee can be charged for prescription drugs. I am here today on behalf of the NDPERS Board to provide information in a neutral capacity so the policy makers are able to make an informed decision regarding the bill.

House Bill 1216 requires that when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement for a prescription drug under a health benefit plan, that it must include any amount paid by the enrollee, or on behalf of the enrollee by another person. The plan may not vary the out-of-pocket maximum or cost-sharing requirement, or otherwise design benefits in a manner that considers the availability of a cost-sharing assistance program for a prescription drug and stipulates that high-deductible health plans that qualify for health savings account are exempt from this cost-share limit until a member reaches their minimum deductible.

Our consultant estimates that the bill would have a financial impact on the NDPERS health insurance plan and estimates a 1.1% increase in premium, or $8,697,000, in the 2025-2027 biennium. The main driver of this additional premium is that under our current grandfathered health plan, copayments do not go towards meeting out-of-pocket maximums and this bill would require these copayments to go towards meeting the out-of-pocket maximum. The majority of NDPERS members participate in this plan.

House Bill 1216 was a bill introduced during the interim, with the analysis provided to the Employee Benefits Programs Committee, which gave the bill a favorable recommendation. The consultant analysis provided to the committee is included as an attachment to the end of my testimony (this was bill draft 68 during the interim).

Madame Chair, I appreciate the committee taking the time to learn more about the impact this bill will have to our state. This concludes my testimony, and I'd be happy to answer any questions the committee may have.

Deloitte Consulting LLP
50 South Sixth Street
Suite 2800
Minneapolis, MN 55402
USA

Tel: 612 397 4000

www.deloitte.com

Memo

Date: June 7, 2024

To: Rebecca Fricke - Executive Director, North Dakota Public Employees Retirement System

Representative Austen Schauer - Chair, Legislative Employee Benefits Programs Committee, North Dakota State Government

From: Tim Egan, Dan Plante, Ford Edgerton, and Karno Sarkar - Deloitte Consulting LLP

Subject: **FINANCIAL REVIEW OF PROPOSED BILL 25.0068.01000**

Deloitte Consulting LLP (Deloitte [i]) was engaged to review the proposed legislation and the potential financial impact to the Uniform Group Insurance Program (Program) administered by the North Dakota Public Employees Retirement System (NDPERS), as well as other considerations that may contribute to the evaluation of the legislation.

The information included in the review relies on data provided by NDPERS, as well as publicly available data and industry studies. From the data provided by NDPERS, some of these data sources were developed by NDPERS, while others were prepared or created by third parties and delivered to NDPERS.

As part of the review, all data was reviewed for reasonableness, but an audit was not performed on the data. To the extent the data contains errors or anomalies that were unknown at the time the data was provided, the analysis may be affected by those issues.

OVERVIEW OF PROPOSED BILL

The Bill creates and enacts a new section to chapter 26.1-36 of the North Dakota Century Code relating to out-of-pocket expenses for health care services. The legislation does the following:

- Defines "cost-sharing", "enrollee", "health benefit plan", and "prescription drug"
- Regulates that an insurer cannot offer a prescription drug plan unless all costs paid by a member or on behalf of a member accrue towards a member's out-of-pocket maximum calculations. This includes any amount paid by any cost-sharing assistance program
- Stipulates that high-deductible health plans that qualify for health savings accounts are exempt from this cost-share limit until a member reaches their minimum deductible

ESTIMATED FINANCIAL IMPACT

Based on the analysis, it is anticipated the proposed legislation will have a financial impact on the Uniform Group Insurance Program. It is estimated the financial impact of the proposed legislation on the Uniform Group Insurance Program is approximately $8,697,000 in the 2025-2027 biennium ending 6/30/2027.

The current health plans offered by the uniform group insurance program include a "grandfathered" health plan (PPO/Basic Grandfathered Plan) and two "non-grandfathered" health plans (PPO/Basic Non-Grandfathered Plan and High Deductible Health Plan (HDHP). A health insurance plan earns a "grandfathered" status under the Patient Protection and Affordable Care Act (PPACA) if it retains the plan provisions that existed at the time of PPACA's enactment in 2010. Consequently, "grandfathered" plans may not include certain plan provisions or consumer protections required by the PPACA for plans enacted or amended post-2010.

In the PPO/Basic Grandfathered Plan, an enrollee's pharmacy copayment currently does not accumulate towards their out-of-pocket maximum. The proposed Bill, however, seeks to revise this aspect, requiring that copayments count towards an enrollee's out-of-pocket maximum. It is anticipated this amendment would lead more enrollees to reach their out-of-pocket maximum, thus shifting any additional claim liability to the Uniform Group Insurance Program, which can lead to higher costs.

A majority of the active and pre-Medicare membership resides in the PPO/Basic Grandfathered plan and could be impacted by this change. The non-grandfathered plans already include copayments in the out-of-pocket maximum; as a result, there would be no anticipated change or financial impact to those plans.

The financial impact estimate is based on the expected change to the percentage of prescription drug claims paid by enrollees under the current plan design that does not include copayments in the out-of-pocket maximum and the proposed design (per the proposed Bill) that would include copayments in the out-of-pocket maximum.

The development of the estimated claims impact utilized an internal Medical Rate Model, which includes medical and pharmacy benefit designs and is based on over 40 million active/non-Medicare retiree claims. The Medical Rate Model functions as a claims repayment model, applying detailed input plan provisions against the claims record database, effectively repricing the claims, and producing the expected plan claim payments versus allowed charges.

As a result of the modeling, it is estimated the plan design changes required as a result of the proposed Bill would produce a 1.1% increase to the expected total costs paid by the Uniform Group Insurance Program. This anticipated change to the expected claims costs was applied to the estimated biennium claims cost for actives and pre-Medicare retirees enrolled in the PPO/Basic Grandfathered plan, as developed during the 2022 biennial renewal process and trended to the 2025-2027 biennium.

It is estimated the financial impact of the proposed legislation on the Uniform Group Insurance Program is approximately $8,697,000 in the 2025-2027 biennium ending 6/30/2027, assuming a 9.4% annual prescription drug trend.

OTHER CONSIDERATIONS

The proposed Bill defines "cost sharing" as any coinsurance, copayment, or deductible under the policy. There may be some payments that would meet the definition that are excluded from the out-of-pocket accumulation. Examples of such are:

- costs for a service or supply furnished by a Preferred Care Provider in excess of such provider's negotiated charge for that service or supply;
- costs related to not pursuing required prior authorization;
- costs for services and supplies determined to be not medically necessary, as determined by the Claims Administrator, for the diagnosis, care, or treatment of the disease or injury

involved. This applies even if they are prescribed, recommended, or approved by the person's attending physician or dentist;

- costs for care, treatment, services, or supplies that are not prescribed, recommended, or approved by the person's attending physician or dentist;

- costs to the extent they are not reasonable charges, as determined by the Claims Administrator

Since the definition of "cost sharing" includes the term "under a health benefit plan" it is assumed that member liabilities for non-covered services as described above would not be required to be included in the out-of-pocket accumulation, and therefore would not constitute a change or result in additional financial impact.

In general, changes to plan design provisions for grandfathered health plans results in the loss of grandfathered status. Since the proposed change increases the value of the PPO/Basic Grandfathered Plan, it would not forfeit its grandfathered status.

Another factor to consider when assessing the proposed Bill's financial impact is the role of cost-sharing assistance programs. A Prescription Drug Copayment Assistance Program is a type of patient assistance program designed to help patients afford the out-of-pocket costs associated with their prescription medications. These programs are typically funded by pharmaceutical companies or non-profit organizations. Examples of these assistance programs include GoodRx, SaveOn, WellRx, among others.

The estimated financial impact did include an estimate of expenses covered by copayment assistance programs, as their management falls outside the purview of the Program. According to the proposed legislation, costs absorbed by cost-sharing assistance programs will also contribute towards a member's prescription drug out-of-pocket maximum. Consequently, a member might experience reduced costs at the point of service when filling a prescription. However, this reduction would not affect the costs incurred by the Program.

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HB 1216
Senate Human Services Committee
March 10, 2025

Good morning, Chair Lee, and Members of the Senate Human Services Committee,

I am Bobbie Will, the ND, MT, SD, and WY State Policy and Advocacy Manager for Susan G. Komen. I live in Representative Karls District 35 and am thankful she is sponsoring this important piece of legislation. I am before you on behalf of breast cancer patients in North Dakota to urge your **support of HB 1216**, which relates to out-of-pocket expenses for prescription drug cost-sharing requirements.

Health insurers have instituted "copay accumulator adjustment programs" which prevent payments made by copay assistance from drug manufacturers and nonprofits from counting toward a patient's cost-sharing requirements. HB 1216 will help breast cancer patients in North Dakota continue to access the treatments they need by ensuring all payments made by or on behalf of a patient count toward their cost-sharing requirements.

According to a recent study of claims data, a vast majority of copay assistance is used for treatments that do not have a generic alternative.[1] Unfortunately, many patients are not aware that copay assistance is not counted toward their deductible or out-of-pocket maximum, and they have to pay hundreds to thousands of dollars out of pocket to continue their treatments.

A breast cancer patient should not be forced to abandon their treatment or skip doses due to costs. Studies have shown that patients are far more likely to abandon their treatment when out-of-pocket costs exceed $100.[2] Unfortunately, we hear from patients who have been forced to stop using their medications due to the high out-of-pocket costs that end up having an increase in negative health outcomes and hospital visits- ultimately resulting in increases to overall health care costs.

As committed partners in the fight against breast cancer, we know how deeply important it is for North Dakota breast cancer patients to not be punished for using copay assistance to help them afford the necessary treatments they need. As such, we support HB 1216 and urge you to pass this critical legislation.

Bobbie Will
bwill@komen.org

[1] IQVIA. An Evaluation of Co-Pay Card Utilization in Brands after Generic Competitor Launch. https://www.iqvia.com/locations/united-states/library/fact-sheets/evaluation-of-co-pay-card-utilization
Accumulator
[2] Gleason PP, Starner CI, Gunderson BW, Schafer JA, Sarran HS. Association of prescription abandonment with cost share for high-cost specialty pharmacy medications. J Manag Care Pharm. 2009;15(8):648-658. doi:10.18553/jmcp.2009.15.8.648

SANFORD HEALTH PLAN

Chair Lee and Members of the Senate Human Services Committee -

Good Morning, my name is Dylan Wheeler - Head of Government Affairs for Sanford Health Plan - here today in opposition to HB1216. As we have consistently expressed this session, Sanford Health Plan supports access to prescription drugs and are aligned with the intent of reducing prescription drug prices for our patients and members. However, HB1216 is not the answer; rather, HB1216 is a veiled attempt by the pharmaceutical industry to drive utilization on brand name products, hold prices high, and inequitably target well-insured members - as opposed to offering similar assistance to those without insurance.

One thing needs to remain clear through the public testimony and legislative work on this bill - the passage or failure of this bill does not affect the availability and usage of prescription drugs coupons. To be clear, I am not speaking on behalf of any pharmaceutical manufacturer who may remove a coupon from the market; rather, the policy of this bill does not change that market availability.

We consistently talk about the rising prices of prescription drugs here at the Capital and debate levers that the state, as policymakers, can pull to drive down costs. HB1216 sets a different precedent in that pharmaceutical manufacturers, if HB1216 becomes law, can continue to escalate prices in the market and then also issue a coupon on that same medication - shifting that cost to individuals, businesses, and families. Either way - health plans, and by extension premium payers in the same risk pool, would bear the increased cost caused by the coupon.

Sanford Health Plan does not currently use coupon accumulator programming - so why would we oppose such a measure? We hear from our employer groups and members about concerns about the rising costs of health care and health insurance. One available lever to health plans that could drive down premium costs or at a minimum hold downward pressure on prescription drug pricing would be to look at coupon accumulators. HB1216 takes that cost saving tool off the market and leaves health plans limited tools to influence premiums. We should maintain health plan flexibility and adapt to the market so that we can respond and use the tools available.

Finally - and as I shared during the 2023 legislative session - public policy that awards those who set a high price (here, pharmaceutical manufacturers) to begin with, and require others pick up that increase (here, through coupons) - should be viewed skeptically.

I appreciate the time and consideration - happy to answer any questions.

Dylan C. Wheeler JD, MPA
Sanford Health Plan

#39791

NORTH DAKOTA

C

33.3% of marketplace plans in NORTH DAKOTA have copay accumulator adjustment policies that harm patients.

HOUSE BILL 1216 is sponsored by Rep Karls

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; and to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans.

To help support this bill, contact Rep Karls
Email: kkarls@ndlegis.gov
Office Address: 2112 Senate Drive Bismark, ND 58501-1978
Phone Number: 701 258 6836

North Dakota gets a C because Medica has a copay accumulator adjustment policy.

Medica is **harming patients** by including these policies.

The Issue

Copay accumulator adjustment policies undermine important patient protections and make it more difficult for people trying to manage a chronic illness to afford medicines they need.

Health insurance companies and pharmacy benefit managers (PBMs) pocket copayments made for enrollees using third-party copay assistance but don't credit the payments to the enrollee's annual deductible or out-of-pocket limit.

ALL COPAYS COUNT COALITION

The Solution

State regulators and policymakers need to ensure that patients are protected.

The insurers that still include copay diversion policies must end this practice immediately. And North Dakota legislators can protect their constituents with chronic illnesses by joining other states by enacting legislation to protect residents from the harmful practices of copay accumulator and copay maximizer policies.

Such legislation would ensure all those living in North Dakota with state-regulated insurance plans are protected.

In addition to new North Dakota's law, a federal rule requires all private health insurance plans, including marketplace and employer-sponsored health plans, to count copay assistance toward patient cost-sharing limits in most cases. The plans listed above have copay diversion policies contrary to this rule. North Dakota insurance regulators can ensure health insurers and pharmacy benefit managers comply with federal rules.

The HELP Copays Act is a federal bill that would enact these same protections in federal law to protect people living with chronic illness with individual and employer health plans. Senators and Members of Congress from North Dakota should support this patient-centered legislation and urge its enactment.

More About Copay Accumulator Adjustment Policies and Vulnerable Patients

Millions of Americans with serious and complex chronic illness endure long and expensive medical journeys to diagnose their condition and find the best medicine to treat it. But when those medicines are considered "specialty medications," their cost can be prohibitive, even with insurance. That's why many people turn to copay assistance programs to help afford their share of the cost.

Copay accumulator adjustment and copay maximizer policies allow insurers and pharmacy benefit managers (PBMs) to keep payments made on an enrollee's behalf without counting those payments toward the enrollee's annual deductible or out-of-pocket limit. These policies undermine access to lifesaving prescription drugs for people living with serious, complex, chronic illnesses.

Read the full report from The AIDS Institute here: www.theaidsinstitute.org/copays

BDAND
Bleeding Disorders Alliance of North Dakota

"When a bandage is not enough, we're here."

Emily Ouellette
HB 1216 Testimony
ND Senate Human Services Committee Hearing
March 10, 2025

Thank you, Chairwoman Lee and the Committee, for hearing our testimony, and thank you to Representative Karls for once again working to protect North Dakota patients' access to lifesaving drugs with HB 1216.

My name is Emily Ouellette. I speak for the community I serve professionally as Executive Director of the Bleeding Disorders Alliance of North Dakota. I also have a personal connection. My husband and nephew, who grew up in Devils Lake, have severe hemophilia.

Hemophiliacs need specialty medicine that they self-infuse 1-3 times per week at home, costing $350,000 to $1,000,000 per year. There are no generic options. This medicine prevents internal bleeds. When patients get their medicine in January, they often reach their deductible immediately. Can you imagine needing to pay your full deductible in one payment at the beginning of the year every January to receive medicine that allows you to safely work or go to school? It is important that our patients access their medicine without financial barriers, so organizations like ours as well as some manufacturers offer financial assistance.

The process for hemophilia patients to receive patient assistance is that they need to fill out an application form from their manufacturer with information like their insurance plan, their prescription details, and other personal information to make sure a patient qualifies. If approved, patients will receive an approval email with a verification number that they forward to their specialty pharmacy where they order their specialty medicine. We, the patients, do not see a physical card or money.

Recently, insurance companies have implemented Copay Accumulator programs where they accept the patient assistance money, but don't count it toward the patient's deductible. Think of it this way, a college student has a $10,000 tuition bill and a $5000 scholarship. The University accepts the $5000 scholarship, but still makes you pay the full $10,000 bill, you know so the student has "skin in the game". The school receives $15,000. Is that fair? This is happening to patients all over the US. It needs to stop. With these programs, hardworking families struggle to access their medication. They take out loans or ration doses and risk permanent joint damage.

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www.bdand.org

Bottom line: When an accumulator is in an insurance policy, the patient is not getting the benefit of the assistance payment even though it is a payment. By voting for this legislation, you would close a loophole that would help patients and make sure all payments count. Currently, 1 out of 3 health insurance plans in North Dakota have a copay accumulator program in place. Supporting HB 1216 stops Medica from having an accumulator adjustor in their plans and prevents Sanford Health and Blue Cross Blue Shield from unexpectedly putting one in future plans. We can join the 21 states who have passed legislation to ensure patients can utilize copay assistance programs as they were intended.

Access to medication allows people like my husband to continue being a contributing member of society, raising a family, and holding a job. It allows my 12-year-old nephew to stay in school and be able to participate in Tae Kwan Do. The treatments are available. They cost a lot, but these patients are well worth the cost. The system is broken - high drug costs and various other practices make it difficult for patients to navigate their health care. This is making it even harder.

Health plans will tell you patients are driven to high cost name brand drugs. Patients with bleeding disorders do not have a generic option. They will tell you we have no skin in the game, no personal costs - we still pay our premiums, multiple doctor visits, lab work, and ancillary supply costs. Health plans still determine their formulary, and patients must still go through the utilization processes they've put in place. I know North Dakota takes pride in being a business-friendly state and some may be concerned about costs to employers. Employers will lose employees if they cannot stay healthy.

Copay assistance doesn't only provide financial relief, it improves adherence, leading to better clinical outcomes. I hope you will protect North Dakota patients in the rare disease community by supporting HB 1216. We want all payments to count, made BY the patient or on BEHALF of the patient.

Thank you.

*AIDS Institute Study – https://www.theaidsinstitute.org/copays/TAI-copay-report-2025

*Global Healthy Living Foundation - https://ghlf.org/copay-assistance-protection/

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    a. If copayment assistance is counted toward patient's deductible and out-of-pocket limit, eventually the patient's copayment will be reduced and PBM will be reimbursing a larger share (or after out-of-pocket limit is reached,100%) of the Rx cost to the pharmacy.
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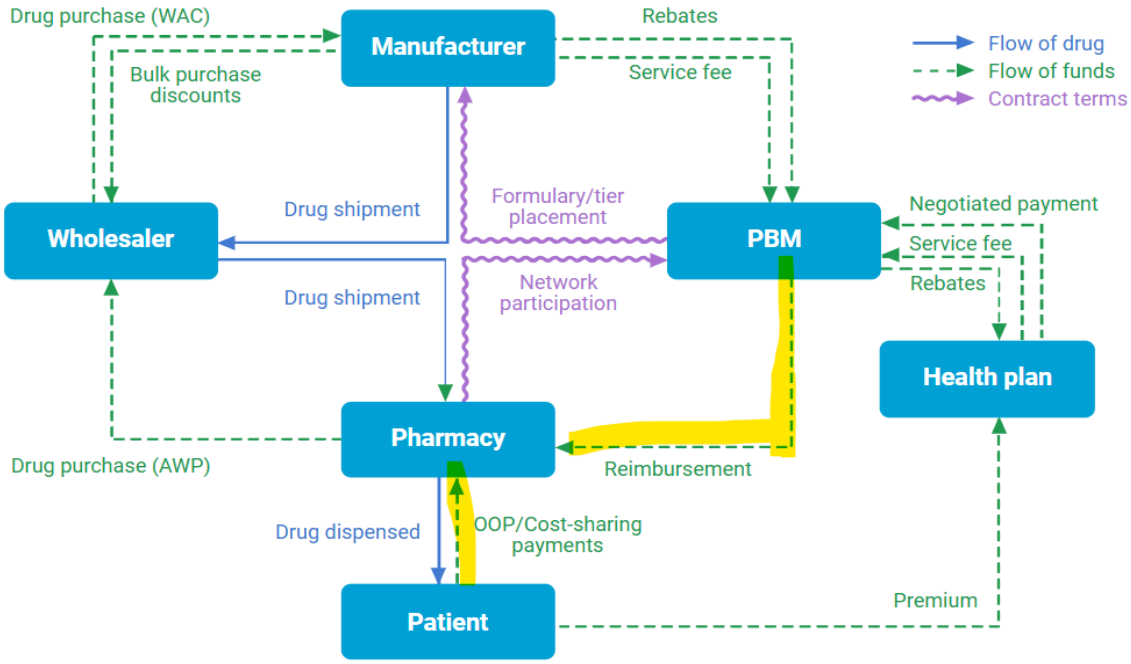

Questions to consider:

1. Insurers/PBMs are claiming that if the copay accumulator goes away, it will raise premiums (which we have data that shows premiums do not increase).
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#39794

Please Support HB 1216 in North Dakota!

Patients for Prescription Access

Copay Assistance **Helps** Patients

Copay Accumulators Hurt Patients

Copay assistance provided by pharmaceutical manufacturers and nonprofit organizations provide a financial lifeline for many people living with chronic conditions who need **lifesaving** medications.

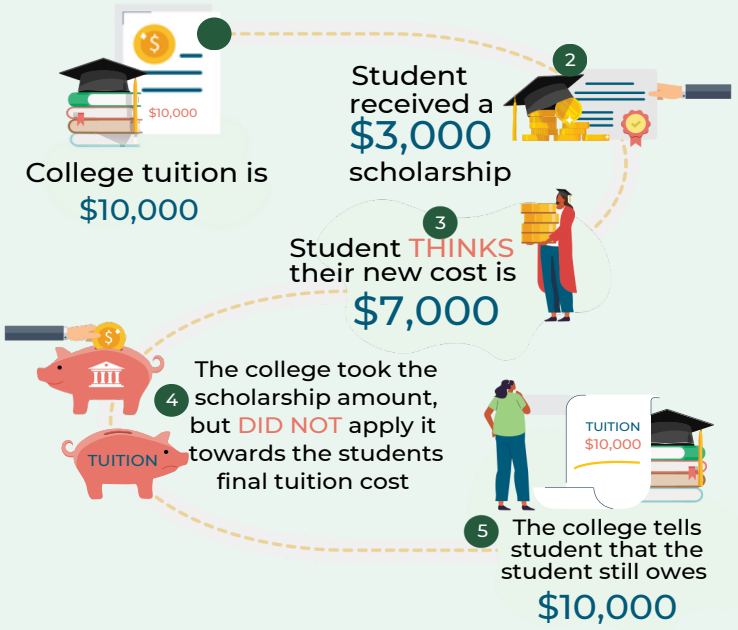
Insurers have raised deductibles, increased use of coinsurance, and added new prescription drug formulary tiers.

Insurers Double Dip While Patients are Denied Life-Essential Medications:

Many Insurers and PBMs are now utilizing copay accumulators that stop copay assistance from counting towards a patient's deductible and maximum out of pocket spending. These practices are creating significant financial and health issues for patients.

- All of the money paid through the copay assistance, which was intended to help the patient, goes directly to the health insurance company.
- Copay accumulators allow the insurance company to double dip and get paid TWICE - once from the copay assistance and then again by patients' deductibles
- This jeopardizes the health of patients and can ultimately result in the use of more expensive health care services, disability, unemployment and loss of independence.

Imagine if this same practice was applied to college tuition...



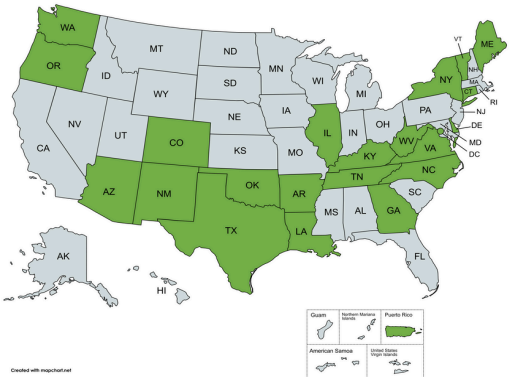
*The college receives $13,000, when the bill was only $10,000.

Call to Action

Lawmakers must pass legislation to prevent harmful and unfair copay accumulator policies, an emerging change in insurance plans.

We must "Stop the Double Dip"

As of Jan 2025, 21 states (and Puerto Rico) have enacted laws banning payer and PBM use of copay accumulator programs: AR, AZ, CO, CT, DE, GA, IL, KY, LA, ME, NC, NM, NY, OK, OR, TN, TX, VA, VT, WA, WV) DC, and Puerto Rico



Copay Accumulator Adjustors
Clearing Up the Misconceptions

Copay Accumulator Adjustment Programs are affecting a tremendous number of patients with a diverse set of health conditions – most affected are those with chronic and/or rare disorders.

- Allowing Health Plans to utilize Copay Accumulator Adjuster programs leave a lot of patients vulnerable and unable to access their medication. Patients are choosing between paying their rent/mortgage, putting food on the table, or paying for their medication.
- Bleeding Disorder patients meet their OOP maximum the first month or two of the year. They depend on Copay Assistance Programs to help them meet their deductible.

The health plans will argue this is manufacturers "gaming" the system or trying to preserve market share to drive more business to higher cost drugs.

- In this version of the bill language, the medicine either doesn't have a generic available OR if it does, the plan still has control over whether the patient can access it through their internal utilization and appeals processes.
- Bottom line is that health plans should be designed to ensure that the most medically appropriate medicine that is covered by the plan is what is approved.
- And if this "gaming the system" argument is truly the case, **why did health plans create these accumulator adjustment programs specifically in the specialty areas where there are no generic equivalents?**

There is a misconception that copay coupons allow patients to circumvent the formulary.

- Health plans still determine:
    - What is on or off formulary and what is preferred and non-preferred.
    - The utilization processes that patients and their doctors must navigate to ask for any exceptions to a preferred drug or for something that not on the formulary.
- Patients should not be penalized for correctly working through the process their plan has laid out for them, whether that is the copay and out-of-pocket costs they have to pay OR the process to gain approval to get access to a medicine that is prescribed for their condition.
- Keep in mind that copay cards are just a patch for a broken system overall; Current health plans and drug prices make it difficult for patients to obtain their medication - manufacturers and some non-profits are providing copay assistance because patients can't afford their out-of-pockets on their medicines.

Costs rise when patients don't have access to their specialty medication.

- Patients experience complications and disease progression, sending them to the Emergency Room, needing avoidable surgeries, and additional treatment they would not have needed had they had access to the medication in the first place. They often miss school and/or work. • A patient's mental health also suffers when they have to deal with complications of their disease, and navigate health plans.

Health Plans say patients have 'no skin in the game' if they rely on Copay Assistance Programs

- Patients still pay the cost of multiple doctor visits, lab work, and ancillary supplies for their infusions. Many patients also pay for physical therapy and other services to treat their bleeding disorder.

For more information, please contact:

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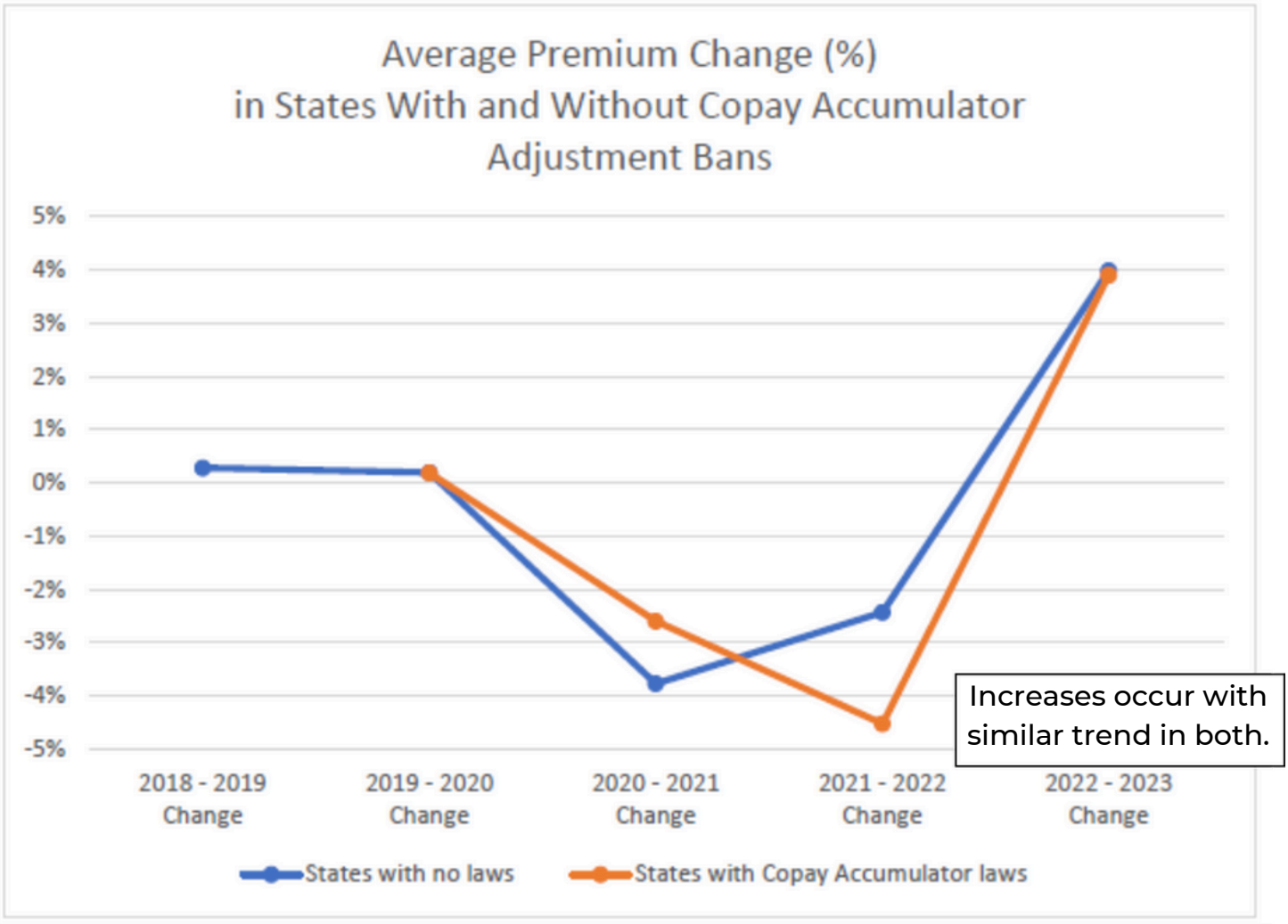
True Facts: Current data shows there is no evidence that Co-Pay Accumulator bans will increase premiums.

Previously, opponents have claimed that there will be a raise in premiums if Co-Pay Accumulator bans are passed. While it's true that healthcare premiums continue to increase, there is no evidence and correlation between passage of bans and trend.

- Fortunately, we now have data from several data sources on premiums from the 21 states and Puerto Rico that have passed Co-Pay Accumulator bans. The data doesn't substantiate those concerns. [1] See the charts and studies below.

- Global Healthy Living Foundation's analysis shows that despite what insurers and pharmacy benefit managers say, protecting patient assistance programs has not increased the cost of health insurance: https://ghlf.org/copay-assistance-protection/

- The AIDS Assistance's 2023 study shows Co-Pay Accumulator laws are not increasing average benchmark premiums in states that passed CAAP laws (at least for the first 16 of the 21w/ existing bans). And in fact, in several states average premiums declined (presumably due to better medication adherence):The-AIDS-Inst.-Copay-Assistance-Does-Not-Increase-Premiums.pdf



1] https://www.kff.org/affordable-care-act/state-indicator/marketplace-average-benchmark-premiums/?activeTab=graph&currentTimeframe=0&startTimeframe=10&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

Assumes law impacted premiums the year after it was passed.

Key:

Blue cells = States with copay accumulator adjustment bans passed between 2019 and 2022;

Orange font = Year law impacted premiums

Marketplace Average Benchmark Premiums by State Copay Assistance Accumulator Bans in Place by 2023

States	2018	2019	2020	2021	2022	2023
Arizona	$516	$471	$442	$436	$390	$410
Illinois	$486	$478	$451	$423	$418	$453
Virginia	$535	$555	$521	$479	$450	$371
West Virginia	$545	$596	$628	$654	$752	$824
Georgia	$483	$487	$463	$456	$394	$413
Arkansas	$364	$378	$365	$394	$387	$416
Connecticut	$545	$475	$570	$580	$581	$627
Kentucky	$422	$460	$471	$476	$387	$422
Louisiana	$474	$454	$500	$545	$541	$565
North Carolina	$627	$618	$558	$516	$504	$512
Oklahoma	$659	$696	$601	$554	$498	$510
Tennessee	$743	$548	$511	$466	$445	$473
Delaware	$589	$684	$548	$540	$548	$549
Maine	$588	$544	$513	$440	$427	$457
New York	$506	$569	$610	$597	$592	$627
Washington	$336	$406	$391	$388	$396	$395
Alabama	$558	$546	$553	$590	$597	$567
Alaska	$726	$702	$724	$675	$712	$762
California	$430	$439	$430	$426	$417	$432
Colorado	$470	$488	$358	$351	$358	$380
District of Columbia	$324	$393	$414	$415	$387	$428
Florida	$466	$477	$468	$457	$456	$471
Hawaii	$438	$493	$474	$478	$484	$469
Idaho	$478	$498	$520	$495	$461	$425
Indiana	$339	$339	$387	$421	$398	$397
Iowa	$713	$762	$742	$523	$502	$484
Kansas	$518	$552	$502	$491	$450	$471
Maryland	$487	$419	$397	$347	$328	$336
Massachusetts	$316	$332	$343	$363	$389	$417
Michigan	$381	$383	$360	$347	$340	$362
Minnesota	$385	$326	$309	$307	$327	$335
Mississippi	$519	$521	$487	$459	$448	$461
Missouri	$529	$499	$483	$479	$442	$473
Montana	$525	$561	$483	$471	$483	$477
Nebraska	$767	$838	$711	$699	$595	$550
Nevada	$432	$410	$374	$393	$383	$386
New Hampshire	$475	$402	$405	$357	$309	$323
New Jersey	$413	$352	$392	$405	$424	$441
New Mexico	$414	$365	$345	$339	$389	$445
North Dakota	$377	$457	$383	$493	$497	$475
Ohio	$371	$380	$375	$375	$375	$413
Oregon	$414	$443	$446	$437	$444	$462
Pennsylvania	$575	$484	$459	$455	$390	$433
Rhode Island	$311	$336	$332	$349	$361	$379
South Carolina	$520	$552	$509	$476	$444	$496
South Dakota	$521	$557	$593	$618	$601	$626
Texas	$434	$444	$432	$436	$424	$461
Utah	$550	$542	$486	$472	$456	$471
Vermont	$505	$622	$662	$669	$749	$841
Wisconsin	$569	$537	$491	$457	$429	$456
Wyoming	$865	$865	$881	$791	$762	$802

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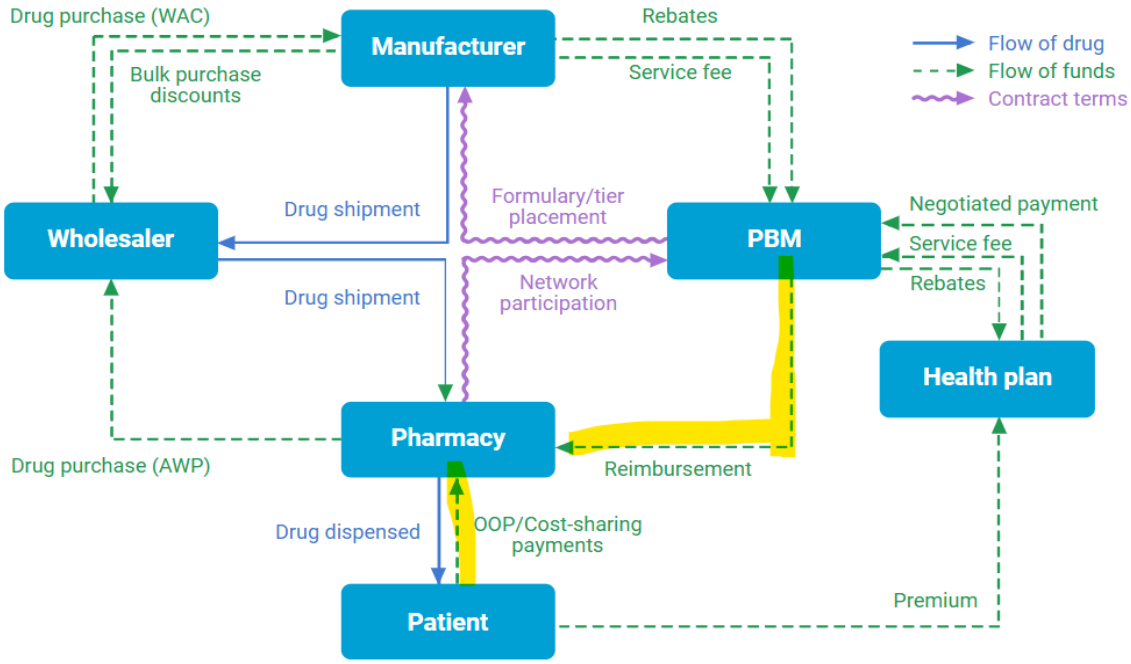

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#39874

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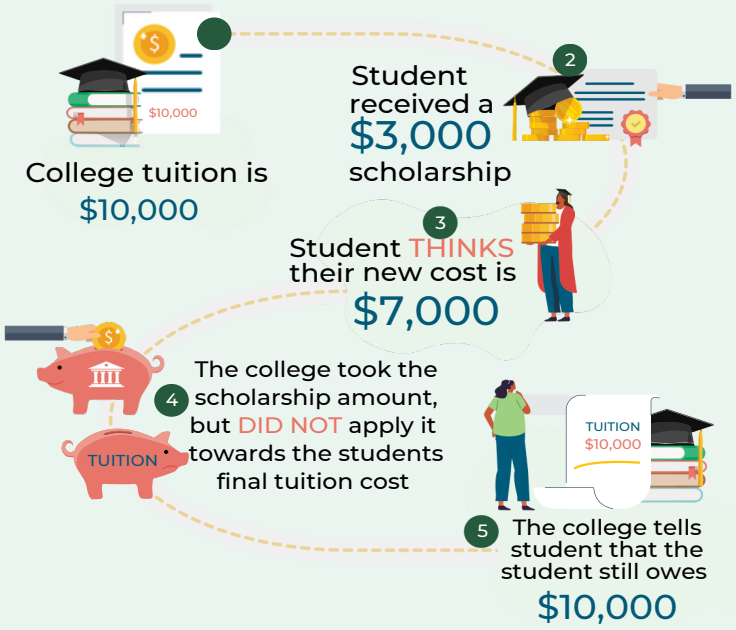

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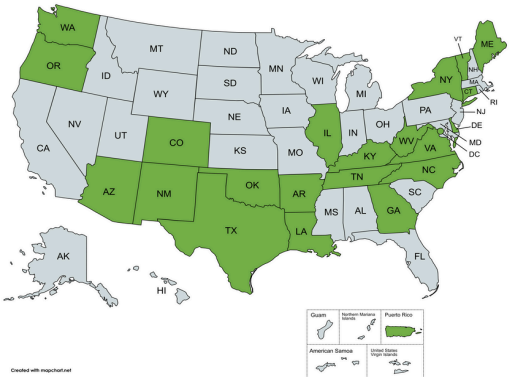

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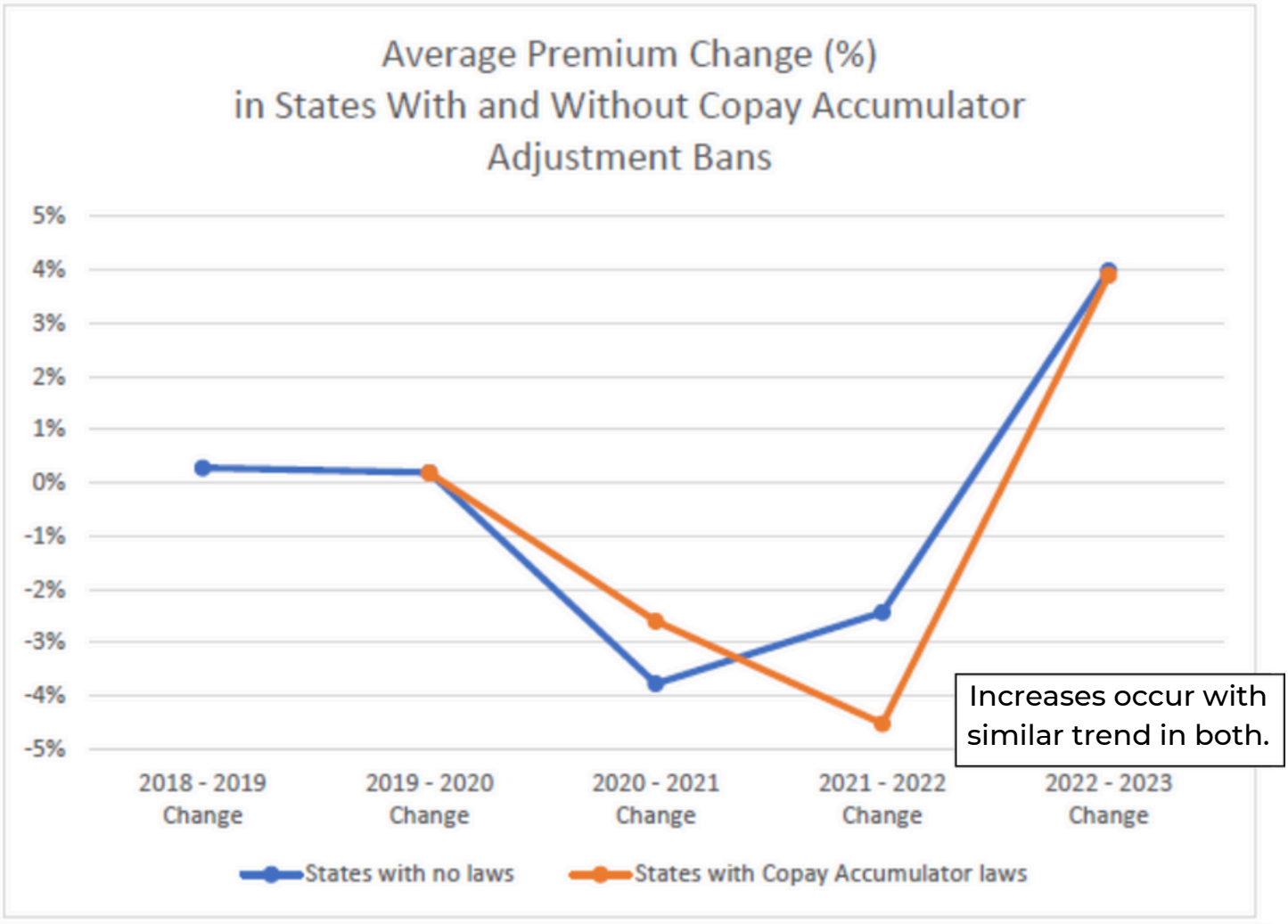

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Key:

Blue cells = States with copay accumulator adjustment bans passed between 2019 and 2022;

Orange font = Year law impacted premiums

Marketplace Average Benchmark Premiums by State Copay Assistance Accumulator Bans in Place by 2023

States	2018	2019	2020	2021	2022	2023
Arizona	$516	$471	$442	$436	$390	$410
Illinois	$486	$478	$451	$423	$418	$453
Virginia	$535	$555	$521	$479	$450	$371
West Virginia	$545	$596	$628	$654	$752	$824
Georgia	$483	$487	$463	$456	$394	$413
Arkansas	$364	$378	$365	$394	$387	$416
Connecticut	$545	$475	$570	$580	$581	$627
Kentucky	$422	$460	$471	$476	$387	$422
Louisiana	$474	$454	$500	$545	$541	$565
North Carolina	$627	$618	$558	$516	$504	$512
Oklahoma	$659	$696	$601	$554	$498	$510
Tennessee	$743	$548	$511	$466	$445	$473
Delaware	$589	$684	$548	$540	$548	$549
Maine	$588	$544	$513	$440	$427	$457
New York	$506	$569	$610	$597	$592	$627
Washington	$336	$406	$391	$388	$396	$395
Alabama	$558	$546	$553	$590	$597	$567
Alaska	$726	$702	$724	$675	$712	$762
California	$430	$439	$430	$426	$417	$432
Colorado	$470	$488	$358	$351	$358	$380
District of Columbia	$324	$393	$414	$415	$387	$428
Florida	$466	$477	$468	$457	$456	$471
Hawaii	$438	$493	$474	$478	$484	$469
Idaho	$478	$498	$520	$495	$461	$425
Indiana	$339	$339	$387	$421	$398	$397
Iowa	$713	$762	$742	$523	$502	$484
Kansas	$518	$552	$502	$491	$450	$471
Maryland	$487	$419	$397	$347	$328	$336
Massachusetts	$316	$332	$343	$363	$389	$417
Michigan	$381	$383	$360	$347	$340	$362
Minnesota	$385	$326	$309	$307	$327	$335
Mississippi	$519	$521	$487	$459	$448	$461
Missouri	$529	$499	$483	$479	$442	$473
Montana	$525	$561	$483	$471	$483	$477
Nebraska	$767	$838	$711	$699	$595	$550
Nevada	$432	$410	$374	$393	$383	$386
New Hampshire	$475	$402	$405	$357	$309	$323
New Jersey	$413	$352	$392	$405	$424	$441
New Mexico	$414	$365	$345	$339	$389	$445
North Dakota	$377	$457	$383	$493	$497	$475
Ohio	$371	$380	$375	$375	$375	$413
Oregon	$414	$443	$446	$437	$444	$462
Pennsylvania	$575	$484	$459	$455	$390	$433
Rhode Island	$311	$336	$332	$349	$361	$379
South Carolina	$520	$552	$509	$476	$444	$496
South Dakota	$521	$557	$593	$618	$601	$626
Texas	$434	$444	$432	$436	$424	$461
Utah	$550	$542	$486	$472	$456	$471
Vermont	$505	$622	$662	$669	$749	$841
Wisconsin	$569	$537	$491	$457	$429	$456
Wyoming	$865	$865	$881	$791	$762	$802

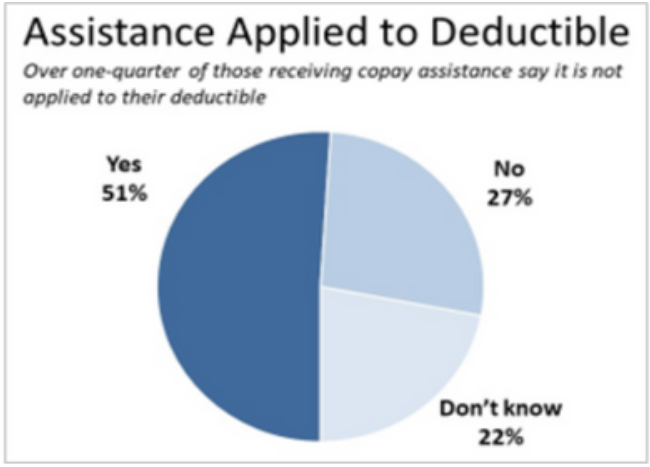
Prescription Drug Copay Assistance and Accumulator Adjustment

Many individuals with cancer and survivors of cancer have difficulty affording the cost of their prescription drugs. This is especially true for newer drugs – including cancer drugs – that do not yet have a generic equivalent. To help temper high prescription costs, many of these individuals receive copay assistance offered through manufacturer programs and charitable patient assistance programs.

Manufacturer programs and charitable patient assistance programs help many cancer patients afford their medications. A patient assistance program's financial support can give patients access to a life-saving drug that they otherwise could not afford. And many of the programs exist for drugs without generic alternatives.

Copay accumulator adjustments are a relatively new insurance practice. These programs allow the enrollee to use copay assistance, but the amount of the support does not count towards the enrollee's out-of-pocket cost obligations like meeting their deductible. Only the funds spent directly by the enrollee count, leaving patients with significant and surprise costs.

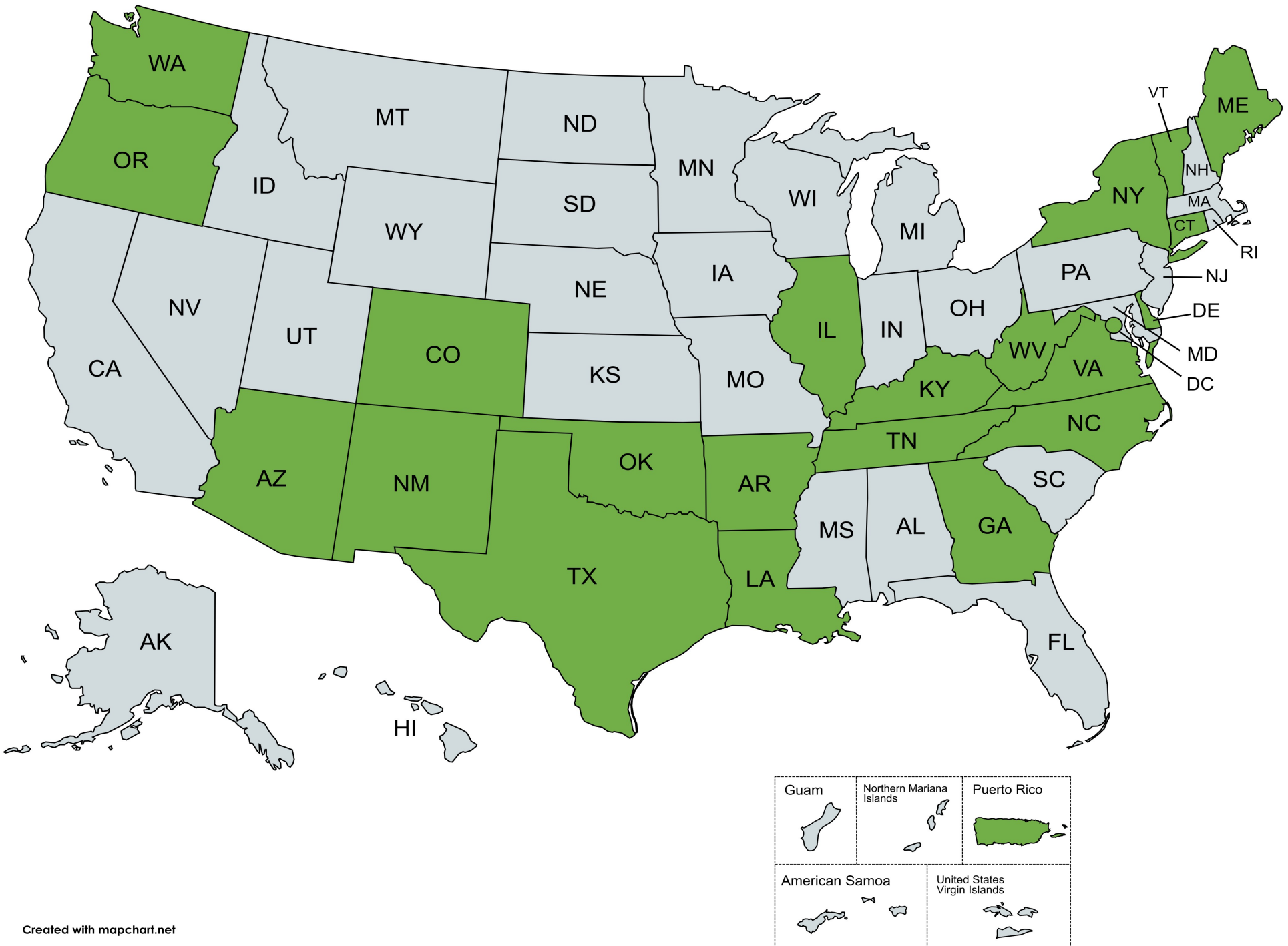
A May 2022 survey[1] conducted by the American Cancer Society Cancer Action Network (ACS CAN) explores cancer patients' and survivors' experiences and perspectives on copay assistance and found:



- Prescription drug costs are a challenge for nearly one-third of cancer patients and survivors (31%), with one-fifth having skipped or delayed taking prescribed medications due to costs.
- Those who have enrolled in copay assistance programs agree that the assistance provides access to medication through the program that they otherwise couldn't afford (83%), while some who were unable to enroll reported declining treatment (8%) or going into debt to cover their prescription drug costs (18%).
- Over a quarter (27%) of those who enrolled report that the assistance they received was not applied to their deductible or other out-of-pocket cost requirements and another 22% were unsure.
- The negative impacts of not being able to benefit from a copay assistance program are even greater among some patient populations, with over one-quarter of Black, Hispanic, and Asian cancer patients and survivors reporting they have declined treatment due to cost after finding they were unable to enroll in a copay assistance program.

ACS CAN supports legislation to restrict the use of copay accumulator adjustment programs.

1 American Cancer Society Cancer Action Network Survivor Views Survey fielded May 16-26, 2022. https://www.fightcancer.org/survivor-views.



Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MANUFACTURER SAFEGUARDS MAY NOT PREVENT COPAYMENT COUPON USE FOR PART D DRUGS

Daniel R. Levinson
Inspector General

September 2014
OEI-05-12-00540

EXECUTIVE SUMMARY: MANUFACTURER SAFEGUARDS MAY NOT PREVENT COPAYMENT COUPON USE FOR PART D DRUGS
OEI-05-12-00540

WHY WE DID THIS STUDY

Pharmaceutical manufacturers offer copayment coupons to reduce or eliminate the cost of patients' out-of-pocket copayments for specific brand-name drugs. The anti-kickback statute prohibits the knowing and willful offer or payment of remuneration to a person to induce the purchase of any item or service for which payment may be made by a Federal health care program. Manufacturers may be liable under the anti-kickback statute if they offer coupons to induce the purchase of drugs paid for by Federal health care programs, including Medicare Part D. The anti-kickback statute applies to all Federal health care programs, but this study focused on Part D. The use of coupons by Medicare beneficiaries could impose significant costs on the Part D program because many coupons encourage beneficiaries to choose more expensive brand-name drugs over less expensive alternative drugs. In two surveys by outside groups, approximately 6 percent to 7 percent of seniors surveyed reported using coupons to purchase prescription drugs.

HOW WE DID THIS STUDY

To identify the safeguards pharmaceutical manufacturers employ to prevent their copayment coupons from being used for drugs paid for by Part D and to identify vulnerabilities in those safeguards, we surveyed 30 manufacturers of the top 100 Part D brand-name drugs with coupons and with the highest Medicare expenditures. We also reviewed selected safeguards offered for a purposive sample of those drugs. In addition, we interviewed staff at various organizations involved in pharmacy claims transactions to understand other vulnerabilities associated with coupon use in Part D.

WHAT WE FOUND

Pharmaceutical manufacturers' current safeguards may not prevent all copayment coupons from being used for drugs paid for by Part D. All surveyed manufacturers provide notices directed to beneficiaries and pharmacists that coupons may not be used in Federal health care programs. Most surveyed manufacturers use pharmacy claims edits to prevent coupons from being processed for drugs covered by Part D. Most of these edits may not prevent all coupons from being processed for Part D-covered drugs. Finally, Part D plans and other entities cannot identify coupons within pharmacy claims.

WHAT WE RECOMMEND

The Office of Inspector General's concurrent Special Advisory Bulletin affirms that pharmaceutical manufacturers are at risk of sanctions if they fail to take appropriate steps to ensure that their copayment coupons do not induce the purchase of Federal health care programs items or services, including but not limited to, drugs paid for by Medicare Part D. For this reason, manufacturers may engage industry stakeholders and the Centers for Medicare & Medicaid Services (CMS) in an effort to identify a solution to ensure that coupons are not used for drugs paid for by Part D. CMS should cooperate with industry stakeholder efforts to improve the reliability of pharmacy claims edits and make coupons transparent. CMS concurred with our recommendation.

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OBJECTIVES

1. To describe safeguards pharmaceutical manufacturers employ to prevent copayment coupon use for drugs paid for by Medicare Part D.
2. To identify vulnerabilities in these safeguards.
3. To identify any other vulnerabilities associated with copayment coupon use for drugs paid for by Medicare Part D.

BACKGROUND

Pharmaceutical manufacturers offer copayment coupons to reduce or eliminate the cost of patients' out-of-pocket copayments for specific brand-name drugs and thereby induce the purchase of those drugs. Although coupons reduce individual patients' immediate costs, coupons may increase the cost of prescription drugs for health insurers, including those offering Medicare prescription drug coverage through Part D plans.[1]

The anti-kickback statute prohibits knowing and willful solicitation, receipt, offer, or payment of remuneration to induce the purchase of any item or service for which payment may be made in whole or in part under a Federal health care program.[2] Pharmaceutical manufacturers may be liable under the anti-kickback statute if they offer coupons to induce the purchase of drugs paid for by Medicare Part D or any other Federal health care program.[3]

Recent surveys by outside organizations found that approximately 6 percent to 7 percent of surveyed seniors reported using manufacturer coupons toward their copayment for prescription drugs purchased through

[1] Joseph S. Ross and Aaron S. Kesselheim, "Prescription Drug Coupons – No Such Thing as a Free Lunch," *The New England Journal of Medicine*, August 28, 2013, http://www.nejm.org/doi/pdf/10.1056/NEJMp1301993. Accessed on August 30, 2013. David Grande, "The Cost of Drug Coupons," *JAMA*, June 13, 2012, http://jama.jamanetwork.com/article.aspx?articleid=1182868. Accessed on June 14, 2012. These articles describe how the use of coupons to encourage brand-name drug utilization could increase insurers' costs. This description applies to Medicare Part D, which uses an insurance model to provide prescription drug benefits.

[2] 42 U.S.C. § 1320a-7b(b).

[3] "Federal health care program" is defined in the anti-kickback statute as "(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5; or (2) any State health care program, as defined in section 1320a-7(h) of this title." 42 U.S.C. § 1320a-7b(f).

their Medicare prescription plans.[4, 5] Applying these results to the population of 36 million Part D beneficiaries, the utilization of copayment coupons to obtain prescription drugs paid for by Part D could exceed 2 million beneficiaries.

Pharmaceutical manufacturers' use of coupons to reduce the cost-sharing obligations for Medicare Part D drugs could impose significant costs on Federal health care programs and taxpayers. A 2013 study from *The New England Journal of Medicine* found that 58 percent of coupons were for brand-name drugs for which a lower cost generic alternative was available.[6] If manufacturer coupons encourage Medicare beneficiaries to obtain more expensive brand-name drugs when lower cost alternatives are available, the coupon may reduce individual beneficiaries' immediate out-of-pocket costs but Part D plans' and the Part D program's costs may increase, ultimately increasing costs to taxpayers.[7]

Medicare Part D Cost Controls

CMS contracts with private insurance companies, called sponsors, to provide Part D prescription drug benefits for approximately 36 million beneficiaries.[8, 9] Sponsors use a variety of methods to control prescription drug coverage costs through the Part D program.

Part D Formularies. Sponsors can establish formularies, or lists of covered drugs, to give preference to more effective drugs over less effective drugs or less expensive drugs over more expensive drugs that treat the same condition. To drive utilization toward equally effective but less expensive drugs, formularies are generally organized into tiers, which have different beneficiary copayments for a prescription drug. Drugs in lower tiers are typically the least expensive and have the lowest beneficiary copayments. Drugs in the subsequent and ascending tiers are,

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[4] National Coalition on Health Care (NCHC), "Seniors' Awareness And Use of Prescription Co-pay Coupons in Medicare," Survey. March 26-30, 2012.

[5] Pharmaceutical Care Management Association (PCMA), "Survey of Seniors Enrolled in the Medicare Prescription Drug Plan," Survey. February 15-17, 2011.

[6] Joseph S. Ross and Aaron S. Kesselheim, "Prescription Drug Coupons – No Such Thing as a Free Lunch," *The New England Journal of Medicine*, August 28, 2013, http://www.nejm.org/doi/pdf/10.1056/NEJMp1301993. Accessed on August 30, 2013.

[7] Joseph S. Ross and Aaron S. Kesselheim, "Prescription Drug Coupons – No Such Thing as a Free Lunch," *The New England Journal of Medicine*, August 28, 2013, http://www.nejm.org/doi/pdf/10.1056/NEJMp1301993. Accessed on August 30, 2013. David Grande, "The Cost of Drug Coupons," *JAMA*, June 13, 2012, http://jama.jamanetwork.com/article.aspx?articleid=1182868. Accessed on June 14, 2012.

[8] The Part D program was established as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173 § 101; Social Security Act, § 1860D-1 and it was codified at 42 U.S.C. § 1395w-101 et seq.

[9] 42 U.S.C. § 1395w-101 et seq.

in general, relatively more expensive and have increasing beneficiary copayments. For example, a lower tier drug is typically a low-cost generic drug for which a beneficiary might have a $5 or $10 copayment, while a higher tier drug is likely to be a more expensive brand-name drug for which a beneficiary might have a $45 copayment.

Generic Substitution. Sponsors can control prescription drug costs by requiring less expensive, chemically equivalent generic drugs to be substituted for costlier brand-name drugs. Generic substitution may reduce the amounts that both Part D plans and beneficiaries pay for covered drugs. For instance, the average brand-name drug prescription costs $89, while the average generic drug prescription costs $23, a difference of $66.[10]

Beneficiary Copayments in Part D

Beneficiaries, Part D plans, and CMS share Part D prescription drug coverage costs. Beneficiary cost sharing begins in the initial benefit stage, which beneficiaries reach after paying their deductible. Beneficiaries' cost-sharing responsibilities for covered drugs then change as they move through different stages of the Part D benefit.[11]

During the initial benefit stage, beneficiaries pay copayments for prescription drugs on the basis of factors such as whether the drug is a generic or a brand, which formulary tier the drug is on, and whether the pharmacy is preferred or nonpreferred by the Part D plan.[12, 13, 14]

After reaching an initial coverage limit set in statute, beneficiaries typically enter the coverage gap stage where their cost-sharing increases.[15, 16] In this stage, in 2013, pharmaceutical manufacturers provided beneficiaries a 50-percent discount on applicable drugs (generally, covered brand-name drugs) at the point of sale.[17] For most generic drugs, in 2013, beneficiaries were responsible for 79 percent of the cost as their copayment.[18]

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[10] Congressional Budget Office, *Effects of Using Generic Drugs on Medicare's Prescription Drug Spending*, September 2010, p. 8.

[11] 42 CFR § 423.104.

[12] *See*, e.g., CMS, Copayment/coinsurance in drug plans, http://www.medicare.gov/part-d/costs/copayment-coinsurance/drug-plan-copayments.html. Accessed on April 24, 2014.

[13] 42 CFR § 423.104(d)(2)(ii).

[14] 42 CFR § 423.120(a)(9).

[15] 42 U.S.C. § 1395w-102(b)(2)(A).

[16] *See*, e.g., CMS, Costs in the coverage gap, http://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html. Accessed on April 30, 2014.

[17] 42 U.S.C. § 1395w-114a.

[18] 42 U.S.C. § 1395w-102(b)(2)(C).

The coverage gap continues until beneficiaries' true out-of-pocket (TrOOP) spending reaches the annual TrOOP threshold.[19] Generally, for brand-name drugs, the full amount of drug costs, including the out-of-pocket amount beneficiaries paid, counts toward their TrOOP.[20] For generic drugs, only the out-of-pocket amount counts toward beneficiaries' TrOOP thresholds.

After reaching the TrOOP threshold, beneficiaries enter the catastrophic benefit stage.[21] During catastrophic coverage, the Part D program pays the majority of beneficiaries' drug costs and beneficiaries are generally responsible for limited cost sharing through copayments.

Copayment Coupons

Pharmaceutical manufacturers typically offer copayment coupons to insured patients to reduce or eliminate patients' out-of-pocket costs for specific brand-name drugs. Manufacturers may contract with coupon vendors to create and administer coupon programs on their behalf. ("Manufacturers" includes all manufacturers or vendors acting on their behalf.) A manufacturer may offer a coupon for a brand-name drug that reduces the copayment for that drug and makes it cheaper than the copayment for a competitor drug. For example, a coupon may reduce a patient's copayment for Brand Drug A from $20 to $4, making the copayment for the brand drug cheaper than the copayment for a generic equivalent, which may be $10. In some cases, the coupon eliminates the copayment altogether.

Pharmaceutical manufacturers may offer copayment coupons for several reasons. It has been reported that manufacturers may use coupons to try to retain market share when generic and other brand-name drugs that treat the same condition become available to patients. It also has been reported that manufacturers may use coupons to attract new patients who may be using an alternative therapy. Additionally, manufacturers indicate that they offer coupons to encourage patients to adhere to their prescription drug regimen. Finally, it has been reported that manufacturers may offer

[19] For 2013, the TROOP threshold was $4,750. Generally, TrOOP spending includes all beneficiary payments (excluding monthly premiums) and any payments made by other approved payers, such as health savings accounts and certain charities. 42 CFR § 423.104(d)(5)(B)(iii); CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 5, § 30.

[20] *See*, e.g., CMS, Costs in the coverage gap, http://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html. Accessed on April 30, 2014.

[21] *See*, e.g., CMS, Catastrophic coverage, http://www.medicare.gov/part-d/costs/catastrophic-coverage/drug-plan-catastrophic-coverage.html. Accessed on May 9, 2014.

coupons to offset the high cost of specialty and biologic drugs, which may not have generic alternatives.[22]

Copayment coupons have become increasingly prevalent. In recent years, the number of coupons has increased from 86 in July 2009[23] to 525 in December 2012.[24] This increase may be related to competition from generic drugs. From 2009 to 2012, numerous "blockbuster" drugs—drugs that have generated $1 billion in sales—lost their patent protection. For many of those drugs, generic versions became available. The number of generic drugs the Food and Drug Administration (FDA) approved increased 27 percent between 2009 and 2012.[25]

Copayment Coupon Formats. Copayment coupons typically are available in four formats: (1) print coupons, (2) electronic coupons, (3) debit cards, and (4) direct reimbursements. Print coupons are printed cards or documents that the patient physically takes or sends to the pharmacy to purchase a prescription drug. Electronic coupons are cardless programs that evaluate prescription drug claims as they are submitted through the pharmacy claims transaction system, which applies copayment reductions. Debit cards include any prepaid and/or bank-authorized card that is processed at the point of sale to pay for some predetermined portion of the copayment. Direct reimbursements are any payments by a manufacturer offered directly to a patient for all or part of the patient's out-of-pocket cost for a purchased prescription drug. Direct reimbursements occur after a prescription drug is purchased and generally do not involve pharmacies.

Most coupons offered by manufacturers are typically in the format of print coupons. Manufacturers offer electronic coupons to a lesser extent. A small number of coupons are offered in the format of debit cards and direct reimbursements. See Table 1, on the next page, for a breakdown of the prevalence of coupon formats among 30 manufacturers surveyed by the Office of Inspector General (OIG).

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[22] Biologics are among the most expensive drugs available. The average cost of a biologic drug is about 22 times that of nonbiologic drugs. "Health Policy Brief: Biosimilars," *Health Affairs*, October 10, 2013, http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_100.pdf. Accessed on December 6, 2013.

[23] Cleveland Research Company, "Co-Pay Cards: The Past, Present, and Future," March 2012.

[24] OIG analysis of drugs available on http://www.internetdrugcoupons.com.

[25] OIG analysis of 2009 to 2012 FDA Abbreviated New Drug Approvals (ANDAs) by month available at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu.

Table 1: Coupon Formats for Manufacturers Surveyed by OIG

Coupon Format	Number of Manufacturers Offering	Percentage of All Coupons Offered by Manufacturers
Print	27	71%
Electronic	22	26%
Debit Card	9	2%
Direct Reimbursement	16	1%

Source: OIG analysis of pharmaceutical manufacturer survey responses, 2013.

Accessing Copayment Coupons. Patients commonly access copayment coupons in four ways. Patients may access or receive coupons from their prescribing physicians. Patients also may access coupons through Web sites and toll-free telephone numbers managed by manufacturers or companies hired to manage their coupon programs. Finally, patients may be given coupons by pharmacists filling their prescriptions.

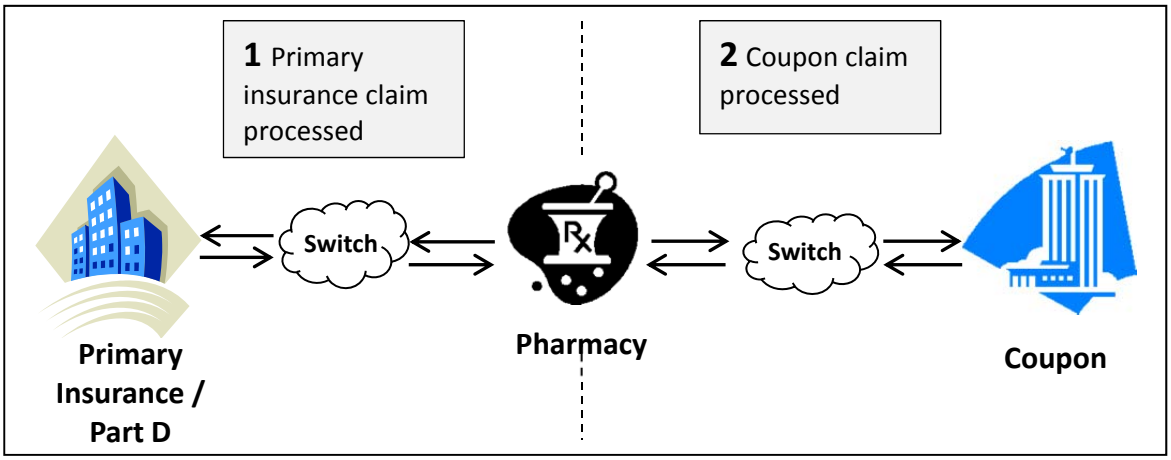
Redeeming Copayment Coupons. Patients typically redeem copayment coupons at pharmacies when they purchase prescription drugs. However, patients do not always redeem coupons at pharmacies and may request reimbursements directly from the manufacturer after purchasing prescription drugs.

Copayment Coupons and Pharmacy Claims Processing

Copayment coupon claims are typically processed in the same way as payments received from a secondary insurance source using the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard D.0 for pharmacy claims. Using this standard format, all pharmacy claims, including coupon claims, are electronically routed from the pharmacy to various payers by companies known as "switches." Once a claim is routed to a payer, the payer sends coverage and payment information back to the pharmacy through the switch.

The processing of primary insurance and coupon claims occurs in real time and involves several steps to coordinate payment for a single claim. First, a patient's primary insurance claim is processed, and the patient's copayment amount is determined. Second, the coupon claim is processed, and how much of the copayment the manufacturer will pay is determined. Finally, the patient pays the remaining copayment balance, if any. See Figure 1, on the next page, for an illustration of how primary insurance and coupon claims are processed.

Figure 1: Processing of Primary Insurance and Coupon Claims



Source: OIG analysis of interview responses, 2013.

The coordination of primary insurance and coupon or secondary payers is facilitated by unique identifiers that route the claim to the entity responsible for paying the claim. One identifier is the Bank Identification Number (BIN), which identifies the responsible payer. Primary insurers, including Part D plans, have BINs that route primary insurance claims to them for payment. Manufacturers also have BINs that route their coupon claims to them for payment. The Processor Control Number (PCN) is a secondary identifier that is internal to an insurance company or manufacturer and further routes the claim within that company.

To attempt to determine a patient's Part D enrollment status before submitting a coupon claim, a pharmacist may submit an optional enrollment verification request, called an E1 transaction, to the Part D Transaction Facilitator. CMS contracts with the Transaction Facilitator to track Part D beneficiaries' benefit stages and to conduct E1 transactions, which provide pharmacists with information about a patient's Part D enrollment status.[26] The pharmacist submits the patient's identification information to the Transaction Facilitator, which compares it to patient information in CMS's Medicare enrollment database to determine whether the patient is enrolled in Part D. Pharmacies pay less than 1 cent per transaction to submit this verification request.[27]

[26] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 14, § 30.4.

[27] CMS, *Changes Involving Medicare Eligibility Queries (E1) and Other TrOOP Facilitator-related Transactions*, December 9, 2010, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoE1ChangesTipSheet_120910.pdf. Accessed on November 30, 2012.

METHODOLOGY

Scope

The anti-kickback statute applies to all Federal health care programs, but this study focused on Medicare Part D. This study analyzed the copayment coupon safeguards of pharmaceutical manufacturers for the most costly brand-name Part D prescription drugs with coupons covered in 2012. These prescription drugs were covered under stand-alone prescription drug plans and Medicare Advantage prescription drug plans. The study did not include coupons for generic drugs because copayment coupons are not commonly offered for generic drugs. This study did not estimate the use of coupons by Part D beneficiaries. It also did not estimate the overall cost of coupons to Part D plans and the Part D program.

Data Collection and Analysis

We collected information on safeguards pharmaceutical manufacturers employ to prevent copayment coupon use for drugs paid for by Medicare Part D through a survey of manufacturers and a review of copayment coupons and coupon Web sites. We collected information on other vulnerabilities through interviews with a variety of industry stakeholders.

We sent an online survey to 34 pharmaceutical manufacturers of drugs with coupons, and 30 responded. We selected these manufacturers by identifying the manufacturers offering the top 100 Part D-covered brand-name drugs with coupons by cost to Part D. The 30 complete surveys we received represented an 88-percent response rate. We analyzed survey responses to determine the extent to which manufacturers surveyed had safeguards in place to prevent the use of coupons for drugs paid for by Part D.

We also reviewed safeguards in place for a subset of the top 100 Part D-covered brand-name drugs with coupons. We attempted to obtain 50 coupons to determine the extent to which manufacturers had safeguards directed to beneficiaries and pharmacists in place. We reviewed these safeguards for the 40 coupons that we obtained.

In addition, we conducted structured interviews with staff at organizations involved in the pharmacy claims transaction process, including pharmacists, coupon vendors, a switching company, and NCPDP, to understand other vulnerabilities associated with coupon use in Part D.

For a discussion of our data collection and analysis, see Appendix A.

Data Limitations

Although we did not verify manufacturers' survey responses, we selected a sample of coupons offered by surveyed manufacturers to review

safeguards on or associated with coupons. We used this information to confirm the accuracy of manufacturers' responses. We could not review safeguards that were not on coupons or on coupon Web sites. For these safeguards, this report relies on self-reported data.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

All surveyed manufacturers provide notices to beneficiaries and pharmacists that copayment coupons may not be used in Federal health care programs

All manufacturers surveyed report providing notices directed to Federal health care program beneficiaries or pharmacists for at least one of the coupon formats they offer. These notices state that copayment coupons may not be used to purchase drugs paid for by Federal health care programs, including Medicare Part D. Notices to beneficiaries and pharmacists are more prevalent for print coupons, which is the most commonly offered coupon format according to manufacturers surveyed. Notices are still widely used for other formats, but to a lesser extent. See Table 2 for the percentages of surveyed manufacturers that report using notices for the coupon formats they offer.

Table 2: Notices by Coupon Format

Notice	Print n = 27	Electronic n = 22	Debit Card n = 9	Direct Reimbursement n = 16	Any Format n = 30
Beneficiary Notices	27 (100%)	16 (73%)	8 (89%)	13 (81%)	30 (100%)
Pharmacist Notices	18 (67%)	7 (32%)	2 (22%)	N/A[28]	20 (67%)

Source: OIG analysis of pharmaceutical manufacturer survey responses, 2013.

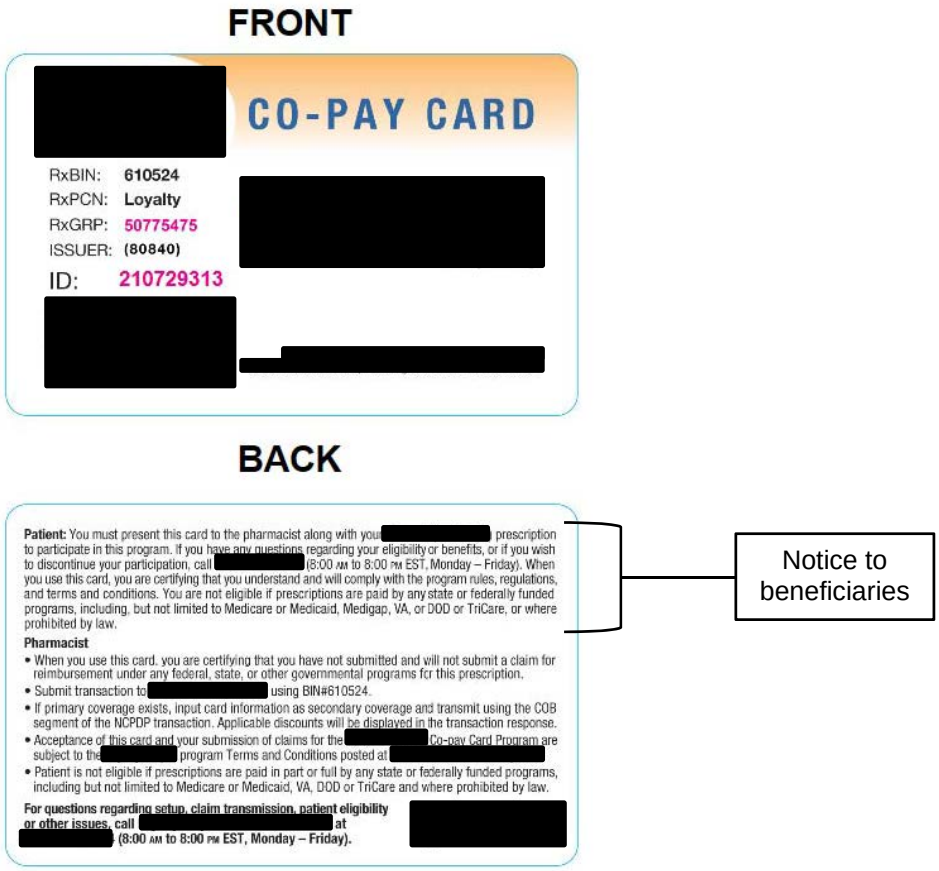
Notices Directed to Beneficiaries. Manufacturers' notices directed to beneficiaries are typically printed on coupons or on materials associated with coupons, such as coupon brochures, Web sites, or advertisements. Notices also can be triggered by eligibility questions asked online or over the telephone. Eligibility questions may ask patients: "Do you purchase your prescription medication through Medicare, Medicaid, or a similar Federal or State prescription drug program?" If patients indicate that they are enrolled in Federal health care programs, these manufacturers notify them that they are not eligible to access the coupon.

OIG's review of 40 coupons offered by surveyed manufacturers found results similar to the survey responses. Nearly all of the coupons OIG obtained had a notice printed on them, and 80 percent had a notice printed on the coupon Web site. Further, 75 percent had an eligibility question online or over the phone. However, only 3 percent had a tracking mechanism on their Web sites to prevent a patient from changing his or her answer to the eligibility question to obtain the coupon.

[28] Notices to pharmacists do not pertain to direct reimbursements because direct reimbursements are not adjudicated by the pharmacy.

Manufacturers' notices to beneficiaries are typically printed in small font. In some instances, notices are printed on the back of a coupon. See Figure 2 for an example of a coupon with a notice printed in small font on the back. This coupon is approximately the size of a credit card.

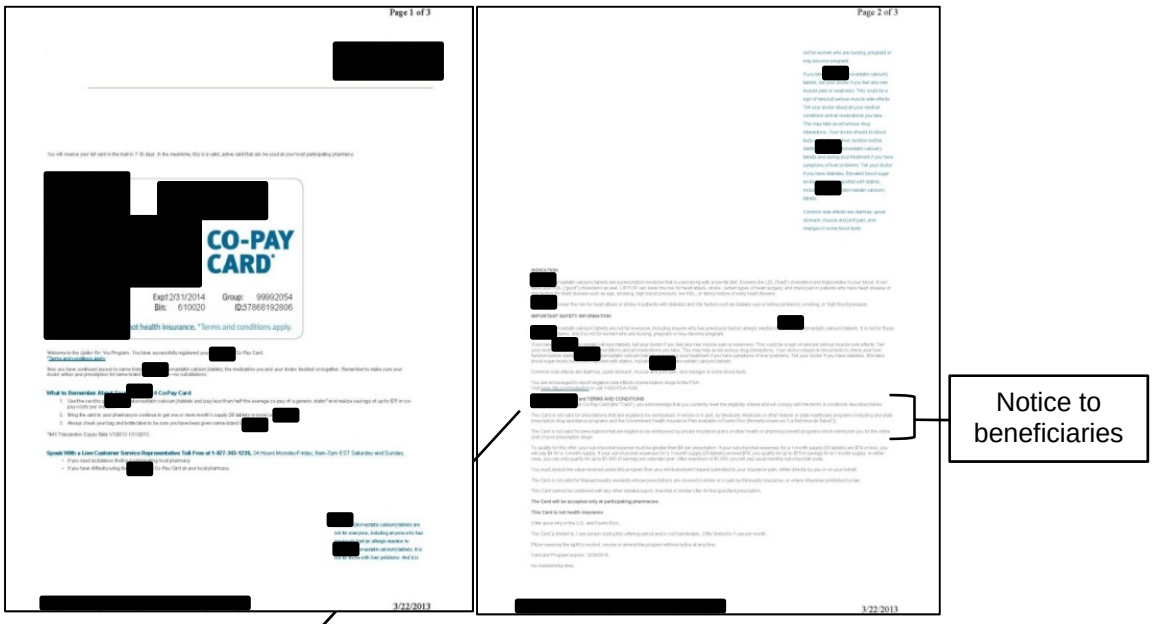
Figure 2: Example of a Coupon With a Notice Printed in Small Font on Back of Coupon



Source: OIG review of manufacturers' copayment coupon safeguards, 2013.

In some instances, notices to beneficiaries, particularly those downloaded and printed from the Internet, are on pages following the coupons and not on the coupons themselves. See Figure 3 for an example of a coupon and a notice on the following page. The actual size of each page below is 8½ by 11 inches.

Figure 3: Example of a Coupon With a Notice Printed on Following Page



[redacted] Co-Pay Card TERMS AND CONDITIONS

By using the [redacted] Co-Pay Card (the "Card"), you acknowledge that you currently meet the eligibility criteria and will comply with the terms & conditions described below:

This Card is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare or other federal or state healthcare programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico [formerly known as "La Reforma de Salud"]).

The Card is not valid for prescriptions that are eligible to be reimbursed by private insurance plans or other health or pharmacy benefit programs which reimburse you for the entire cost of your prescription drugs.

Source: OIG review of manufacturers' copayment coupon safeguards, 2013.

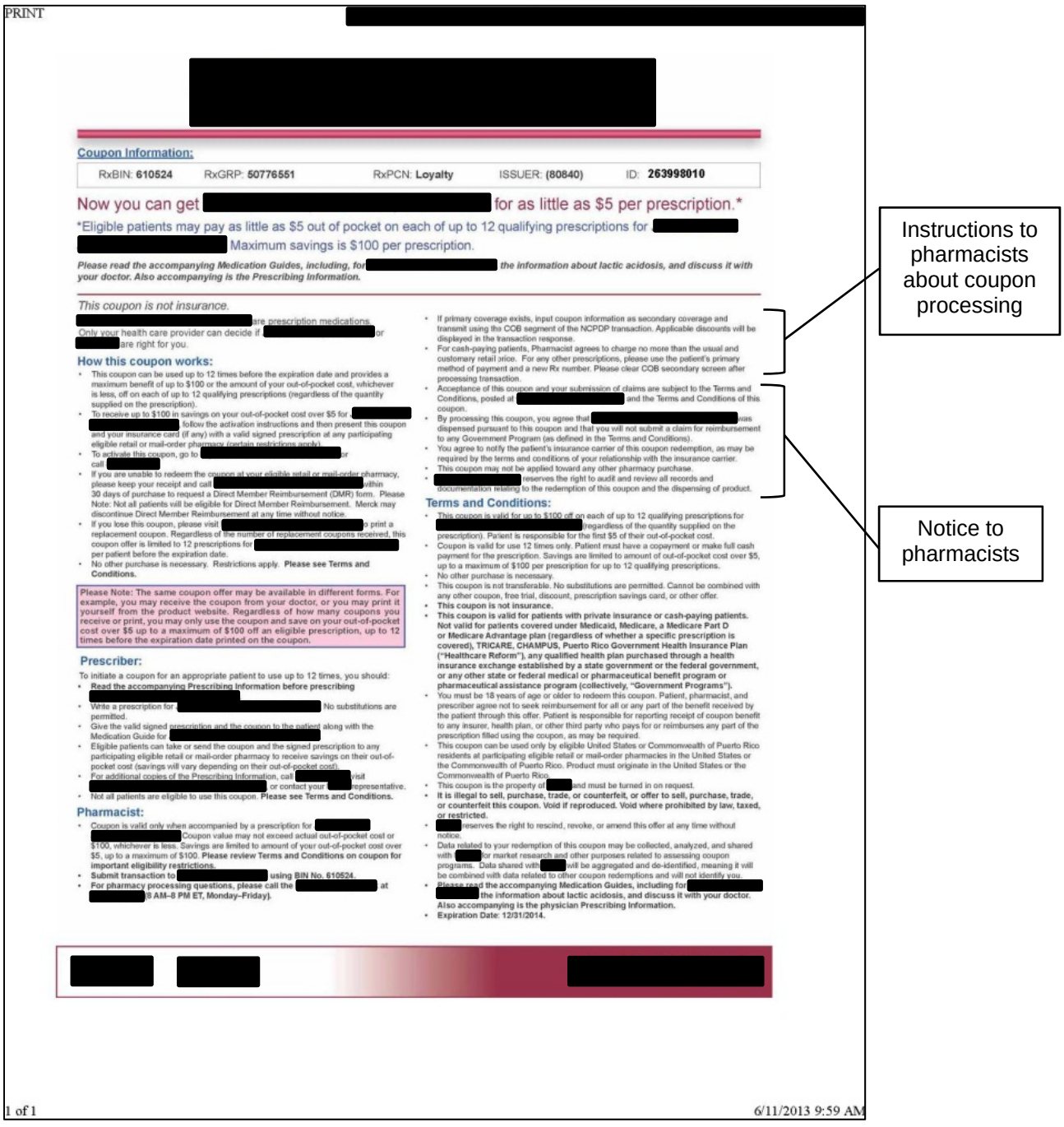
Notices Directed to Pharmacists. Two-thirds of manufacturers surveyed report providing notices to pharmacists for at least one of the coupon formats they offer. See Table 2, on page 9, for the percentage of survey manufacturers that report using notices to pharmacists broken out by coupon format.

Manufacturers' notices to pharmacists typically include reminders to pharmacists not to accept coupons for drugs paid for by Federal health care programs. These notices may include statements such as "Do not process coupon if Government beneficiary." Or, they may include more specific language, such as "Pharmacist: When you use this card, you are certifying that you have not submitted and will not submit a claim for reimbursement under any Federal, State, or other Governmental programs for this prescription." Notices to pharmacists can be printed on coupons or on associated materials. They also may appear as alerts to pharmacists through the pharmacy claims transaction system.

OIG's review of the 40 coupons obtained found that slightly more than half, or 58 percent, of coupons we reviewed had notices with specific language directed to pharmacists.

Manufacturers' notices to pharmacists, in some instances, are printed in small font among other types of information, such as instructions on how to process the coupon. See Figure 4 for an example of a coupon with a notice printed among instructions to pharmacists. The actual size of the coupon below is 8½ by 11 inches.

Figure 4: Example of a Coupon With a Notice Printed Among Instructions to Pharmacists



Source: OIG review of manufacturers' copayment coupon safeguards, 2013.

Additionally, manufacturers' notices may be sent through alert messages within the pharmacy claims transaction system. Studies show that pharmacists may experience "alert fatigue" because of the high volume of drug alert notices that appear through the pharmacy claims transaction system.[29] A notice to check enrollment status in Federal health care programs may be one of the many notices that pharmacists receive.

Manufacturers' notices to beneficiaries and pharmacists only communicate information stipulating the terms and conditions of copayment coupons. These notices cannot necessarily stop coupons from being processed to purchase drugs paid for by Federal health care programs.

Most surveyed manufacturers use pharmacy claims edits to prevent copayment coupons from being processed for drugs paid for by Part D

Most surveyed manufacturers report having edits in the pharmacy claims transaction system to prevent the use of copayment coupons for drugs paid for by Part D. Twenty-eight of thirty manufacturers surveyed use claims processing edits for at least one of the coupon formats they offer. Of these manufacturers, 13 offered specific information about their edits. More of these manufacturers report using edits for print coupons than for other coupon formats. See Table 3 for information about a breakdown of these edits by coupon formats offered.

Table 3: Claims Processing Edits by Coupon Format

Edit	Print n = 27	Electronic n = 22	Debit Card n = 9	Direct Reimbursement n = 16	Any Format n = 30
Primary Insurance Information	7 (26%)	3 (14%)	1 (11%)	2 (13%)	9 (30%)
Benefit Stage Information	5 (19%)	3 (14%)	0 (0%)	1 (6%)	6 (20%)
Patient Date of Birth	4 (15%)	1 (5%)	0 (0%)	0 (0%)	5 (17%)

Source: OIG analysis of pharmaceutical manufacturer survey responses, 2013.

All of the manufacturers that offered specific information about their claims processing edits use proxies to approximate Part D coverage. The data these manufacturers' edits use as proxies are routinely transmitted on pharmacy claims and include information about a patient's primary insurance, Part D benefit stage, and date of birth. Manufacturers rely on proxies to approximate Part D coverage because they lack access to Part D enrollment status. CMS indicated that Part D enrollment data are not

[29] John R. Horn and Philip D. Hantse, "Making Computerized Screening Work for You," *Pharmacy Times*, February 2006, p. 26.

available to manufacturers because they contain sensitive health care information.[30]

Thirty Percent of Manufacturers Use Edits Relying on Primary Insurer's BIN. These manufacturers report having a claims processing edit that uses the primary insurer's BIN for at least one of the coupon formats they offer. The primary insurer's BIN is the only information identifying a patient's primary insurance that is transmitted to manufacturers on the coupon claim. Manufacturers attempt to determine which BINs are used by insurance companies that offer Part D plans by assembling lists of BINs from previously adjudicated primary insurer pharmacy claims and other sources, such as payer sheets.[31] The edit compares the primary insurer's BIN on the coupon claim to the list of collected BINs. If the edit identifies that the primary insurer's BIN represents an insurance company that offers a Part D plan, the claims processing system may automatically stop the coupon from being processed and/or send a message to the pharmacist that the patient is not eligible to use the coupon.

Four surveyed manufacturers report using an edit that relies on the primary insurer's BIN and PCN, the secondary identifier specifying unique insurance plans offered by the same insurance company. The PCN must be obtained from the primary insurance claim because it is not transmitted on the coupon claim. These edits use the BIN and PCN in combination to determine whether the primary insurance claim is being submitted to a Part D plan or a commercial plan within the same insurance company.

Twenty Percent of Manufacturers Use Edits Relying on the Part D Benefit Stage. These manufacturers report having a claims processing edit that uses Part D benefit stage information for at least one of the coupon formats they offer. Benefit stage fields contain data only if the claim is for a Part D beneficiary. If the edit identifies data in these fields, the edit either automatically stops the coupon from being processed or sends a message to the pharmacist to reverse the claim.

Seventeen Percent of Manufacturers Use Edits Relying on Patient Date of Birth. These manufacturers report having an edit that uses the patient's date of birth for at least one of the coupon formats they offer. Manufacturers use edits relying on patient's date of birth to calculate a

[30] Because Part D enrollment status is unavailable to manufacturers, those manufacturers that did not offer specific information about their edits likely use proxies and face the same challenges outlined in this report.

[31] Payer sheets are templates created to help claims processors communicate necessary claims processing information to pharmacies, vendors, and other entities. Information on payer sheets can vary by insurance plan but generally contains the BIN.

patient's age. Manufacturers may require pharmacists to submit the patient date of birth as part of the coupon claim. If a pharmacy claim indicates that the patient is at or older than a certain threshold—typically age 62 or 65—these edits will either stop the coupon from being processed or send a message to the pharmacist to verify Part D enrollment.

Surveyed manufacturers' pharmacy claims edits may not prevent copayment coupons from being processed for drugs paid for by Part D

Pharmaceutical manufacturers' claims processing edits currently in use may not stop all coupons from being processed for drugs paid for by Part D because manufacturers cannot accurately identify a beneficiary's Part D enrollment status. Manufacturers' claims processing edits use proxies that are substitutes for but do not replicate actual enrollment information. These proxies use data that may be unreliable or cannot be obtained by all manufacturers.

Claims Processing Edits Using Primary Insurance BINs Cannot Always Accurately Identify Part D Coverage. Manufacturers' claims processing edits that use primary insurers' BINs cannot always identify Part D coverage because they may be unreliable proxies. These edits may not be reliable because they use BIN lists that are collected at a point in time and may not be accurate or current. Further, BINs may not provide the specificity needed to determine whether a patient is enrolled in a Part D plan. Coupon vendors report that the BIN indicates the insurance company but does not, in most cases, distinguish a company's Part D plan from other commercial plans the company offers. To avoid stopping coupon claims associated with commercial plans, manufacturers' BINs lists may contain only BINs known to be exclusively for insurance companies' Part D plans. For instance, one manufacturer reported that its BIN edit relies on a list of BINs dedicated to Part D plans. Thus, this manufacturer's claims processing edit would allow coupons to be processed for claims containing BINs for insurance companies that offer both Part D and commercial plans.

Claims Processing Edits Using Patient Date of Birth Cannot Identify All Part D Beneficiaries. Manufacturer claims processing edits that rely on patient date of birth cannot always approximate Part D coverage. These edits may not identify all Part D beneficiaries because not all Medicare beneficiaries fit a specific age demographic. In fact, 17 percent of Medicare beneficiaries are disabled and under age 65.[32] Additionally,

[32] Henry J. Kaiser Family Foundation, "Medicare at a Glance," November 14, 2012, http://kff.org/medicare/fact-sheet/medicare-at-a-glance-fact-sheet/. Accessed on November 27, 2013.

some individuals who are eligible for Medicare may be enrolled in commercial plans and not in Part D.

Some Claims Processing Edits Use More Accurate Proxies To Identify Part D Coverage, but Cannot Be Used by All Manufacturers. Claims processing edits that more accurately determine Part D enrollment are imperfect because these edits use information that cannot be obtained by all manufacturers. These edits rely on the more accurate proxies of BIN/PCN and benefit stage information.

While edits that rely on the primary insurer's BIN/PCN are more accurate proxies, access to this combination of information is limited. To access the BIN/PCN, a manufacturer's coupon vendor needs to have access to primary insurance claims because the PCN is not transmitted as part of the coupon claim. OIG identified one entity with such access to the BIN/PCN. This entity plays a dual role as a coupon vendor and a switching company that electronically routes claims, giving it access to the primary insurance claim containing the BIN/PCN that indicates Part D insurance.

For other manufacturers' coupon vendors to access the PCN, NCPDP would need to revise its pharmacy claims transaction standards to enable the PCN to be transmitted as part of the coupon claim. Revising the NCPDP standards is an industrywide process that typically takes years to complete and requires all involved entities to update their claims transaction systems to comply with the new standards. The current NCPDP standards were updated and released in 2009.

Edits that rely on benefit stage information also are more accurate proxies, but access to this information also is limited. Although some manufacturers report having this edit, it is unclear how they obtain benefit stage information. As cited by NCPDP guidance, only entities that report Part D beneficiaries' financial TrOOP amounts are allowed to request or receive this information, such as insurance companies that offer Part D plans.[33, 34]

Other Vulnerabilities in Claims Processing Edits Exist. In addition to the vulnerabilities associated with the proxies manufacturers use for edits, there may be implementation errors in claims processing edits. Most surveyed manufacturers have no way to verify that edits are being applied

[33] NCPDP, "NCPDP WG9 Medicare Part D Questions and Answers," Version 3.0, August 2013, p. 12. Accessed at http://www.ncpdp.org/members/wg09/NCPDP_WG9_Medicare_Part_D_FAQ_Document_v3.0.pdf on January 30, 2014.

[34] Entities that can obtain benefit stage information may include State pharmaceutical assistance programs.

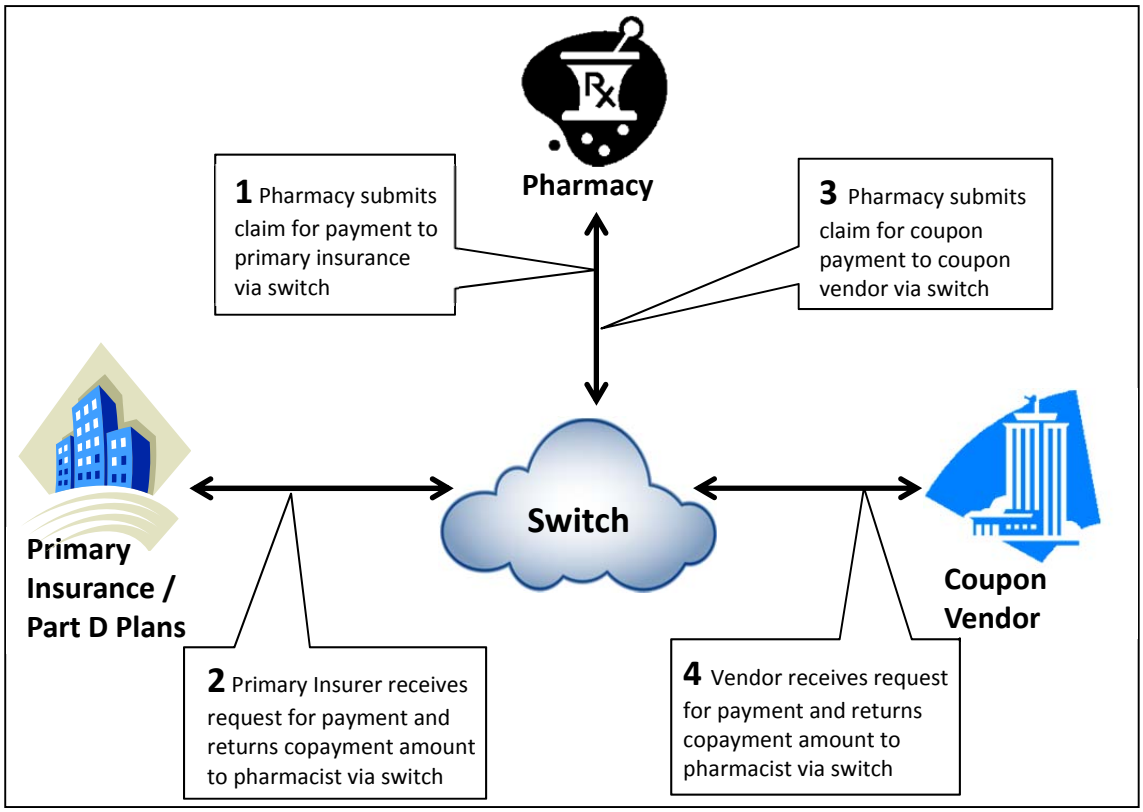
correctly because they do not audit claims processing edits. Only 30 percent of manufacturers surveyed report having auditing practices in place to analyze claims processing edits. These audits may include reviews of processes used to identify and reject claims for Part D beneficiaries or retrospective reviews that assess the number of coupons processed and rejected as a result of the edits.

Part D plans and other entities cannot identify copayment coupons within pharmacy claims

It is difficult for entities other than manufacturers to identify coupons as they are processed through the pharmacy claims transaction system or after they are adjudicated. Coupons are not transparent in the pharmacy claims transaction system to entities other than manufacturers. This vulnerability impedes other entities, including Part D plans, other primary insurers, and pharmacies, from preventing the use of coupons for drugs paid for by Part D and oversight entities, like CMS and OIG, from monitoring the use of coupons.

Primary insurers, including Part D plans, cannot identify coupons as they are processed or after they are adjudicated because of the way coupons are processed. Coupons are typically processed as secondary insurance claims, after a patient's primary insurance claim, including Part D, has been processed. Because of this, Part D plans, like other primary insurers, cannot identify when a coupon is used. See Figure 5, on the next page, for an illustration of how, as a coupon claim is processed, it is not submitted to primary insurers.

Figure 5: Transmission of Information Among Payers and Entities Coordinating Coupon Claims Processing



Source: OIG analysis of interview responses, 2013.

Further, specific coupon formats may be difficult, or impossible, for pharmacists dispensing to beneficiaries on behalf of Part D plans to identify as coupon claims are processed through the pharmacy claims transaction system. When pharmacies cannot identify coupons, they do not know to attempt to verify Part D enrollment to prevent the use of coupons to purchase drugs paid for by Part D. Coupon formats that are difficult to identify include electronic coupons, debit cards, and direct reimbursements. Electronic coupons may be difficult for pharmacists to identify because they are automatically applied as prescriptions are submitted through the pharmacy claims transaction system rather than being presented by patients at the point of sale as with print coupons. Debit card coupons may be difficult to identify because patients may use them to pay their copayments without handing the card to the pharmacist. Finally, direct reimbursements cannot be identified by pharmacists because they are offered directly to patients and processed outside of the pharmacy claims transaction system.

It is also difficult to identify coupons after they are adjudicated. As previously stated, it not always possible to distinguish coupon claims from secondary insurance claims because both manufacturers and insurers use

BINs to route claims within the pharmacy claims transaction system. Manufacturers currently do not disclose the BINs associated with their coupons to outside entities. Compiling an accurate and comprehensive list of BINs that route coupon claims without manufacturer involvement would be challenging because coupons expire and BINs, while typically on print coupons, are not generally found on other coupon formats. Because BINs that route coupon claims are not distinguishable from BINs that route insurance claims, entities that conduct oversight, such as CMS and OIG, cannot analyze pharmacy claims to determine whether manufacturer safeguards to prevent the use of coupons for drugs paid for by Part D are effectively stopping the coupons.

CONCLUSION AND RECOMMENDATION

The anti-kickback statute prohibits knowing and willful solicitation, receipt, offer, or payment of remuneration to induce the purchase of any item or service for which payment may be made in whole or in part under a Federal health care program. Pharmaceutical manufacturers may be liable under the anti-kickback statute if they offer coupons to induce the purchase of drugs paid for by Medicare Part D or any other Federal health care program.

Pharmaceutical manufacturers report that they employ safeguards directed at preventing the use of copayment coupons for drugs paid for by Part D. All surveyed manufacturers provide notices to beneficiaries and pharmacists that coupons may not be used in Federal health care programs for at least one of the coupon formats they offer. In addition, most surveyed manufacturers have implemented pharmacy claims edits to prevent coupons from being processed for drugs paid for by Part D.

However, manufacturers' edits may not reliably prevent coupons from being processed for drugs paid for by Part D. In particular, most manufacturers' claims edits only approximate Part D coverage using proxy data that may be unreliable. Additionally, the proxy data that are currently available may not be obtained by all manufacturers.

In addition to potentially implicating the anti-kickback statute, manufacturers' use of coupons to reduce the cost-sharing obligations for drugs paid for by Medicare Part D could impose costs on Part D plans, on the Part D program, and ultimately on Part D beneficiaries. While coupons provide an immediate financial benefit to beneficiaries by reducing their out-of-pocket costs, they may increase the cost of prescription drugs for Part D plans.[35] Coupons may increase costs for Part D plans because they may encourage the purchase of more expensive brand-name drugs instead of less expensive alternative treatments, such as generic drugs.

To protect themselves from excessive costs, Part D plans may have an interest in preventing the use of coupons for drugs paid for by their plans.

[35] Manufacturers that desire to assist Federal health care program beneficiaries who cannot afford their copayments have the option of donating to independent charities that provide copayment support without regard for the particular medication a patient may be using. For OIG's guidance specifically related to such charities, see OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf, and OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf.

However, a lack of coupon transparency impedes Part D plans from distinguishing coupon claims from secondary insurance claims as they are processed. Because entities other than manufacturers cannot identify coupons within pharmacy claims, Part D plans cannot implement their own edits to stop coupon claims as they are processed.

Concurrently with the issuance of this report, OIG is issuing a Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons. This document affirms that the offerors of coupons ultimately bear the responsibility to operate these programs in compliance with Federal law. Pharmaceutical manufacturers that sponsor copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services, including, but not limited to, drugs paid for by Medicare Part D. Failure to take such steps may be evidence of intent to induce the purchase of drugs paid for by these programs, in violation of the anti-kickback statute.

Improving the reliability of pharmacy claims edits and making coupons transparent within pharmacy claims will likely require the coordination and cooperation of multiple stakeholders within the pharmacy claims transaction process, including CMS. For this reason, pharmaceutical manufacturers may engage industry stakeholders, including CMS, in an effort to identify a solution to ensure that coupons are not used for drugs paid for by Part D.

We recommend that CMS:

Cooperate with industry stakeholder efforts to identify a solution to prevent coupons from being used to purchase drugs paid for by Part D

As the oversight entity of the Part D program and the custodian of Part D enrollment data, CMS should cooperate with industry stakeholder efforts to improve the reliability of pharmacy claims edits and make coupons transparent. For example, CMS could consider all options to facilitate verification of Part D enrollment status before a coupon is processed. Or CMS could explore the possibility of making any feasible changes to the Part D program to facilitate Part D enrollment verification. Additionally, CMS could explore with all involved entities how best to make coupons universally identifiable and transparent in pharmacy claims transactions.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation. CMS specifically noted that it concurs with our recommendation to work with relevant stakeholders to improve the reliability of pharmacy claims edits that facilitate verification of Part D enrollment and to explore how best to make coupons universally identifiable and transparent in pharmacy claims data.

For the full text of CMS's comments, see Appendix B.

APPENDIX A

Discussion on Data Collection and Analysis

We collected information about pharmaceutical manufacturer safeguards directed at preventing the use of coupons for drugs paid for by Medicare Part D through a survey of manufacturers and a review of copayment coupon safeguards. We collected information about other vulnerabilities associated with coupon use from interviews with staff at organizations involved in the pharmacy claims processing system.

Drug Selection. We selected the top 100 Part D-covered brand-name drugs by cost that have copayment coupons for the study. These 100 drugs with coupons represent approximately 59 percent of all Part D drug costs.

To select the top 100 Part D-covered brand-name drugs with coupons, we first identified brand-name drugs that were paid for by Part D as of June 2012 using Prescription Drug Event (PDE) data and First DataBank data.[36, 37] Using these data, we matched the NDCs for brand-name drugs in First DataBank data to NDCs in PDE data. Because multiple NDCs exist for a single brand-name drug, we collapsed brand-name drugs by the HICL_SEQNO identifier.[38] Next, we summed the total cost for each drug in PDE data by the HICL_SEQNO and the brand name. We then ranked each drug by its total cost.

Next, we compiled a list of 520 coupons from www.internetdrugcoupons.com as of December 2012. Internet Drug Coupons publishes a list of pharmaceutical manufacturer coupons and is recognized by the industry as a reliable listing for coupons.

Finally, we matched the list of coupons to the list of the Part D-covered brand-name drugs. We selected the first 100 Part D-covered brand-name drugs—ranked by total drug cost—with coupons. Because coupons are offered by drug and generally are not unique by package size, dosage form, or route of administration, we matched the common brand name for the drugs associated with these coupons to the brand names and the HICL_SEQNO identifiers in First DataBank.

[36] The PDE data represent each purchase of a Part D drug by a beneficiary and contain the National Drug Code (NDC), a universal identifier that specifies the pharmaceutical manufacturer, drug name, dosage form, strength, and package size.

[37] First DataBank data provide product information, including drug name, standard therapeutic class, and whether the drug is a brand-name drug or a generic drug.

[38] The HICL_SEQNO identifies a drug's unique combination of active ingredients, irrespective of the package size, dosage form, route of administration, or strength.

Survey of Pharmaceutical Manufacturers. In May 2013, we conducted an online survey of the 34 pharmaceutical manufacturers of the top 100 Part D-covered brand-name drugs with copayment coupons.

We identified these manufacturers through information on the coupons and Internet searches. We also asked manufacturers to verify this information. We made one followup attempt by email. We received 30 complete surveys, an 88-percent response rate.

The survey asked manufacturers to provide responses about the safeguards in place for the coupons they offer. We asked manufacturers to report the coupon formats they offer and distribution methods through which patients obtain coupons. We also asked manufacturers about the types of safeguards they have in place for each coupon format they offer. We asked them questions about coupon safeguards directed to Part D beneficiaries, safeguards directed to pharmacists, and safeguards within the pharmacy claims transaction system. We did not ask manufacturers to specify the particular safeguards in place for each of the top 100 Part D-covered brand-name drugs.

We analyzed survey responses to identify specific manufacturer safeguards and determine the extent to which manufacturers surveyed had safeguards in place. For each type of safeguard identified, we calculated the number of manufacturers using the safeguard for at least one of their coupon formats. We also calculated the number of manufacturers with each safeguard by coupon format.

OIG Review of Coupon Safeguards. We reviewed copayment coupon safeguards for a subset of the top 100 Part D-covered brand-name drugs with coupons to determine whether safeguards directed to beneficiaries and pharmacies existed. OIG attempted to obtain 50 coupons, and we reviewed safeguards for the 40 coupons that we obtained. The coupons we attempted to obtain were associated with 24 manufacturers, all of which were included in the population of manufacturers that OIG surveyed. We reviewed coupon safeguards that manufacturers had in place from February to June 2013.

We reviewed and determined the extent to which manufacturers had safeguards directed to beneficiaries on the Internet, over the telephone, and on the print coupons. For safeguards on the Internet and over the telephone, we determined whether: (1) there was a notice about coupon use in Federal health care programs and (2) the notice was triggered by an eligibility question for Part D coverage. For safeguards on the coupons, we determined whether there was a notice directed to beneficiaries about coupon use in Federal health care programs. For each of these safeguards,

we calculated the number of manufacturers using it and identified vulnerabilities.

We reviewed and determined the extent to which manufacturers had safeguards directed to pharmacists on the coupons. For these safeguards, we determined whether: (1) there was a general notice on the coupons about coupon use in Federal health care programs and (2) there was a specific notice on the coupons that pharmacists will not submit a claim to a Federal health care program for the prescription with the coupons. We considered a general notice to be any other language directed to pharmacists stating that Federal health care beneficiaries are ineligible to use coupons. We considered a specific notice to be any language that indicates the pharmacist agrees or certifies that he or she will not submit a claim for reimbursement under any Federal health care program or certifies that the patient is not enrolled in any Federal health care program. For each of these safeguards, we calculated the number of manufacturers using the safeguard and identified vulnerabilities.

As part of our review, we attempted to obtain the coupons for which we reviewed safeguards. For coupons available online, we attempted to download coupons and obtained 40 of them. For coupons available over the telephone, we attempted to receive coupons through the mail but obtained none of them.

Structured Interviews. We conducted structured interviews with staff at organizations involved in the pharmacy claims transaction process, including pharmacists, coupon vendors, a switching company, and NCPDP, regarding their experience processing pharmacy claims and coupon claims. We conducted these interviews from February to August 2013.

We reviewed structured interview responses to understand other vulnerabilities associated with coupon use. In particular, we discussed the pharmacy claims transaction system and the extent to which coupons are identifiable within it. We also reviewed interview responses to identify vulnerabilities in current safeguards.

APPENDIX B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUL 30 2014

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs" (OEI-05-12-00540)

The Centers for Medicare & Medicaid Services (CMS) appreciate the opportunity to provide comments on the above mentioned draft report. This draft report assesses the vulnerability of the Part D program to the use of manufacturer's copayment coupons. We are also concerned about the appropriate use of manufacturer's copayment coupons and agree with the OIG that the use of manufacturer's coupons to reduce cost-sharing obligations for drugs paid for by Medicare Part D could impose costs on Part D plans, the Part D program, and ultimately Part D beneficiaries.

OIG Recommendation

The CMS should cooperate with industry stakeholder efforts to identify a solution to prevent coupons from being used to purchase drugs paid for by Part D.

Specifically, the OIG noted that CMS should cooperate with industry stakeholder efforts to improve the reliability of pharmacy claim edits, including considering all options and any feasible changes to the Part D program, to facilitate verification of Part D enrollment status before a coupon is processed. The OIG also suggested that CMS could explore with all involved entities how best to make coupons universally identifiable and transparent in pharmacy claims transactions.

CMS Response

The CMS concurs with the recommendation to work with all relevant stakeholders to find a meaningful solution to prevent inappropriate use of manufacturers' copayment coupons for drugs paid for by Part D. CMS concurs with OIG's suggested recommendation to work with relevant stakeholders to improve the reliability of pharmacy claim edits that facilitate verification of Part D enrollment and to explore how best to make coupons universally identifiable and transparent in pharmacy claims data.

Thank you for the opportunity to review and comment on the draft OIG report.

ACKNOWLEDGMENTS

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Laura Kordish, Deputy Regional Inspector General.

Melissa Baker served as the team leader for this study, and Jonathan Jones served as the lead analyst. Central office staff who provided support include Clarence Arnold and Meghan Kearns.

Office of Inspector General

http://oig.hhs.gov

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House Bill 1216
North Dakota Senate Health and Human Services Committee
AHIP Testimony

Thank you for the opportunity to speak before you today. My name is Alex Kelsch, and I am testifying today on behalf of America's Health Insurance Plans (AHIP).

AHIP respectfully opposes HB 1216 because it restricts health plans' ability to hold down drugs costs.

Everyone should be able to get the medications they need at a cost they can afford. However, drug prices continue to rise out of control, and pharmacy costs now represent over 24 cents[1] out of every dollar of premium spent on health care.

Unfortunately, HB 1216 does nothing to control the soaring prices of prescription drugs set by pharmaceutical manufacturers. Instead, it would financially reward drug manufactures for steering patients towards more expensive brand-name drugs, increase premiums, and reduce wages for North Dakotans.

Drug manufacturers intentionally use copay coupons to keep drug prices high.

Drug manufacturers acknowledge their drugs are unaffordable for patients. But rather than addressing this by lowering their prices, they instead offer copay coupons to hide the actual cost of those drugs.

Drug manufacturers offer these promotions only to very specific patients for a very short period of time. Once a patient hits their deductible, drug manufacturers discontinue the patient's coupons – which hides the underlying prices from patients, enticing them to continue with the most expensive drug, even when there are less expensive drugs available.

It is important to note, the federal government considers copay coupons to be an illegal kickback if used by an enrollee in Medicare or Medicaid because they induce a patient to use a specific drug[2].

In the commercial market, coupons are often offered only for a limited time – once the patient hits their deductible, drugmakers discontinue the patient's assistance.

These promotions are used to increase sales, raising costs for everyone.

There are multiple studies by the U.S. House Oversight Committee[3], Harvard[4], the Congressional Research Service[5], and others, that found that drug manufacturers use patient assistance programs as a sales tool – focusing on their rates of return, encouraging patients to stay on branded drugs after a generic is introduced, and subsidizing third-party foundations to drive sales and attract patients who otherwise might not have used the high-priced drug.

Purchasers of health care use guardrails to hold drug manufacturers accountable for pricing schemes such as copay coupons.

Employers and purchasers of health care have worked hard to develop guardrails to hold drug

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[1] *Where Does Your Health Care Dollar Go?* America's Health Insurance Plans. October 2024. https://www.ahip.org/health-care-dollar/

[2] *See 42* U.S.C § 1320a-7b; *Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons*. Department of Health and Human Services, Office of the Inspector General. September 2014. Available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf.

[3] U.S. House Committee on Oversight and Reform; Drug Pricing Investigation, Majority Staff Report. December 10, 2021. https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf

[4] Dafny, et. al. When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization. American Economic Journal: Economic Policy 9, no. 2 (May 2017): 91–123. https://www.hbs.edu/ris/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf

[5] Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs). Congressional Research Service. June 15, 2017. https://crsreports.congress.gov/product/pdf/R/R44264/5.

companies accountable for their problematic pricing schemes and keep costs low for North Dakotans. These employer and health plan guardrails do not result in higher costs for patients but instead maximize the value of coupons to benefit all patients and plan sponsors and reduce drug manufacturers' ability to avoid fair negotiations on prices.

AHIP commissioned the actuarial firm Wakely[6] to analyze the impact of requiring health plans to count all third-party payments towards an enrollee's cost sharing obligations. Wakely found that bills like these will:

- **Increase premiums**, with the largest increases in the individual marketplace
- **Result in adverse selection** into lower premium plans, such as Bronze plans, resulting in **higher premiums and consumers dropping their coverage.**
- **Reduce wages** for workers who receive coverage at work, due to **higher employer costs.**
- **Encourage use of more expensive drugs** over cheaper alternatives.

Legislation like this will reduce manufacturers' incentives to offer lower prices because they can continue to replace real price reductions with coupons. As a result, drug companies will make more money while North Dakota families and businesses continue to foot the bill through lower wages, higher premiums, and higher out-of-pocket expenses.

The legislature should focus on solutions that forbid market manipulation.

Instead of taking away the few tools that health plans and employers use to address ever increasing drug prices, we recommend that North Dakota legislators focus on fixing the market distortion caused by drug manufacturer pricing schemes, including copay coupons.

AHIP stands ready to work together with policymakers on real solutions to ensure every patient has access to the high-quality drugs that they need and improve health care affordability.

[6] https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=0938-AV41&meetingId=628923&acronym=0938-HHS/CMS

Good afternoon, Madam Chair, Members of the Senate Human Services committee. My name is Megan Hruby and I am with Blue Cross Blue Shield of North Dakota.

I am here this morning to provide some important perspective on House bill 1216, the bill relating to copay coupons and accumulator programs for prescription drugs. BCBSND is opposed to HB 1216 as currently written because despite the sponsors best intentions, this bill will not lower costs for consumers in North Dakota. We share the same goal as the advocates here today, which is more affordable prescriptions. We simply disagree on the best way to get there.

I want to start by saying clearly, whether this bill passes or fails, the coupons will remain. Anyone who receives a coupon today, will still have a coupon regardless of what happens with the bill. There was a lot of confusion about that last Session, so let's clear that up. The coupons stay no matter what. This bill only impacts how much of the cost of the coupons is shifted from pharma to health insurers.

Unfortunately, what else will stay if this bill continues as currently written is the inflated cost the people of North Dakota are paying for specialty brand-name drugs because of manufacturers' coupon schemes.

Here is what you will hear me ask you to consider today:

1. The coupons are a targeted marketing effort meant to increase profits for drug manufacturers. These coupons are not available to everyone. They are only available to the well insured. If this bill intends to help consumers, it should require companies to offer the coupons to all who could benefit from the medications, all year long.

2. This bill does not help consumers. Overall, it increases costs for everyone. If you look at the attached Harvard Magazine article, manufacturer sponsored coupons increase costs 8% or more than $1 billion in one drug class alone.

3. This bill benefits pharmaceutical companies most. Health insurance costs in the fully insured marketplace in North Dakota are regulated by Commissioner Jon Godfread. Drug manufacturers, however, set drug prices. It is drug manufacturers who stand to profit most from this bill through maintaining higher drug costs. No commissioner or agency regulates the prices drug manufacturers charge for medication.

Myth Busting: There is no double dipping.

Proponents of HB 1216 routinely reference “double dipping”. There is no double dipping. They say that insurance companies take money from the coupons and then turn around and charge the consumer for their deductible. That is false. Insurance companies don’t see the coupons and receive no compensation for them. Coupons, by nature, have no cash value. They are a manufacturer discount intended to entice you to buy their product. The coupon is between the pharmaceutical company, the consumer and the pharmacist.

Take the example of Trikafta, as the proponents mentioned. Say that Trikafta is a drug that costs $28,000 per month, or $336,000 annually. Trikafta is covered by the patient’s insurance. The patient, when they shopped for insurance, signed a contract with the insurance company stating that for $300 monthly premium ($3,600 annually) and a $5,000 deductible, the insurance company would pay for the patient’s health care whether it cost $10,000 or $1 million. The consumer then goes to the pharmacy to pick up their prescription for Trikafta. They have a coupon for $5,000. The drug cost then becomes $23,000. The amount the patient is responsible for is the $5,000 deductible for which they agreed. The insurance carrier is responsible for:

- the remaining $331,000 for the drug annually
- the costs of the patient’s doctor appointments
- any hospital stays
- emergencies
- additional health issues (pickleball injury, annual physical, car accident, etc)

The pharmacist has a contract where they are reimbursed $28,000 for Trikafta. So, the pharmacist receives $28,000 in reimbursement regardless of whether there is a coupon for $5,000 off or not. The pharmacist, like the insurance company, doesn’t have any idea which consumers will come in with a coupon and which will not.

The coupons are a targeted marketing effort meant to increase pharmaceutical profits.

Pharmaceutical gift cards are not a charitable effort – they are clearly targeted at commercially insured individuals for use on a specific drug purchase. If they were using the gift card for a medical procedure, would the pharmaceutical company allow it? No. They only allow the gift card to be used if the consumer purchases the name brand drug that the company manufactures. So, if you are following with me, it is a kick back, which is why it is not allowed under TRICARE, Medicare and Medicaid. It is illegal for pharmaceutical companies to offer copay assistance for medications that you purchase

through Medicare due to the Social Security Amendments of 1972. Included in those amendments is the Anti-Kickback Statute (AKS).

Regardless of this bill and coupons, carriers are paying the vast majority of the cost of these very expensive drugs. Speaking for BCBSND, we do it gladly. Newer drugs are improving and saving lives. Pharmaceutical spend is our fastest rising area at 20% annually, with 58% of that being on specialty drugs. Examples of these include cell and gene therapies at up to $4 million per treatment, oncology drugs ranging between $5,000 and $150,000 per month and of course, GLP1 diabetic medications at over $1,000 per member per month. If what the pharma companies are doing were truly altruistic, they would lower the cost of the drug rather than give out gift cards for thousands of dollars to a *select* population. They would also provide them to the uninsured, who arguably need them the most. But they don't. They only provide them to people who have commercial insurance because they know they can pass laws like these and recoup even more money, borne by insurance consumers via higher premiums.

This bill does not help consumers as a whole.

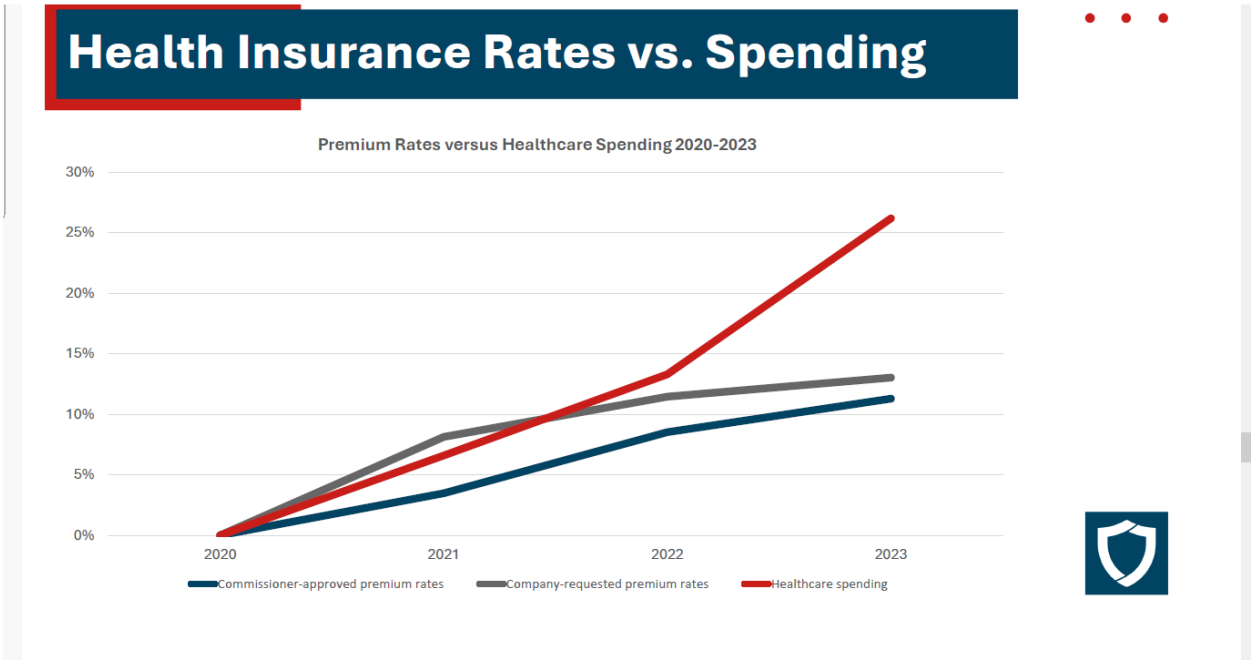
Pharmaceutical drug makers provide coupons for brand medications to market new drugs and encourage prescribers and patients to utilize their products. I linked to my testimony an article from Harvard Magazine entitled "How Coupons Keep Drugs Costly." In it, the authors discuss a recent study conducted by Rauner professor of business administration Leemore Dafny. Dafny and her colleagues estimated that "if you banned coupons, multiple sclerosis (MS) drug prices would be 8 percent lower, which in the U.S. means about a billion dollars less in spending"— That estimate is for MS prescriptions alone. https://www.harvardmagazine.com/2022/12/right-now-coupons-keep-drugs-costly

The Dafny study also shows that the share of brand-name prescription drug spending that included a coupon rose from 26 percent in 2007 to 90 percent in 2017. And the number of drugs with available coupons rose from about 200 in 2008 to more than 800 in 2018.

This bill is a balloon squeezer. Passing this bill will "lower" initial costs for commercially insured North Dakotans who receive a copay coupon at the expense of commercially insured North Dakotans who do not receive coupons.

The entities this bill benefits most are the pharmaceutical companies.

In the United States, there is no regulation of prescription drug pricing. Rather drug companies set their own prices. In contrast, in North Dakota, carrier premium rates are reviewed and approved by the North Dakota Insurance Department. What that means is that health insurance carriers must share two to five years of data to justify each year's premium rate. The Commissioner almost always cuts the rate we ask for, and then approves those rates. Carriers cannot charge more than the rate approved. One thing of note is that this legislation would not apply to self-funded ERISA plans, as it has a direct tie to and impact on ERISA plan benefit administration and therefore has an "impermissible connection with" ERISA plans that has consistently been struck down by federal courts, including the U.S. Supreme Court.



I've heard the sponsors of the bill say that insurers would "pocket money from your grandma or church if they helped you pay…" I will share very clearly with you that if our members get a gift of money from their grandmother, charitable websites, their church, or the like, and use it towards their copay, BCBSND 100% applies and counts it toward your deductible, because they could use it for anything; an MRI, hospital stay, or a doctor's visit – it isn't tied to use for a brand-name pharmaceutical. And let's also be clear, Grandma isn't raising the price of her cookies to recover the costs of her gift to you nor is Grandma requiring you or BCBSND to go purchase her cookies to get the assistance. Grandma doesn't benefit monetarily.

As stated, BCBSND opposes this bill. However, BCBSND could potentially support HB 1216 with the following amendments.

1. Amend the bill to require pharmaceutical companies extend the coupons to the insured and uninsured, twelve months of the year (to ensure that folks can receive their medications whenever they need them, not just once they get a few cycles in) with an accountability measure in place to prove that the manufacturers are doing so.

2. Amend the bill to mirror the proponents' intent and ban the offering of copay coupons for brand-name drugs with a biologically equivalent, generic therapeutic alternative or biosimilar drug available.

The spending on consumer coupons for prescription drugs is substantial, with figures reaching into the billions of dollars annually. Passage of this bill allows drug manufacturers to pick winners (those on their newest, brand name drugs receiving a coupon) and losers (the uninsured, those on government programs like TriCare, Medicare, and Medicaid; and those policy holders who do not receive a copay coupon but will have to pay for the increased costs.) The best and most altruistic solution would be to eliminate coupons altogether and have pharmaceutical companies lower the price of their drugs by an equivalent amount. But since that option isn't on the table, BCBSND respectfully asks for consideration of the amendments or a Do Not Pass vote.

Thank you for your consideration and I will stand for any questions.

February 4, 2025

To Whom It May Concern:

Patients all over North Dakota rely on financial assistance from third parties such as drug companies and non-profits to afford their medications. This type of financial assistance is especially important to patients that have high deductible plans or plans with high out-of-pocket costs. Unfortunately, many insurers have instituted copay accumulator adjustment policies, which do not count third party assistance toward a patient's deductible and out-of-pocket costs.

North Dakota should pass HB 1216, which would ban the use of copay accumulator adjustment programs. By passing this legislation North Dakota legislators will directly improve access to medications while sending a message that patients should come before insurance companies bottom lines.

Banning copay accumulator adjustment programs will not only ensure affordable access to medications, but when patients can afford their medications, they also have better adherence. By improving access and adherence to medications patients will see better overall health outcomes and prevent complications that could result in costlier interventions such as surgery or long hospital stays.

When patients with chronic diseases suddenly find they cannot afford their medications because their financial assistance did not count toward their out-of-pocket costs many simply forego purchasing their medications. Passing HB 1216 will significantly improve patient access to medications, especially for those most vulnerable patients with high deductible plans.

We respectfully urge you to support HB 1216.

Sincerely,

American Cancer Society Cancer Action Network
Bleeding Disorders Alliance of North Dakota
Coalition of State Rheumatology Organizations
Cystic Fibrosis Association of North Dakota
National Bleeding Disorders Foundation
North Dakota Rural Health Association
Susan G. Komen
WomenHeart Jamestown

HB1216
Senate Human Services Committee
March 10, 2025
Testimony of Karen M Cossette, Bismarck

Good morning Madame Chair and members of the committee. I support HB1216.

Let me quickly tell you about myself. I was born with cystic fibrosis. I was hospitalized the first time for a "tune-up" the summer I was age 16. A "tune-up" is 10 to 14 days of hospitalization with intense IV antibiotic treatment, numerous breathing treatments and chest physiotherapy each day, nutrition support and rest. My next "tune-up" wasn't until college. Then in 1996, I started needing a "tune-up" every 3 months. This continued for over 20 years. In 2012, a new drug, Orkambi, became available that fixed my cystic fibrosis on a cellular level. My hospitalizations dropped to once every other year or so. As the years have passed, there have been newer drugs that work even better. The current iteration, which I am taking is called Trikafta. For me, it is simply a miracle. My last "tune-up" was in March 2019. In September 2022, all of my nebulized medications were removed from my active medications list. I am able to maintain normal lung function without breathing treatments!

As with all new medications, Orkambi was very expensive, $20,000 per month. However, I have good insurance and the pharmaceutical company, Vertex, has a copay assistance program that covered the initial copay, which for me was $5,000. Now Trikafta is $28,000 per month. Vertex still covers the copay, but my insurance has changed and copay assistance programs do not count toward my deductible. In order to fill my medication the first month of the insurance year, I have to come up with $5,000 to get my medication. I'm lucky in that an organization called "Health Well" gives me a grant to cover my copay. Sooner or later, health insurance companies will find a way to work around that as well.

Listening to testimony in January, I heard discussion that I'd pay the $5,000 deductible throughout the insurance year without the assistance to cover my copay. I agree, I would pay that amount. However, payment plans can be setup with providers apart from pharmacies. In order to get my medication, $5,000 must be paid. Period.

I also heard that the copay assistance rewards my choice of their drug. Let me be the first to tell you, if a lollipop a day had the same results for me as Trikafta, I'd order a lot of lollipops! I will take the drug that works. My alternative here is to go back to constant coughing, quarterly 2 week hospitalizations, and a grueling schedule of breathing treatments with 3 to 4 different nebulized medications multiple times a day. Most importantly, I'd have to be on disability again.

We pay for insurance so it will cover the expensive things like hospitalizations, ER visits and medications.

Thank you for allowing me to tell my story.

Respectfully submitted,

Karen M. Cossette, Bismarck, ND

Karen Cossette

HB1216

Service date	Provider or facility name	Prescription name	Rx cost	Plan paid	Your share/ Your Cost
12/28/2024	CVS SPECIALTY 02921	TRIKAFTA TAB -	$ 28,669.68	$ 28,669.68	$ -
11/26/2024	CVS SPECIALTY 02921	TRIKAFTA TAB -	$ 28,669.68	$ 28,669.68	$ -
11/01/2024	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 26,918.65	$ 26,918.65	$ -
10/04/2024	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 25,834.73	$ 25,834.73	$ -
09/06/2024	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 25,834.73	$ 25,834.73	$ -
08/13/2024	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 25,834.73	$ 25,834.73	$ -
07/09/2024	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 25,834.73	$ 25,834.73	$ -
06/10/2024	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 25,834.72	$ 19,932.68	$ 5,902.04
05/13/2024	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 25,834.73	$ 25,834.73	$ -
04/18/2024	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 25,834.73	$ 25,834.73	$ -
03/14/2024	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 25,834.73	$ 25,834.73	$ -
02/15/2024	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 25,834.73	$ 25,834.73	$ -
01/17/2024	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 25,834.73	$ 25,834.73	$ -
12/22/2023	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 24,395.40	$ 24,395.40	$ -
11/24/2023	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 24,395.40	$ 24,395.40	$ -
10/25/2023	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 24,395.40	$ 24,395.40	$ -
09/27/2023	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 24,395.40	$ 24,395.40	$ -
09/05/2023	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 24,395.40	$ 24,395.40	$ -
07/31/2023	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 24,395.40	$ 24,395.40	$ -
07/06/2023	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 24,395.40	$ 24,395.40	$ -
06/06/2023	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 24,395.39	$ 18,407.20	$ 5,988.19
05/05/2023	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 24,395.40	$ 24,395.40	$ -
04/06/2023	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 24,395.40	$ 24,395.40	$ -
03/09/2023	SANFORD PHARMACY BI	TRIKAFTA TAB -	$ 25,343.24	$ 25,343.24	$ -

2025 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

HB 1216
3/18/2025

Relating to out-of-pocket expenses for prescription drugs, relating to self-insurance health care plans.

3:30 p.m. Chairman Lee opened the hearing.

Members Present: Chairman Lee, Vice-Chairman Weston, Senator Van Oosting, Senator Clemens, Senator Hogan, Senator Roers.

Discussion Topics:

- Removal of Cost-Based Analysis
- Grandfather and non-grandfather clauses
- Policies in Other States
- Generic Medication
- Cost Benefit analysis

3:30 p.m. Rebecca Fricke, Executive Director of North Dakota Public Employee Retirement System, answered committee questions.

3:41 p.m. Dylan Wheeler, Government Affairs for Sanford Health Plan, answered committee questions.

3:54 p.m. Chairman Lee recessed the hearing.

4:46 p.m. Charman Lee reconvened the hearing.

4:47 p.m. Representative Karen Karls testified in favor.

4:51 p.m. Chairman Lee closed the hearing.

Andrew Ficek, Committee Clerk

2025 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

HB 1216
3/19/2025

Relating to out-of-pocket expenses for prescription drugs; relating to self-insurance health care plans.

3:32 p.m. Chairman Lee opened the hearing.

Members Present: Chairman Lee, Vice-Chairman Weston, Senator Van Oosting, Senator Clemens, Senator Hogan, Senator Roers.

Discussion Topics:

- Copay Coupons
- Anti-Kickback Statute
- Enrollment Date
- Health Benefit Plan Renewal

3:34 p.m. Megan Ruby, Blue Cross Blue Shield of North Dakota, answered committee questions.

3:41 p.m. Ben Hanson, American Cancer Society Cancer Action Network, answered committee questions.

3:50 p.m. Chrystal Bartuska, ND Insurance Department, answered committee questions.

3:54 p.m. Senator Roers moved Amendment LC#25.0068.01004.

3:54 p.m. Senator Hogan seconded the motion.

Senators	Vote
Senator Judy Lee	Y
Senator Kent Weston	Y
Senator David A. Clemens	Y
Senator Kathy Hogan	Y
Senator Kristin Roers	Y
Senator Desiree Van Oosting	AB

Motion Passed 5-0-1.

3:55 p.m. Senator Hogan moved Do Pass as amended and rerefer to Appropriations.

Motion failed for lack of a second.

3:56 p.m. Senator Weston moved Do Not Pass as amended.

3:56 p.m. Senator Roers seconded the motion.

Senators	Vote
Senator Judy Lee	Y
Senator Kent Weston	Y
Senator David A. Clemens	Y
Senator Kathy Hogan	N
Senator Kristin Roers	Y
Senator Desiree Van Oosting	AB

Motion passed 4-1-1.

Senator Roers will carry the bill.

3:59 p.m. Chairman Lee closed the hearing.

Andrew Ficek, Committee Clerk

CO
3/19/25
1053

25.0068.01004
Title.03000

Adopted by the Senate Human Services Committee
March 19, 2025

Sixty-ninth
Legislative Assembly
of North Dakota

PROPOSED AMENDMENTS TO

HOUSE BILL NO. 1216

Introduced by

Representatives Karls, Hagert, Kiefert, Wagner

Senators Boschee, Dever, Sorvaag

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; ~~and~~ to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans; and to provide for application.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 26.1-36 of the North Dakota Century Code is created and enacted as follows:

Out-of-pocket expenses - Prescription drugs.

1. As used in this section:
   a. "Cost-sharing" means any coinsurance, copayment, or deductible under a health benefit plan.
   b. "Enrollee" means an individual entitled to prescription drug coverage under a health benefit plan.
   c. "Health benefit plan" has the same meaning as provided under section 26.1-36.3-01.
   d. "Prescription drug" means a drug for which a prescription is required:
      (1) Without a generic equivalent; or
      (2) With a generic equivalent and the enrollee has obtained access to the drug through prior authorization, a step therapy protocol, or the heath care insurer's expectations and appeals process.

2. To the extent permitted by federal law and regulation, an insurer may not deliver, issue, execute, or renew a health benefit plan providing prescription drug coverage unless when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement for a prescription drug under the health benefit plan, the health benefit plan provides for the inclusion of any amount paid by the enrollee or paid on behalf of the enrollee by another person. The health benefit plan may not vary the out-of-pocket maximum or cost-sharing requirement, or otherwise design benefits in a manner that takes into account the availability of a cost-sharing assistance program for a prescription drug.

3. If application of this section would result in ineligibility of a health benefit plan that is a qualified high-deductible health plan to qualify as a health savings account under section 223 of the Internal Revenue Code [26 U.S.C. 223], the requirements of this section do not apply with respect to the deductible of the health benefit plan until after the enrollee has satisfied the minimum deductible under section 26 U.S.C. 223.

SECTION 2. AMENDMENT. Section 26.1-36.6-03 of the North Dakota Century Code is amended and reenacted as follows:

26.1-36.6-03. Self-insurance health plans - Requirements. (Effective through July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.
2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22,

26.1-36-23.1, and 26.1-36-43. Section 54-52.1-04.18 applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

Self-insurance health plans - Requirements. (Effective after July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.
2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22, 26.1-36-23.1, and 26.1-36-43. Section 1 of this Act applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

SECTION 3. APPLICATION. This Act applies to health benefit plans that are delivered, issued, executed, or renewed after the effective date of this Act.

REPORT OF STANDING COMMITTEE
HB 1216

Human Services Committee (Sen. Lee, Chairman) recommends **AMENDMENTS (25.0068.01004)** and when so amended, recommends **DO NOT PASS** (4 YEAS, 1 NAY, 1 ABSENT OR EXCUSED AND NOT VOTING). HB 1216 was placed on the Sixth order on the calendar. This bill does not affect workforce development.

2025 SENATE APPROPRIATIONS

HB 1216

2025 SENATE STANDING COMMITTEE MINUTES

Appropriations - Human Resources Division
Harvest Room, State Capitol

HB 1216
3/31/2025

Relating to the out of pocket expenses for prescription drugs; to amend and reenact section 26.1 36.6 03 of the North Dakota Century Code, relating to self insurance health care plans; and to provide for application.

11:10 a.m. Chairman Dever opened the hearing.

Members present: Chairman Dever and Senators Cleary, Davison, Magrum and Mathern.

Discussion Topics:

- Fiscal Note
- Medication with No Generic Brand
- Copay Accumulators
- Public Employee Retirement System (PERS)
- Maximum Out of Pocket

11:11 a.m. Karen Karls, House Representative, District 35, testified in favor.

11:14 a.m. Rebecca Fricke, Executive Director, ND Public Employees Retirement System (ND PERS), testified neutral.

11:31 a.m. Senator Clearly moved Do Pass.

11:31 a.m. Senator Davison seconded the motion.

Senators	Vote
Senator Dick Dever	Y
Senator Sean Cleary	Y
Senator Kyle Davison	Y
Senator Jeffrey J. Magrum	N
Senator Tim Mathern	Y

Motion passed 4-1-0

Senator Dever will carry the bill.

11:35 a.m. Chairman Dever closed the hearing.

Joan Bares, Committee Clerk

2025 SENATE STANDING COMMITTEE MINUTES

Appropriations Committee
Harvest Room, State Capitol

HB 1216
4/1/2025

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans; and to provide for application.

9:03 a.m. Chairman Bekkedahl called the meeting to order.

Members Present: Chairman Bekkedahl, Vice-Chairman Erbele, and Senators Burckhard, Cleary, Conley, Davison, Dever, Dwyer, Magrum, Mathern, Meyer, Schaible, Sickler, Sorvaag, Thomas, Wanzek.

Discussion Topics:

- Language Changes
- Effective Date

9:05 a.m. Rebecca Fricke, PERS Executive Director, testified as neutral.

9:09 a.m. Chairman Bekkedahl closed the hearing.

Elizabeth Reiten, Committee Clerk

2025 SENATE STANDING COMMITTEE MINUTES

Appropriations Committee
Harvest Room, State Capitol

HB 1216
4/3/2025

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans; and to provide for application.

8:29 a.m. Chairman Bekkedahl called the meeting to order.

Members Present: Chairman Bekkedahl, Vice-Chairman Erbele, and Senators Burckhard, Cleary, Conley, Davison, Dever, Dwyer, Magrum, Mathern, Meyer, Schaible, Sickler, Sorvaag, Thomas, Wanzek.

Discussion Topics:

- High and Low-Deductible Benefits
- PERS and Outside PERS Coverage
- Estimated Fiscal Cost
- Effective Date
- Non-Grandfathered Clause

8:30 a.m. Representative Karls testified in favor and submitted testimony #44602.

8:36 a.m. Rebecca Fricke, PERS Executive Director, testified in favor.

8:42 a.m. Senator Mathern moved amendment LC 25.0068.01005.

8:42 a.m. Senator Cleary seconded the motion.

Senators	Vote
Senator Brad Bekkedahl	Y
Senator Robert Erbele	Y
Senator Randy A. Burckhard	Y
Senator Sean Cleary	Y
Senator Cole Conley	Y
Senator Kyle Davison	Y
Senator Dick Dever	Y
Senator Michael Dwyer	Y
Senator Jeffery J. Magrum	Y
Senator Tim Mathern	Y
Senator Scott Meyer	Y
Senator Donald Schaible	Y
Senator Jonathan Sickler	Y
Senator Ronald Sorvaag	Y
Senator Paul J. Thomas	Y

Senator Terry M. Wanzek	Y

Motion Passed 16-0-0.

8:44 a.m. Chairman Bekkedahl closed the hearing.

Elizabeth Reiten, Committee Clerk

Further amended on 04/07/2025

25.0068.01005
Title.

Prepared by the Legislative Council staff for Representative Karls
April 1, 2025

Sixty-ninth
Legislative Assembly
of North Dakota

PROPOSED AMENDMENTS TO

HOUSE BILL NO. 1216

Introduced by

Representatives Karls, Hagert, Kiefert, Wagner

Senators Boschee, Dever, Sorvaag

In place of amendments (25.0068.01004) adopted by the Senate, House Bill No. 1216 is amended by amendment (25.0068.01005) as follows:

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; ~~and~~ to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans; and to provide for application.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 26.1-36 of the North Dakota Century Code is created and enacted as follows:

Out-of-pocket expenses - Prescription drugs.

1. As used in this section:
   a. "Cost-sharing" means any coinsurance, copayment, or deductible under a health benefit plan.
   b. "Enrollee" means an individual entitled to prescription drug coverage under a health benefit plan.
   c. "Health benefit plan" has the same meaning as provided under section 26.1-36.3-01.
   d. "Prescription drug" means a drug for which a prescription is required:
      (1) Without a generic equivalent; or
      (2) With a generic equivalent and the enrollee has obtained access to the drug through prior authorization, a step therapy protocol, or the heath care insurer's expectations and appeals process.

2. To the extent permitted by federal law and regulation, an insurer may not deliver, issue, execute, or renew a health benefit plan providing prescription drug coverage unless when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement for a prescription drug under the health benefit plan, the health benefit plan provides for the inclusion of any amount paid by the enrollee or paid on behalf of the enrollee by another person. The health benefit plan may not vary the out-of-pocket maximum or cost-sharing requirement, or otherwise design benefits in a manner that takes into account the availability of a cost-sharing assistance program for a prescription drug.

3. If application of this section would result in ineligibility of a health benefit plan that is a qualified high-deductible health plan to qualify as a health savings account under section 223 of the Internal Revenue Code [26 U.S.C. 223], the requirements of this section do not apply with respect to the deductible of the health benefit plan until after the enrollee has satisfied the minimum deductible under section 26 U.S.C. 223.

SECTION 2. AMENDMENT. Section 26.1-36.6-03 of the North Dakota Century Code is amended and reenacted as follows:

26.1-36.6-03. Self-insurance health plans - Requirements. (Effective through July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.
2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22,

26.1-36-23.1, and 26.1-36-43. Section 54-52.1-04.18 applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

Self-insurance health plans - Requirements. (Effective after July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.
2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22, 26.1-36-23.1, and 26.1-36-43. Section 1 of this Act applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

SECTION 3. APPLICATION. Except as provided in section 4 of this Act, this Act applies to health benefit plans that are delivered, issued, executed, or renewed on or after the effective date of this Act.

SECTION 4. APPLICATION. This Act applies to the public employees retirement system uniform group insurance program health insurance benefits coverage effective January 1, 2026, regardless of the health insurance benefits coverage contract issuance or renewal date.

2025 SENATE STANDING COMMITTEE MINUTES

Appropriations Committee
Harvest Room, State Capitol

HB 1216
4/7/2025

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans; and to provide for application.

8:31 a.m. Chairman Bekkedahl called the meeting to order.

Members Present: Chairman Bekkedahl, Vice-Chairman Erbele, and Senators Burckhard, Cleary, Conley, Davison, Dever, Dwyer, Magrum, Mathern, Meyer, Sickler, Sorvaag, Thomas, Wanzek.
Members Absent: Senator Schaible.

Discussion Topics:

- Impact on Commercial Market Data
- Effective Date

8:32 a.m. Representative Karls, District 35, testified in favor and submitted testimony #44708.

8:34 a.m. Senator Mathern moved amendment LC 25.0068.01007.

8:34 a.m. Senator Cleary seconded the motion.

Senators	Vote
Senator Brad Bekkedahl	Y
Senator Robert Erbele	Y
Senator Randy A. Burckhard	Y
Senator Sean Cleary	Y
Senator Cole Conley	Y
Senator Kyle Davison	Y
Senator Dick Dever	Y
Senator Michael Dwyer	Y
Senator Jeffery J. Magrum	Y
Senator Tim Mathern	Y
Senator Scott Meyer	A
Senator Donald Schaible	A
Senator Jonathan Sickler	Y
Senator Ronald Sorvaag	Y
Senator Paul J. Thomas	Y
Senator Terry M. Wanzek	Y

Motion Passed 14-0-2.

8:38 a.m. Senator Mathern moved a Do Pass as Amended.

8:39 a.m. Senator Dever seconded the motion.

Senators	Vote
Senator Brad Bekkedahl	N
Senator Robert Erbele	Y
Senator Randy A. Burckhard	Y
Senator Sean Cleary	Y
Senator Cole Conley	Y
Senator Kyle Davison	Y
Senator Dick Dever	Y
Senator Michael Dwyer	Y
Senator Jeffery J. Magrum	N
Senator Tim Mathern	Y
Senator Scott Meyer	A
Senator Donald Schaible	A
Senator Jonathan Sickler	Y
Senator Ronald Sorvaag	Y
Senator Paul J. Thomas	N
Senator Terry M. Wanzek	Y

Motion Passed 11-3-2.

Senator Sorvaag will carry the bill.

Additional Written Testimony:

Rebecca Fricke, ND PERS Executive Director, submitted testimony in favor #44688 and #44689.

8:40 a.m. Chairman Bekkedahl closed the hearing.

Elizabeth Reiten, Committee Clerk

Prepared by the Legislative Council
staff for Representative Karls
April 4, 2025

Sixty-ninth
Legislative Assembly
of North Dakota

PROPOSED AMENDMENTS TO

VC 4/7/25
1 of 3

HOUSE BILL NO. 1216

Introduced by

Representatives Karls, Hagert, Kiefert, Wagner

Senators Boschee, Dever, Sorvaag

In place of amendments (25.0068.01004) adopted by the Senate, House Bill No. 1216 is amended by amendment (25.0068.01007) as follows:

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; ~~and~~ to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans; to provide for application; and to provide an effective date.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 26.1-36 of the North Dakota Century Code is created and enacted as follows:

Out-of-pocket expenses - Prescription drugs.

1. As used in this section:
   a. "Cost-sharing" means any coinsurance, copayment, or deductible under a health benefit plan.
   b. "Enrollee" means an individual entitled to prescription drug coverage under a health benefit plan.
   c. "Health benefit plan" has the same meaning as provided under section 26.1-36.3-01.
   d. "Prescription drug" means a drug for which a prescription is required:
      (1) Without a generic equivalent; or
      (2) With a generic equivalent ~~and~~, if the enrollee has obtained access to the drug through prior authorization, a step therapy protocol, or the heath care insurer's expectations and appeals process.

2. To the extent permitted by federal law and regulation, an insurer may not deliver, issue, execute, or renew a health benefit plan providing prescription drug coverage unless when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement for a prescription drug under the health benefit plan, the health benefit plan provides for the inclusion of any amount paid by the enrollee or paid on behalf of the enrollee by another person. The health benefit plan may not vary the out-of-pocket maximum or cost-sharing requirement, or otherwise design benefits ~~in a manner that takes into account~~accounting for the availability of a cost-sharing assistance program for a prescription drug.

3. If application of this section would result in ineligibility of a health benefit plan that is a qualified high-deductible health plan to qualify as a health savings account under section 223 of the Internal Revenue Code [26 U.S.C. 223], the requirements of this section do not apply with respect to the deductible of the health benefit plan until after the enrollee has satisfied the minimum deductible under section 26 U.S.C. 223.

SECTION 2. AMENDMENT. Section 26.1-36.6-03 of the North Dakota Century Code is amended and reenacted as follows:

26.1-36.6-03. Self-insurance health plans - Requirements. (Effective through July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.
2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22,

26.1-36-23.1, and 26.1-36-43. Section 54-52.1-04.18 applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

Self-insurance health plans - Requirements. (Effective after July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.
2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22, 26.1-36-23.1, and 26.1-36-43. Section 1 of this Act applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

SECTION 3. APPLICATION. This Act applies effective January 1, 2026, to the public employees retirement system uniform group insurance program health insurance benefits coverage, regardless of the health insurance benefits coverage contract issuance or renewal date. This Act applies effective January 1, 2026, or upon the next renewal after January 1, 2026, to health benefit plans.

SECTION 4. EFFECTIVE DATE. This Act becomes effective on January 1, 2026.

REPORT OF STANDING COMMITTEE
AMENDED HB 1216

Appropriations Committee (Sen. Bekkedahl, Chairman) recommends **AMENDMENTS (25.0068.01007)** and when so amended, recommends **DO PASS** (11 YEAS, 3 NAYS, 2 ABSENT OR EXCUSED AND NOT VOTING). HB 1216, as amended, was placed on the Sixth order on the calendar. This bill does not affect workforce development.

Deloitte.

Deloitte Consulting LLP
50 South Sixth Street
Suite 2800
Minneapolis, MN 55402
USA

Tel: 612 397 4000

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Memo

Date: April 3, 2025

To: Rebecca Fricke - Executive Director, North Dakota Public Employees Retirement System

Representative Austen Schauer - Chair, Legislative Employee Benefits Programs Committee, North Dakota State Government

From: Tim Egan, Dan Plante, Ford Edgerton, and Karno Sarkar - Deloitte Consulting LLP

Subject: **FINANCIAL REVIEW OF PROPOSED BILL 25.0068.01005**

Deloitte Consulting LLP (Deloitte [i]) was engaged to review the proposed legislation and the potential financial impact to the Uniform Group Insurance Program (Program) administered by the North Dakota Public Employees Retirement System (NDPERS), as well as other considerations that may contribute to the evaluation of the legislation.

The information included in the review relies on data provided by NDPERS, as well as publicly available data and industry studies. From the data provided by NDPERS, some of these data sources were developed by NDPERS, while others were prepared or created by third parties and delivered to NDPERS.

As part of the review, all data were reviewed for reasonableness, but an audit was not performed on the data. To the extent the data contain errors or anomalies that were unknown at the time the data were provided, the analysis may be affected by those issues.

OVERVIEW OF PROPOSED BILL

The current Bill creates and enacts a new section to chapter 26.1-36 of the North Dakota Century Code relating to out-of-pocket expenses for health care services.

This Bill is an amendment to a prior Bill 25.0068.01000 that was previously introduced in 2024. The amendment changes the effective date of Bill 68 to January 1, 2026. After this date, all prescription drug member cost sharing expenses must apply towards a health plan's out-of-pocket maximum.

ESTIMATED FINANCIAL IMPACT

Based on the analysis of this bill, it is anticipated the proposed amendment will have a financial impact on the Uniform Group Insurance Program. It is estimated the financial impact of the proposed legislation on the Uniform Group Insurance Program is approximately $5,313,000, or 0.62%, in the 2025 – 2027 biennium ending 6/30/2027.

The current health plans offered by the uniform group insurance program include a "grandfathered" health plan (PPO/Basic Grandfathered Plan) and two "non-grandfathered" health plans (PPO/Basic Non-Grandfathered Plan and High Deductible Health Plan (HDHP)).

In the PPO/Basic Grandfathered Plan, an enrollee's pharmacy copayment currently does not accumulate towards their out-of-pocket maximum. The proposed Bill, however, seeks to revise this aspect, requiring that copayments count towards an enrollee's out-of-pocket maximum. It is anticipated this amendment would lead more enrollees to reach their out-of-pocket maximum, thus shifting any additional claim liability to the Uniform Group Insurance Program, which can lead to higher costs.

A majority of the NDPERS membership resides in the PPO/Basic Grandfathered plan and could be impacted by this change. The non-grandfathered plans already include copayments in the out-of-pocket maximum; as a result, there would be no anticipated change or financial impact to those plans.

The financial impact estimate is based on the expected change to the percentage of prescription drug claims paid by enrollees under the current plan design that does not include copayments in the out-of-pocket maximum and the proposed design (per the proposed Bill) that would include copayments in the out-of-pocket maximum.

The development of the estimated claims impact utilized an internal Medical Rate Model, which includes medical and pharmacy benefit designs and is based on over 40 million active/non-Medicare retiree claims. The Medical Rate Model functions as a claims repayment model, applying detailed input plan provisions against the claims record database, effectively repricing the claims, and producing the expected plan claim payments versus allowed charges.

As a result of the modeling, it is estimated the plan design changes required as a result of the proposed Bill would produce a 0.62% increase to the expected total costs paid by the Uniform Group Insurance Program. This anticipated change to the expected claims costs was applied to the estimated biennium claims cost for NDPERS population enrolled in the PPO/Basic Grandfathered plan from 1/1/2026 to 6/30/2027, which were derived from the Sanford 2025 – 2027 renewal rates. Considerations were also made for seasonality of claims for the 18-month period that is impacted during the biennium, as well as the current mix of membership between grandfathered and non-grandfathered plans.

It is estimated the financial impact of the proposed legislation on the Uniform Group Insurance Program is approximately $5,313,000, or 0.62%, in the 2025-2027 biennium ending 6/30/2027.

ID	Department	2025-2027 FTE	Monthly Change	25-27 Funding Adjustments General	Other	Total
101	Office of the Governor	19.00	$11.05	$ 5,039.83	$ -	$ 5,039.83
108	Office of the Secretary of State	35.00	$11.05	$ 8,218.13	$ 1,065.77	$ 9,283.90
110	Office of Management and Budget	115.00	$11.05	$ 19,755.75	$ 10,748.49	$ 30,504.24
112	Information Technology Department	528.00	$11.05	$ 31,674.58	$ 108,379.66	$ 140,054.24
117	Office of the State Auditor	66.00	$11.05	$ 10,592.65	$ 6,914.13	$ 17,506.78
120	Office of the State Treasurer	13.00	$11.05	$ 2,469.13	$ 979.17	$ 3,448.31
125	Office of the Attorney General	272.00	$11.05	$ 46,580.90	$ 25,568.25	$ 72,149.15
127	Office of the Sate Tax Commissioner	118.00	$11.05	$ 31,300.00	$ -	$ 31,300.00
140	Office of Administrative Hearings	5.00	$11.05	$ -	$ 1,326.27	$ 1,326.27
150	Legislative Assembly	0.00	$11.05	$ -	$ -	$ -
160	Legislative Council	70.00	$11.05	$ 18,567.80	$ -	$ 18,567.80
180	Judicial Branch	406.00	$11.05	$ 106,937.38	$ 755.85	$ 107,693.22
188	Legal Counsel of Indigents	43.00	$11.05	$ 11,107.55	$ 298.39	$ 11,405.93
190	Retirement and Investment Office	35.00	$11.05	$ -	$ 9,283.90	$ 9,283.90
192	Public Employees Retirement System	40.50	$11.05	$ -	$ 10,742.80	$ 10,742.80
195	Ethics Commission	3.00	$11.05	$ 795.76	$ -	$ 795.76
201	Department of Public Instruction	86.25	$11.05	$ 8,533.64	$ 14,344.54	$ 22,878.18
204	Center for Distance Education	33.00	$11.05	$ 8,472.50	$ 280.89	$ 8,753.39
215	ND University System	168.83	$11.05	$ 32,967.80	$ 11,815.07	$ 44,782.87
226	Department of Trust Lands	30.00	$11.05	$ -	$ 7,957.63	$ 7,957.63
227	Bismarck State College	338.25	$11.05	$ 29,608.34	$ 60,113.91	$ 89,722.25
228	Lake Region State College	115.15	$11.05	$ 13,286.65	$ 17,257.37	$ 30,544.03
229	Willliston State College	99.74	$11.05	$ 11,111.71	$ 15,344.75	$ 26,456.46
230	University of North Dakota	2191.95	$11.05	$ 116,284.81	$ 465,139.23	$ 581,424.03
232	UND Medical Center	529.06	$11.05	$ 58,940.87	$ 81,394.54	$ 140,335.41
235	North Dakota State University	1805.96	$11.05	$ 91,017.32	$ 388,021.22	$ 479,038.55
238	ND State College of Science	326.54	$11.05	$ 35,512.61	$ 51,103.51	$ 86,616.12
239	Dickinson State University	170.80	$11.05	$ 19,481.33	$ 25,824.09	$ 45,305.42
240	Mayville State University	226.92	$11.05	$ 14,445.96	$ 45,745.53	$ 60,191.49
241	Minot State University	421.16	$11.05	$ 44,685.79	$ 67,028.69	$ 111,714.48
242	Valley City State University	217.44	$11.05	$ 29,415.21	$ 28,261.67	$ 57,676.88
243	Dakota College Bottineau	87.85	$11.05	$ 11,884.32	$ 11,418.27	$ 23,302.58
244	ND Forest Service	34.00	$11.05	$ 7,347.08	$ 1,671.57	$ 9,018.64
250	State Library	26.75	$11.05	$ 6,136.87	$ 958.68	$ 7,095.55
252	School for the Deaf	46.86	$11.05	$ 11,472.45	$ 957.36	$ 12,429.81
253	N.D. Vision Services	27.75	$11.05	$ 7,131.92	$ 228.89	$ 7,360.81
270	Dept of Career and Technical Ed	23.50	$11.05	$ 5,806.12	$ 427.36	$ 6,233.47
303	Department of Environmental Quality	174.00	$11.05	$ 14,803.06	$ 31,351.17	$ 46,154.24
313	Veterans Home	114.79	$11.05	$ 8,001.42	$ 22,447.11	$ 30,448.53
316	Indian Affairs Commission	4.00	$11.05	$ 1,061.02	$ -	$ 1,061.02
321	Department of Veterans Affairs	9.00	$11.05	$ 2,050.43	$ 336.86	$ 2,387.29
325	Department of Human Services	2762.35	$11.05	$ 519,575.41	$ 213,149.64	$ 732,725.05
360	Protection and Advocacy Project	29.50	$11.05	$ 7,825.00	$ -	$ 7,825.00
380	Job Service North Dakota	158.61	$11.05	$ 4,485.01	$ 37,586.97	$ 42,071.98
401	Office of the Insurance Commissioner	49.00	$11.05	$ -	$ 12,997.46	$ 12,997.46
405	Industrial Commission	9.75	$11.05	$ -	$ 2,586.23	$ 2,586.23
406	Office of the Labor Commissioner	13.00	$11.05	$ 3,068.15	$ 380.16	$ 3,448.31
408	Public Service Commission	45.00	$11.05	$ 7,104.27	$ 4,832.17	$ 11,936.44
412	Aeronautics Commission	7.00	$11.05	$ -	$ 1,856.78	$ 1,856.78
413	Department of Financial Institutions	38.00	$11.05	$ -	$ 10,079.66	$ 10,079.66
414	Office of the Securities Commissioner	12.00	$11.05	$ -	$ 3,183.05	$ 3,183.05
471	Bank of North Dakota	189.00	$11.05	$ -	$ 50,133.05	$ 50,133.05
473	North Dakota Housing Finance Agency	56.00	$11.05	$ -	$ 14,854.24	$ 14,854.24
474	Mineral Resources	110.00	$11.05	$ 29,177.97	$ -	$ 29,177.97
475	North Dakota Mill & Elevator Association	172.00	$11.05	$ -	$ 45,623.73	$ 45,623.73
485	Workforce Safety & Insurance	260.14	$11.05	$ -	$ 69,003.24	$ 69,003.24
504	Highway Patrol	205.00	$11.05	$ 39,830.89	$ 14,546.23	$ 54,377.12
530	Department of Corrections and Rehabilitation	971.79	$11.05	$ 247,281.03	$ 10,490.39	$ 257,771.42
540	Adjutant General	240.00	$11.05	$ 20,807.48	$ 42,853.54	$ 63,661.02
601	Department of Commerce	64.80	$11.05	$ 13,609.78	$ 3,578.70	$ 17,188.47
602	Department of Agriculture	81.00	$11.05	$ 12,418.03	$ 9,067.56	$ 21,485.59
627	Upper Great Plains Transportation Institute	43.88	$11.05	$ 3,389.07	$ 8,250.29	$ 11,639.36
628	Branch Research Centers	107.16	$11.05	$ 21,279.00	$ 7,145.65	$ 28,424.64
630	NDSU Extension Service	256.44	$11.05	$ 35,203.65	$ 32,818.15	$ 68,021.80
638	Northern Crops Institute	18.35	$11.05	$ 2,059.85	$ 2,807.57	$ 4,867.42
640	NDSU Main Research Center	370.53	$11.05	$ 61,120.20	$ 37,164.45	$ 98,284.65
649	Agronomy Seed Farm	3.00	$11.05	$ -	$ 795.76	$ 795.76
670	Racing Commission	2.00	$11.05	$ 504.05	$ 26.45	$ 530.51
701	State Historical Society	85.50	$11.05	$ 20,366.32	$ 2,312.92	$ 22,679.24
709	Council on the Arts	7.00	$11.05	$ 1,856.78	$ -	$ 1,856.78
720	Game & Fish Department	170.00	$11.05	$ -	$ 45,093.22	$ 45,093.22
750	Department of Parks & Recreation	76.00	$11.05	$ 18,419.80	$ 1,739.52	$ 20,159.32
770	State Water Commission	102.00	$11.05	$ -	$ 27,055.93	$ 27,055.93
801	Department Of Transportation	1013.00	$11.05	$ -	$ 268,702.55	$ 268,702.55
	State Total	**16806.85**	$11.05	**$ 1,951,880.39**	**$ 2,506,207.83**	**$ 4,458,088.22**

25.0068.01007
Title.

Prepared by the Legislative Council staff for Representative Karls
April 4, 2025

Sixty-ninth
Legislative Assembly
of North Dakota

PROPOSED AMENDMENTS TO

HOUSE BILL NO. 1216

Introduced by

Representatives Karls, Hagert, Kiefert, Wagner

Senators Boschee, Dever, Sorvaag

In place of amendments (25.0068.01004) adopted by the Senate, House Bill No. 1216 is amended by amendment (25.0068.01007) as follows:

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; ~~and~~ to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans; to provide for application; and to provide an effective date.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 26.1-36 of the North Dakota Century Code is created and enacted as follows:

Out-of-pocket expenses - Prescription drugs.

1. As used in this section:
   a. "Cost-sharing" means any coinsurance, copayment, or deductible under a health benefit plan.
   b. "Enrollee" means an individual entitled to prescription drug coverage under a health benefit plan.
   c. "Health benefit plan" has the same meaning as provided under section 26.1-36.3-01.
   d. "Prescription drug" means a drug for which a prescription is required:
      (1) Without a generic equivalent; or
      (2) With a generic equivalent and the enrollee has obtained access to the drug through prior authorization, a step therapy protocol, or the heath care insurer's expectations and appeals process.

2. To the extent permitted by federal law and regulation, an insurer may not deliver, issue, execute, or renew a health benefit plan providing prescription drug coverage unless when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement for a prescription drug under the health benefit plan, the health benefit plan provides for the inclusion of any amount paid by the enrollee or paid on behalf of the enrollee by another person. The health benefit plan may not vary the out-of-pocket maximum or cost-sharing requirement, or otherwise design benefits in a manner that takes into account the availability of a cost-sharing assistance program for a prescription drug.

3. If application of this section would result in ineligibility of a health benefit plan that is a qualified high-deductible health plan to qualify as a health savings account under section 223 of the Internal Revenue Code [26 U.S.C. 223], the requirements of this section do not apply with respect to the deductible of the health benefit plan until after the enrollee has satisfied the minimum deductible under section 26 U.S.C. 223.

SECTION 2. AMENDMENT. Section 26.1-36.6-03 of the North Dakota Century Code is amended and reenacted as follows:

26.1-36.6-03. Self-insurance health plans - Requirements. (Effective through July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.
2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22,

26.1-36-23.1, and 26.1-36-43. Section 54-52.1-04.18 applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

Self-insurance health plans - Requirements. (Effective after July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.
2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22, 26.1-36-23.1, and 26.1-36-43. Section 1 of this Act applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

SECTION 3. APPLICATION. This Act applies effective January 1, 2026, to the public employees retirement system uniform group insurance program health insurance benefits coverage, regardless of the health insurance benefits coverage contract issuance or renewal date. This Act applies effective January 1, 2026, or upon the next renewal after January 1, 2026, to health benefit plans.

SECTION 4. EFFECTIVE DATE. This Act becomes effective on January 1, 2026.

2025 SENATE STANDING COMMITTEE MINUTES

Appropriations Committee
Harvest Room, State Capitol

HB 1216
4/17/2025

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs; to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans; and to provide for application.

3:19 p.m. Chairman Bekkedahl called the meeting to order.

Members Present: Chairman Bekkedahl, Vice-Chairman Erbele, and Senators Burckhard, Cleary, Conley, Davison, Dever, Dwyer, Magrum, Mathern, Meyer, Schaible, Sickler, Sorvaag, Thomas, Wanzek.

Discussion Topics:

- Restrictiveness of Policy
- Rare and Life-Threatening Disease Definition
- Fiscal Note Impact
- Pilot Project
- Specific Drugs Included
- Prescription Costs

3:20 p.m. Senator Davison moved to reconsider their actions.

3:20 p.m. Senator Dever seconded the motion.

Senators	Vote
Senator Brad Bekkedahl	Y
Senator Robert Erbele	Y
Senator Randy A. Burckhard	Y
Senator Sean Cleary	Y
Senator Cole Conley	Y
Senator Kyle Davison	Y
Senator Dick Dever	Y
Senator Michael Dwyer	Y
Senator Jeffery J. Magrum	Y
Senator Tim Mathern	N
Senator Scott Meyer	Y
Senator Donald Schaible	Y
Senator Jonathan Sickler	Y
Senator Ronald Sorvaag	N
Senator Paul J. Thomas	Y
Senator Terry M. Wanzek	Y

Motion Passed 14-2-0.

3:21 p.m. Chairman Bekkedahl opened discussion.

3:22 p.m. Rebecca Fricke, ND PERS Executive Director, testified as neutral.

3:28 p.m. Chairman Bekkedahl introduced amendment 25.0068.01009 and submitted testimony #45071.

3:34 p.m. Senator Davison moved amendment LC 25.0068.01009.

3:35 p.m. Senator Thomas seconded the motion.

Senators	Vote
Senator Brad Bekkedahl	Y
Senator Robert Erbele	N
Senator Randy A. Burckhard	N
Senator Sean Cleary	N
Senator Cole Conley	N
Senator Kyle Davison	Y
Senator Dick Dever	N
Senator Michael Dwyer	Y
Senator Jeffery J. Magrum	Y
Senator Tim Mathern	N
Senator Scott Meyer	N
Senator Donald Schaible	N
Senator Jonathan Sickler	Y
Senator Ronald Sorvaag	N
Senator Paul J. Thomas	Y
Senator Terry M. Wanzek	Y

Motion Failed 7-9-0.

3:35 p.m. Alex Kelsch, America's Health Insurance Plans Lobbyist, testified in opposition.

3:51 p.m. Senator Cleary moved a Do Pass.

3:51 p.m. Senator Dever seconded the motion.

Senators	Vote
Senator Brad Bekkedahl	N
Senator Robert Erbele	N
Senator Randy A. Burckhard	N
Senator Sean Cleary	Y
Senator Cole Conley	Y
Senator Kyle Davison	N
Senator Dick Dever	Y
Senator Michael Dwyer	N
Senator Jeffery J. Magrum	N
Senator Tim Mathern	Y

Senator Scott Meyer	N
Senator Donald Schaible	Y
Senator Jonathan Sickler	N
Senator Ronald Sorvaag	Y
Senator Paul J. Thomas	N
Senator Terry M. Wanzek	Y

Motion Failed 7-9-0.

3:52 p.m. Senator Davison moved a Do Not Pass.

3:52 p.m. Senator Magrum seconded the motion.

Senators	Vote
Senator Brad Bekkedahl	Y
Senator Robert Erbele	Y
Senator Randy A. Burckhard	Y
Senator Sean Cleary	N
Senator Cole Conley	N
Senator Kyle Davison	Y
Senator Dick Dever	N
Senator Michael Dwyer	Y
Senator Jeffery J. Magrum	Y
Senator Tim Mathern	N
Senator Scott Meyer	Y
Senator Donald Schaible	N
Senator Jonathan Sickler	Y
Senator Ronald Sorvaag	N
Senator Paul J. Thomas	Y
Senator Terry M. Wanzek	Y

Motion Passed 10-6-0.

Senator Roers will carry the bill.

3:54 p.m. Chairman Bekkedahl closed the hearing.

Elizabeth Reiten, Committee Clerk

REPORT OF STANDING COMMITTEE
AMENDED HB 1216 (25.0068.04000)

Appropriations Committee (Sen. Bekkedahl, Chairman) recommends **DO NOT PASS** (10 YEAS, 6 NAYS, 0 ABSENT OR EXCUSED AND NOT VOTING). HB 1216, as amended, was placed on the Fourteenth order on the calendar. This bill does not affect workforce development.

25.0068.01009
Title.

Prepared by the Legislative Council
staff for Senator Bekkedahl
April 16, 2025

Sixty-ninth
Legislative Assembly
of North Dakota

PROPOSED AMENDMENTS TO

HOUSE BILL NO. 1216

Introduced by

Representatives Karls, Hagert, Kiefert, Wagner

Senators Boschee, Dever, Sorvaag

In place of amendment (25.0068.01007) proposed in the journal by the Senate, House Bill No. 1216 is amended by amendment (25.0068.01009) as follows:

A BILL for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to out-of-pocket expenses for prescription drugs prescribed to treat rare and life-threatening diseases; ~~and~~ to amend and reenact section 26.1-36.6-03 of the North Dakota Century Code, relating to self-insurance health care plans; to provide a statement of legislative intent; to provide for application; and to provide an effective date.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 26.1-36 of the North Dakota Century Code is created and enacted as follows:

Out-of-pocket expenses - Prescription drugs prescribed to treat rare and life-threatening diseases.

1. As used in this section:
   a. "Cost-sharing" means any coinsurance, copayment, or deductible under a health benefit plan.
   b. "Enrollee" means an individual entitled to prescription drug coverage under a health benefit plan.
   c. "Health benefit plan" has the same meaning as provided under section 26.1-36.3-01.
   d. "Prescription drug" means a drug for which a prescription is required:
      (1) Without a generic equivalent; or

(2) With a generic equivalent and the enrollee has obtained access to the drug through prior authorization, a step therapy protocol, or the heath care insurer's expectations and appeals process.

2. To the extent permitted by federal law and regulation, an insurer may not deliver, issue, execute, or renew a health benefit plan providing prescription drug coverage unless when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement for a prescription drug prescribed to treat a rare and life-threatening disease under the health benefit plan, the health benefit plan provides for the inclusion of any amount paid by the enrollee or paid on behalf of the enrollee by another person. The health benefit plan may not vary the out-of-pocket maximum or cost-sharing requirement, or otherwise design benefits in a manner that takes into account the availability of a cost-sharing assistance program for a prescription drug prescribed to treat a rare and life-threatening disease.

3. The enrollee's physician shall:

a. Determine whether a prescription drug is prescribed to treat a rare and life-threatening disease.

b. Provide the enrollee with a medical certification verifying the determination.

4. If application of this section would result in ineligibility of a health benefit plan that is a qualified high-deductible health plan to qualify as a health savings account under section 223 of the Internal Revenue Code [26 U.S.C. 223], the requirements of this section do not apply with respect to the deductible of the health benefit plan until after the enrollee has satisfied the minimum deductible under section 26 U.S.C. 223.

SECTION 2. AMENDMENT. Section 26.1-36.6-03 of the North Dakota Century Code is amended and reenacted as follows:

26.1-36.6-03. Self-insurance health plans - Requirements. (Effective through July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14,

26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.

2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22, 26.1-36-23.1, and 26.1-36-43. Section 54-52.1-04.18 applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

Self-insurance health plans - Requirements. (Effective after July 31, 2025)

1. The following policy provisions apply to a self-insurance health plan or to the administrative services only or third-party administrator, and are subject to the jurisdiction of the commissioner: sections 26.1-36-03, 26.1-36-03.1, 26.1-36-05, 26.1-36-10, 26.1-36-12, 26.1-36-12.4, 26.1-36-12.6, 26.1-36-13, 26.1-36-14, 26.1-36-17, 26.1-36-18, 26.1-36-19, 26.1-36-23, 26.1-36-29, 26.1-36-37.1, 26.1-36-38, 26.1-36-39, 26.1-36-41, 26.1-36-44, and 26.1-36-46.
2. The following health benefit provisions applicable to a group accident and health insurance policy under chapter 26.1-36 apply to a self-insurance health plan and are subject to the jurisdiction of the commissioner: sections 26.1-36-06, 26.1-36-06.1, 26.1-36-07, 26.1-36-08, 26.1-36-08.1, 26.1-36-09, 26.1-36-09.1, 26.1-36-09.2, 26.1-36-09.3, 26.1-36-09.5, 26.1-36-09.6, 26.1-36-09.7, 26.1-36-09.8, 26.1-36-09.9, 26.1-36-09.10, 26.1-36-09.11, 26.1-36-09.12, 26.1-36-09.13, 26.1-36-09.14, 26.1-36-09.15, 26.1-36-11, 26.1-36-12.2, 26.1-36-20, 26.1-36-21, 26.1-36-22, 26.1-36-23.1, and 26.1-36-43. Section 1 of this Act applies to a self-insurance health plan and is subject to the jurisdiction of the commissioner.

SECTION 3. LEGISLATIVE INTENT. It is the intent of the sixty-ninth legislative assembly that the public employees retirement system use an amount necessary from the health insurance reserve fund established in section 54-52.1-06 for the payment of any expenditures related to this Act for the period beginning January 1, 2026, and ending June 30, 2027.

SECTION 4. APPLICATION. This Act applies effective January 1, 2026, to the public employees retirement system uniform group insurance program health insurance benefits coverage, regardless of the health insurance benefits coverage contract issuance or renewal date. This Act applies effective January 1, 2026, or upon the next renewal after January 1, 2026, to health benefit plans.

SECTION 5. EFFECTIVE DATE. This Act becomes effective on January 1, 2026.