2023 SENATE HUMAN SERVICES

SB 2378

2023 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

SB 2378
2/8/2023

Relating to clinician-administered drugs.

9:02 AM **Madam Chair Lee** called the hearing to order. **Senators Lee, Cleary, Clemens, K. Roers, Weston, Hogan** were present**.**

Discussion Topics:
- Product integrity
- Delays patient care
- White bagging model
- Brown bagging model

9:03 AM **Senator Meyer** introduced SB 2378 testimony in favor

9:05 AM **Mike Schwab, Executive Vice President, North Dakota Pharmacists Association,** testified in favor. #19759

9:16 AM **Mark Hardy, Executive Director, North Dakota Board of Pharmacy,** testified in favor. #19638

9:25 AM **Tim Blasil, President, ND Hospital Association** introduced Erick Christenson.

9:25 AM **Erik Christenson, Chief Executive Officer, Heart of America Medical Center,** testified in favor. #19636

9:40 AM **Maari Loy, Pharmacy Operations, Senior Manager, Essentia Health,** testified online in favor. #19707

9:48 AM **Alex Sommer, Prime Therapeutics,** testified in opposition. #20311

9:52 AM **Michelle Mack, Senior Director, State Affairs for the Pharmaceutical Care Management Association** testified in opposition. #19718, #19719

9:58 AM **Karlee Tebbutt, Regional Director, State Affairs, AHIP, Guiding Greater Health,** testified in opposition. #19754

10:05 AM **Chrystal Bartuska, Life Health and Medicare Division Director, North Dakota Insurance Department,** verbally testified neutrally.

Additional written testimony:
Brian Henderson, Coalition of State Rheumatology Organizations in favor #19680
Courtney Koebele, Executive Director, North Dakota Medical Association in favor #19670
Kindyl Boyer, Advocacy Director, National Infusion Center Association in favor #19682
Caroly Bodell, Registered Pharmacist in favor #19756
Andrew Askew, Vice President, Public Policy in favor #20362
Margaret Reynolds, Senior Director Government Affairs in opposition #19617
Travis Butchello, Director State Government Affair, Healthcare Distribution Alliance in opposition #19727

10:11 AM **Senator Cleary** closed the hearing.

Patricia Lahr, Committee Clerk

2023 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

SB 2378
2/15/2023

Relating to clinician-administered drugs.

10:34 AM **Madam Chair Lee** called the meeting to order. **Senators Lee, Cleary, Clemens, K. Roers, Weston, Hogan** were present**.**

Discussion Topics:
- Consumer choice piece
- Hospital side
- Provider side

10:34 AM **Mike Schwab**, **Executive Vice President, ND Pharmacist Association** verbally provided information.

10:36 AM **Chrystal Bartuska**, **Life & Health and Medicare Division Director, North Dakota Insurance Department,** verbally provided additional information.

10:52 AM **John Ward, representing Prime Therapeutics,** verbally provided additional information.

11:02 AM **Madam Chair Lee** closed the meeting.

Patricia Lahr, Committee Clerk

2023 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

SB 2378
2/15/2023

Relating to clinician-administered drugs.

3:54 PM **Madam Chair Lee** called the meeting to order. **Senators Lee, Cleary, Clemens, K. Roers, Weston** were present**. Senator Hogan** was absent**.**

Discussion Topics:
- Consumer choice piece
- Hospital side
- Provider side

Senator Lee calls for discussion

Senator K. Roers moves **Do NOT PASS.**
Senator Cleary seconded.

Roll call vote.

Senators	Vote
Senator Judy Lee	N
Senator Sean Cleary	Y
Senator David A. Clemens	N
Senator Kathy Hogan	AB
Senator Kristin Roers	Y
Senator Kent Weston	N

Motion failed 2-3-1.

(Held vote for **Senator Hogan**)
Senator Hogan voted NO at 4:15 PM on 2/15/2023.

Additional Information:
Megan Houn, Vice President of Public Policy and Government affairs, Blue Cross Blue Shield of North Dakota in opposition #20990

3:56 PM **Madam Chair Lee** closed the meeting.

Patricia Lahr, Committee Clerk

2023 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

SB 2378
2/15/2023

Relating to clinician-administered drugs.

4:18 PM **Madam Chair Lee** called the meeting to order. **Senators Lee, Cleary, Clemens, K. Roers, Weston, Hogan** are present**.**

Discussion Topics:

- Hogan vote

4:19 PM Vote held on 2/15/2023 at 3:54PM, whereby Senator Roers moved DO NOT PASS and Senator Cleary seconded, included all Senators except **Senator Hogan. Senator Hogan** voted **NO** on SB 2378.

Final vote on DO NO PASS on SB 2378.

Senators	Vote
Senator Judy Lee	N
Senator Sean Cleary	Y
Senator David A. Clemens	N
Senator Kathy Hogan	N
Senator Kristin Roers	Y
Senator Kent Weston	N

Motion failed 2-4-0.

Senator Hogan moves **DO PASS**.
Senator Weston seconded.

Roll call vote.

Senators	Vote
Senator Judy Lee	Y
Senator Sean Cleary	N
Senator David A. Clemens	Y
Senator Kathy Hogan	Y
Senator Kristin Roers	N
Senator Kent Weston	Y

Motion passed 4-2-0.

Senator Lee will carry SB 2378.

4:22 PM **Madam Chair** closed the hearing.

Patricia Lahr, Committee Clerk

REPORT OF STANDING COMMITTEE

SB 2378: Human Services Committee (Sen. Lee, Chairman) recommends **DO PASS** (4 YEAS, 2 NAYS, 0 ABSENT AND NOT VOTING). SB 2378 was placed on the Eleventh order on the calendar. This bill does not affect workforce development.

2023 HOUSE HUMAN SERVICES

SB 2378

2023 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

SB 2378
3/14/2023

Relating to clinician-administered drugs.

Chairman Weisz called the meeting to order at 3:35 PM.

Chairman Robin Weisz, Vice Chairman Matthew Ruby, Reps. Karen A. Anderson, Mike Beltz, Kathy Frelich, Dawson Holle, Dwight Kiefert, Carrie McLeod, Todd Porter, Brandon Prichard, Karen M. Rohr, Jayme Davis, and Gretchen Dobervich. Rep. Clayton Fegley not present.

Discussion Topics:

- White bagging
- Brown bagging
- Safety and product integrity
- Pharmacy benefits manager
- PBM practices
- Challenges of handling medication
- Healthcare expenditures

Mike Schwab, Executive Vice President of the North Dakota Pharmacists Association, supportive testimony #26358.

Marky Hardy, Executive Director of the North Dakota State Board of Pharmacy, supportive testimony #24884.

Melissa Hauer, North Dakota Hospital Association, introducing Erik Christensen.

Erik Christenson, CEO, Heart of America Medical Center, supportive testimony #24916.

Sen. Meyer introduced SB 2378, spoke in favor of the bill.

Rep. Kasper, spoke in favor of the bill.

Dr. Maari Loy, Essentia Health Pharmacy Operations Senior Manager, supportive testimony #24656.

Alex Kelsch, Attorney, Lobbyist, Americas Health Insurance Plans, supportive testimony #27237.

Vice Chairman Ruby presided as Chairman at 4:30 PM.

Alex Sommer, Prime Therapeutics, opposition testimony #24401.

Michelle Mack, Manager at the Pharmaceutical Association, opposition testimony #24782, #24783.

Megan Houn, Blue Cross Blue Shield of ND, spoke in opposition of the bill.

Additional written testimony:
Terry Dick, ND Pharmacist, #24512
Courtney Koebele, NDMA, #24491
Kathleen Nelson, ND Pharmacist, #24602

Vice Chairman Ruby adjourned the meeting at 4:54 PM.

Phillip Jacobs, Committee Clerk

2023 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

SB 2378
3/21/2023

Relating to clinician-administered drugs.

Chairman Weisz called the meeting to order at 3:52 PM.

Chairman Robin Weisz, Vice Chairman Matthew Ruby, Reps. Karen A. Anderson, Mike Beltz, Clayton Fegley, Kathy Frelich, Dawson Holle, Dwight Kiefert, Carrie McLeod, Todd Porter, Brandon Prichard, Karen M. Rohr, Jayme Davis, and Gretchen Dobervich. All present.

Discussion Topics:

- Committee work

Chairman Weisz called for a discussion on SB 2378.

Rep. McLeod moved a do pass on SB 2378.

Seconded by Rep. Rohr.

Roll call vote:

Representatives	Vote
Representative Robin Weisz	Y
Representative Matthew Ruby	Y
Representative Karen A. Anderson	Y
Representative Mike Beltz	Y
Representative Jayme Davis	Y
Representative Gretchen Dobervich	Y
Representative Clayton Fegley	N
Representative Kathy Frelich	Y
Representative Dawson Holle	Y
Representative Dwight Kiefert	Y
Representative Carrie McLeod	Y
Representative Todd Porter	N
Representative Brandon Prichard	N
Representative Karen M. Rohr	Y

Motion carries 11-3-0. Carried by Rep. Weisz.

Vice Chairman Ruby adjourned the meeting at 4:00 PM.

Phillip Jacobs, Committee Clerk

REPORT OF STANDING COMMITTEE

SB 2378: Human Services Committee (Rep. Weisz, Chairman) recommends **DO PASS** (11 YEAS, 3 NAYS, 0 ABSENT AND NOT VOTING). SB 2378 was placed on the Fourteenth order on the calendar.

TESTIMONY

SB 2378

Margaret Reynolds
Government Affairs Principal

February 7, 2023

6625 W 78th Street
Edina, MN 55439

651-341-3161

Senate Human Services Committee
600 E Boulevard Ave
Bismarck, ND 58505

Chair Lee and members of the Senate Human Services Committee:

On behalf of Cigna, I respectfully submit testimony regarding SB2378. Cigna is a global health services company dedicated to improving the health, well-being and peace of mind of those they serve. Cigna delivers choice, predictability, affordability and access to quality care through integrated capabilities and connected, personalized solutions that advance whole person health.

The clinician-administered drugs, aka white bagging, bill will negatively impact patient care by limiting health plans' ability to leverage the specialized expertise of specialty pharmacies to treat complex and rare conditions. By virtue of how rare some of these diseases are, providers who treat patients with rare conditions often have limited treatment experience. Specialty pharmacies, in contrast, treat significantly more patients and have clinical staff trained in these conditions.

Accredo, a Cigna company, is an industry-leading specialty pharmacy providing highly personalized care nationwide to patients with complex and chronic health conditions. Accredo employs approximately 500 condition-focused pharmacists and 350 proprietary clinical protocols to ensure patients are taking the right medication and staying adherent. Its 15 condition-specific Therapeutic Resource Centers are pharmacy practices that specialize in caring for members with the most complicated and costly condition categories, including immune disorders, blood disorders, and rare diseases/gene therapies. For those who need the highest degree of clinical support, this unique pharmacy model enables members and their caregivers to engage with highly trained, highly trusted specialist pharmacists and nurses that provide personalized care, conduct sophisticated safety and quality reviews, and offer the information and counseling patients need to achieve healthier outcomes. White bagging is, at its core, a tool utilized by health plans and clients that leverages specialty pharmacies to safely distribute certain drugs to help improve affordability.

It should be noted that specialty medications are the largest and fastest-growing segment of the U.S. pharmacy market.[1] And while only four percent of Americans use specialty drugs, they account for 65%

[1] Anderson, Leigh Ann. Specialty Pharmacy and Medicines: A One-to-One Approach. Drugs.com. 7, May, 2021

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of total drug spend and 19% of total health care spend.[2] As the costs of these drugs rise, it will continue to make it more difficult for patients to afford care. This bill would limit health plans' ability to leverage innovative solutions like white bagging that make prescription drugs more affordable while protecting patient safety and improving care.

Provider-administered infusions and injections that are included in Cigna's white bagging policies cost an average of nearly $509,000 per patient per year in hospital outpatient facilities according to Cigna's internal data. Our white bagging policies cut those costs by nearly $253,000 per patient per year while allowing patients to continue care with their same provider and maintaining our high standards for affordable, quality care.

Overall, this bill will increase the cost of care by protecting provider mark-ups of specialty medications and depriving plans of cost saving site of care tools.

Sincerely,

Margaret Reynolds
Government Affairs Principal

[2] Cigna National Trend Report, 2022

February 8, 2023

Testimony on Senate Bill 2378

A BILL to an Act to create and enact section 19-02.1 of the North Dakota Century Code, relating to clinician-administered drugs.

Erik Christenson, PharmD, MBA
CEO
Heart of America Medical Center
Rugby, ND 58368

I wish to share with the senators of the State of North Dakota my experience as a pharmacist and administrator in rural health care and how these experiences relate to the delivery of pharmacy services. I started as a pharmacist in Rugby, North Dakota in 2000. I have worked as a hospital and retail pharmacist, pharmacy owner, director of pharmacy, and most recently as a hospital administrator. Much of my professional life has been dedicated to providing health care to rural North Dakotans and I have a passion to assure that these patients continue to have viable access to good health care.

One of the major concerns expressed by the patients I have worked with over the years is the concern of having the freedom to choose the providers they wish to utilize for their health care needs. Most recently, this concern was raised when the Heart of America Medical Center joined a new accountable care organization. I have and will continue to work hard to assure our community has choice when it comes to the providers they utilize. This is a valid concern as these patients often have limited resources and they must be able to choose a provider that meets their needs given these limited resources.

I have the unique perspective regarding limited networks of care as a pharmacist. The pharmacy industry over the years has seen a rise in limited provider choices due to insurers narrowing the pharmacy selection available to patients. Many patients are forced to choose a mail order pharmacy over their local pharmacy provider. This limited network can serve to increase confusion and frustration for the patients. It also does not appear that these limited networks are saving money for the patients or society as a whole. From 2012 to 2022 the annual prescription drug expenditures for Medicare have

increased from $67.5 Billion to $143.2 Billion. (CMS, 2023) The narrowed networks created by the large pharmacies, pharmacy benefit managers, and insurers are not allowing for a competitive environment that would help reduce costs. Instead, these large companies are cornering the market and forcing our communities to pay more for needed medications.

One of most critical programs for vulnerable hospitals is the 340B program. This program provides significant dollars to rural hospitals allowing them to continue to provide lifesaving services to low-income patients and those living in rural communities. This is a budget neutral program when administrated correctly is very successful. However, when insurance companies are allowed to corner the medication market and removed the ability of hospitals to purchase medications these 340B dollars are no longer available to these same hospitals. Instead, the insurance company and their own mail order pharmacies are able to capture these drug rebates. In fact, a recent analysis indicated that pharmacy benefit manager-controlled pharmacies operated by Walgreens, Caremark, Express Scripts, and OptumRx have siphoned away $2.58 billion from the 340B program. (Okon, 2022) That is $2.58 billion that will not be used to help vulnerable or rural patient populations.

To further highlight the problem on allowing insurers to enforce limited access to medications in the form of mail order delivery I want to summarize the experience of a North Dakota hospital infusion center. In many cases the process set up by the insurance company requires the hospital to get prior authorization 10-15 days before initial shipment. It then takes another 3-5 days to process the order. Finally, there must be an authorization of shipment with the patient. It generally requires the hospital to contact the insurer 6-10 time during this set up process and about 8 hours of time on the phone to complete. In many cases the medication shipment is delayed or interrupted during this process. There are documented cases of treatments being delayed due to this inefficient and unnecessary process. In the end this process costs the patient in time due to rescheduled appointments and quality in delayed care. The hospital must spend more resources to accomplish this process. The insurance company makes extra profit by cornering the medication market and drug rebates, but they are not ultimately responsible for the patient.

In summary, I support the passage of this legislation as I feel that it is important to assure that our citizens have access to good care and that large out of state companies do not inhibit that access. This bill will support rural hospitals and assure us we have access to the medications we must provide to our patients. This access must be readily available under normal supply chains and not limited in order to support the bottom lines of big business. There is good reason to believe that limited drug delivery

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models do not save money for the patients or the community as a whole and in fact can hamper affordable care. Good health care is important to North Dakotans, and I feel this bill will help to assure good health care in our state.

Respectfully,

Erik Christenson

References:

CMS (2023). National Health Expenditure Data. Centers for Medicare and Medicaid Services. Retrieved on February, 5 2023. https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet

Okon, T (2022). Hospitals and for-profit PBMs are diverting billions in 340B savings from patients in need. *Statnews.com* Retrieved on February 6, 2023 from: https://www.statnews.com/2022/07/07/for-profit-pbms-diverting-billions-340b-savings/

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Mark J. Hardy, PharmD
Executive Director

Senate Bill No 2378 – Clinician Administered Drugs

Senate Human Services Committee – Roughrider Room
9:00 AM - Wednesday – February 8, 2023

Madam Chair Lee, Members of the Senate Human Services Committee for the record I am Mark Hardy, Executive Director of the North Dakota State Board of Pharmacy. Thank you for the opportunity to testify on this important legislation.

The Board of Pharmacy is aware of the business model this legislation is focused on when the dispensing and administration of medications are completed by different practitioners. This practice is labeled as "*white*" or "*brown*" bagging models. These models have been increasing in nature given the rising number of medications that have significant costs associated with them. In many cases the patient's healthcare plan dictates requirements to use a specific pharmacy on these medications, often owned by the Pharmacy Benefit Manager for the plan, which restricts the patient's ability to utilize the pharmacy of their choice.

The nature of many medications requires special handling, storage and shipping challenges. In these models, the burden falls on the practitioners and dispensing pharmacists to ensure each medication is safe and effective for administration. As the drug supply chain moves to implement the federally enacted Drug Supply Chain and Security Act these "bagging" models may be scrutinized, given the unique chain of custody.

There are many patient safety concerns around these practices, which is the forefront of the Board's support of this legislation. We have had several complaints and concerns from patients about delays and issues with the delivery of pharmaceuticals into the state. If a patient desires their services to be obtained from a mail order pharmacy, then that is understandable, and they are accepting of the services they receive. However, when forced into using models of care that they do not desire it creates consternation, especially when things do not go as expected.

The nature of these delivery models puts healthcare professionals in an uncomfortable position, where they do not know how drugs were stored or handled and are unable to assure that they were not adulterated or misbranded in some way prior to administering them to a patient. This is why some health systems have not allowed these models of care to occur in their facilities, which leads to patients trying to determine where they can get their care. Also, these models lead to fragmentations in the patient's prescription services which prevents pharmacists from having a full picture of the patient's therapies to ensure optimal therapeutic outcomes.

This could result in missing drug interactions, duplicative therapies or other safeguards the patient should be afforded in their care.

The Board would always advocate for patient’s choice to assure the patient has the opportunity to choose the pharmacy they feel best meets their pharmaceutical care needs and not be required to use a location based on the third party’s requirements.

Another consequence which occurs when a patient choice is lost is when their insurance changes the patient’s consistency of pharmacy services are disrupted. This causes much unnecessary stress and difficulty in reestablishing their models of care.

We appreciate the opportunity to testify on Senate Bill 2378.

I'd be happy to answer any questions.

Senate Human Services Committee
SB 2378
February 8, 2023

Chair Lee and Committee Members, I'm Courtney Koebele, executive director of the North Dakota Medical Association. I present this testimony on behalf of the North Dakota Medical Association. The North Dakota Medical Association is the professional membership organization for North Dakota physicians, residents, and medical students. NDMA supports SB 2378.

The practice involves insurance companies forcing medications that are administered in a clinic to be purchased through an insurer's exclusive pharmacy of choice. The medications, specifically for one patient, are then sent to a physician's office or a hospital where they are administered to patients. This new practice is being used for chemotherapy medications, certain ophthalmologic medications, and other physician administered drugs. The practice adds unnecessary complexity to the physician/patient relationship, raises patient safety issues, and may cause delays in patient care.

The required use of "white bagging" replaces the current system where a clinic has a supply of needed medications in stock that can be used to address the patient's needs. When the insurer requires the drug to be ordered for the patient from their pharmacy, it limits the physician's ability to adjust the medications as needed when treating the patient.

With white bagging, drugs are not always delivered in time for the patient's appointment. If medications aren't available when needed, the patient must reschedule, which may result in less adherence and scrambled treatment plans. The unintended consequence is the impact on patients, such as wasted travel time, time off work, and frustrations of navigating a more complex system.

Another inefficiency created in white bagging is that the medication arrives in time, but the physician changed the treatment. The drug is now wasted, and the needed therapeutic isn't available. Using the existing model of care, it's easier for the onsite pharmacy to make that change.

This bill does not mandate the use of local pharmacies and allows the patient and provider to choose if white bagging is appropriate for them or not.

NDMA requests a DO PASS recommendation on the bill. Thank you for the opportunity to testify today. I would be happy to answer any questions.

Coalition of State Rheumatology Organizations

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February 7, 2023

Senate Human Services Committee
600 E Boulevard Ave
Bismarck, ND 58505

Re: Support for SB 2378

The Coalition of State Rheumatology Organizations (CSRO) is a national organization composed of over 30 state and regional professional rheumatology societies, including our member organization covering North Dakota. CSRO was formed by physicians to ensure excellence and access to the highest quality care for patients with rheumatologic, autoimmune, and musculoskeletal disease. It is with this in mind that we write to you regarding SB 2378.

As you consider SB 2378, CSRO would like to share its support, and the importance of ensuring that providers continue to be able to provide care for patients through the buy and bill acquisition model for provider administered prescription drugs.

Many rheumatology practices currently use the "buy and bill" method of acquisition for provider administered drugs. Under this model a practice will purchase, store, prepare, and administer certain provider administered drugs. The practice will then bill the payer for the cost of the drug and its administration once a patient receives treatment.

Payers have begun to require that providers use an alternate acquisition system called "white bagging" for provider administered drugs. White bagging is a policy in which insurance companies internally manage the purchase and delivery of provider administered specialty medications through a specialty pharmacy of the insurer's choice rather than allowing the provider, where the patient will receive treatment, to purchase and manage drug inventory for their patients. CSRO believes this new system is flawed for a number of reasons, and that North Dakota policymakers should act to curtail its mandatory use by payers.

White Bagging Reduces Patient Safety and Increases Practice Liability

CSRO has serious concerns with product integrity for drugs prepared outside of rheumatologists' offices. Under the white bagging model practices do not have control over the handling, preparation, and storage conditions of the drug prior to its administration. Improper handling on the part of a specialty pharmacy can have serious consequences for patients, and white bagging removes practices' ability to prevent adverse events through internal oversight. Patients will face delays in treatment and unnecessary hardships, as compared

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COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

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to the practice sourcing products from its own inventory for in-office administration. **Indeed, in a national survey of rheumatologists, 69% of respondents indicated they experienced operational and safety issues associated with white bagging.[1]** While practices' responsibility for much of the pre-administration handling is removed under the white bagging model, their liability is not. Practices may still be held liable for adverse events that occur because of circumstances they no longer control under a white bagging model.

White Bagging Requirements Delay Care and Increase Drug Waste

White bagging would significantly increase instances of drug waste, which complicates the acquisition system's ability to achieve savings. Under the new policy, drugs will be assigned to a specific patient prior to administration by the specialty pharmacy, whereas under buy and bill drugs do not have to be assigned until the time of administration. Providers cannot administer a drug assigned to one patient to a different patient, whereas they may do so with drugs acquired through "buy and bill."

For example, if a dosing change is required or the therapy is discontinued or interrupted for any reason, the drug provided by the specialty pharmacy would end up as waste. It is not uncommon for pre-administration evaluation to necessitate dosing changes, which the white bagging model offers no ability to resolve without drug waste or inability of the patient to get the needed dose of medication. This would certainly result in unnecessary drug waste and increased expenditures for the patient in terms of money and health.

Additionally, the present "buy and bill" system offers providers flexibility that would prevent patients from suffering major inconveniences should delays or other mistakes occur on the part of the specialty pharmacy or their delivery system. Delays can result from a variety of factors, including failed delivery, incorrect medications being delivered, medications shipped to the wrong address, prior authorization issues, and out of stock medications. Not only would the drug be wasted, but the patient, practice, and payer's time is also wasted with potential harm to the patient due to their inability to get the needed medication. **68% of respondents to CSRO's national survey indicated that medication delivery was delayed when white bagged, which caused patient appointments to be canceled and increased chances of drug waste.[2]**

These logistical hurdles are not only borne by patients, but also physician practices. Due to the aforementioned issues, the requirement to white bag drugs will massively increase the complexity of inventory management, which will add to already untenable administrative burdens borne by physician practices. Practices will now have to keep track of individual drugs for individual patients, which drugs can be used if treatment is delayed, how long

[1] CSRO national survey of rheumatology practices, data available upon request.
[2] CSRO national survey of rheumatology practices, data available upon request.

CSRO
Coalition of State Rheumatology Organizations

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of a delay is acceptable for reuse if treatment is delayed among other issues. As a result, inventory will have to be more granular, which presents and overhead and inventory nightmare.

White Bagging Requirements Reduce Affordability for Patients

Due to the expensive nature of many specialty medications, patients are often responsible for large cost-sharing amounts out of their own pockets. Many patients are unable to afford these amounts all at once, and providers work with patients to spread these payments over time to help ensure they are able to afford and receive treatment. However, under a white bagging model, there is the possibility that patients may need to meet their cost-sharing obligations in their entirety before the specialty pharmacy will ship the medication. An inability to meet these costs up front can interrupt critical treatment that is preventing the progression of disease.

For these reasons, CSRO requests your support for SB 2378. We appreciate your consideration of our comments.

Respectfully,

Gary Feldman, MD, FACR
President, CSRO

Madelaine Feldman, MD, FACR
Vice President Advocacy & Government Affairs, CSRO

The Nation's Advocacy Voice for In-Office Infusion

3307 Northland Dr, Ste 160 ▪ Austin, TX 78731
www.infusioncenter.org ▪ info@infusioncenter.org

Senate Human Services Committee
600 E Boulevard Ave
Bismarck, ND
58505

February 7, 2023

Re: Support for ND SB 2378

Dear Senators:

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 SB 2378.

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.

In the infusion space, reimbursement rates for drug administration do not cover the actual expense of administering medications. Infusion providers have historically relied on what is known as "buy-and-bill" to purchase medications for their practices in bulk and then billing patients for their individual treatments. Margins incurred from the buy-and-bill model allow offices to cover administration and overhead costs, and ultimately keeps community-based providers in business.

However, some insurance companies have implemented policies that require North Dakota patients to purchase medications from specialty pharmacies—a practice known as "white

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bagging." When a payor requires a patient's medication to be acquired from a specialty pharmacy, the drug is provided by a third-party pharmacy, generally one the payor is affiliated with, and the provider bills for administration only. Specialty pharmacy mandates circumvent the buy-and-bill model infusion providers rely on. If North Dakota infusion centers can no longer afford to treat patients due to forced "white bagging," their long-standing patients who rely on them for consistent, local, and quality care will have nowhere to go.

In addition to disrupting the economics of non-hospital infusion offices, specialty pharmacy mandates add unnecessary waste and costs, and ultimately harm patients. White bagging requires that patients pay for their medications before they receive them and before they are even shipped to their providers' offices. If for any reason a patient is unable to receive their treatment, due to weight fluctuation or a change in their condition, that medication, which has already been paid for, is now wasted. However, the patient is still responsible for paying for the drug. By law, the drug cannot be returned, and it cannot be administered to another patient.

These medications cost thousands of dollars and wasting them is completely avoidable through the buy-and-bill model that infusion offices currently use. For many of our providers, working with a specialty pharmacy has led to delays and disruptions in treatment schedules. Practices have reported receiving different quantities than what was ordered or experienced processing and shipping delays.

On behalf of the providers we serve, we urge the North Dakota Senate Human Services Committee to advance SB 2378 and ensure healthcare providers have the flexibility to obtain and administer complex provider-administered drugs in the way that is right for their office.

Sincerely,

Kindyl Boyer

Kindyl Boyer
Director of Advocacy
National Infusion Center Association

Senate Human Services Committee
SB 2378
February 8, 2023

Chair Lee and committee members, thank you for this opportunity to weigh in on this important issue to health care in North Dakota. My name is Maari Loy, and I serve as the Essentia Health Pharmacy Operations Senior Manager in Fargo. Prior to joining Essentia, I worked as a pharmacist in other health-systems in Fargo after graduating from NDSU's Pharmacy School. I am a Central Cass High graduate, and my family and I continue to live in Casselton.

Essentia Health is an integrated health system serving patients in the Midwest. We employee roughly 15,000 employees who serve patients and communities through our 14 hospitals, 77 clinics, six long-term care facilities, three assisted living facilities, three independent living facilities, six ambulance services, and one research institute. Essentia Health is an accredited accountable care organization by the National Committee for Quality Assurance and is focused on the triple aim of better health, improving patient experience, and lowering costs.

A trend is growing in infusions centers that threatens the timeliness and safety of medication administration to patients. Increasingly, insurance payers are demanding that clinics "white bag" medications. White bagging — called this because of the white bags in which pharmacies traditionally deliver medications — is a process in which the patient's insurance company dictates which pharmacy can be used to dispense the drug. These specialty pharmacies are often owned by or affiliated with the insurance companies' pharmacy benefit manager (PBM). This requirement to use the PBM designated specialty pharmacy is fraught with issues that impact patient safety and the timeliness of therapy.

White bagging can cause delays in medication administration. For example, patients may arrive to their clinic ready for their chemotherapy infusion only to be told that their medication has not arrived from the specialty pharmacy. While the clinic infusion pharmacy routinely stocks this drug and has a supply ready for patients, white bagging can cause a delay in shipment because the clinic has not received the medication in time for the patient's scheduled infusion. This is because of the demands of the insurance company. A delay in shipment can also occur if a patient has a change in medication dosage or therapy. To make things worse, if the original drug has already been shipped, the white bagging process can prevent the drug from being returned. In this case, the patient must pay for both the original drug as well as the new prescription. Situations like this could be prevented if the insurance company allows the clinic infusion pharmacy to dispense the drug. What's more, these are not hypothetical situations occurring in some distant state. They are occurring here in North Dakota for our neighbors on a regular basis.

The added burden of managing the white bagged drugs creates several potential safety issues. The provider must know when the medication needs to be reordered from the specialty pharmacy, especially if the order is changing for any reason. It can be difficult to know the exact timing needed for the reordering process when the provider has to work with an unfamiliar pharmacy and shipping, temperature storage, and supply chain challenges. Then, the clinic infusion pharmacy must assure the orders have arrived, potentially from one of multiple specialty pharmacies, ensure that the arrival of

the shipments matches the patient's treatment dates, and that the correct drug and dose have arrived. Medication that is white bagged must be stored separately because these drugs can only be given to that specific patient. Since these white bagged medications are shipped to the clinic infusion pharmacy outside of the normal supply chain process, there is a large potential for error and patient safety concerns.

So why are insurance companies trying to push the white bagging method? One reason insurance companies give for supporting white bagging is cost savings. Unfortunately, they mean cost savings for themselves – not the patients seeking what is often life-saving drugs who are forced to pay more out-of-pocket for these drugs. Simply put, when white bagging occurs, the insurance company can shift the drug from the patient's medical benefit coverage to the pharmacy benefit coverage, where there are increased co-pays or other out-of-pocket costs and there may be no out-of-pocket maximum for drugs. So, while white bagging may have cost savings to the payer, patients are stuck with increased cost, significant barriers to care, and disruptions to the patient-provider relationship.

This is why SB 2378 has been introduced to prohibit insurance companies from demanding white bagging of medications that are typically administered in a clinic infusion center. This bill will prevent this process that can ultimately cost additional money and cause harm to patients. Support for this bill will be crucial to allow physicians and patients to make the choice that is best for patients — rather than being dictated by insurance companies.

Thank you for your time and consideration.

Sincerely,

Maari Loy, PharmD, BCPS, MBA
Operations Senior Manager - Essentia Health Fargo

Home address: 1052 Morningside Ct; Casselton, ND 58012

Date: February 8, 2023

To: Members of the Senate Human Services Committee

From: Michelle Mack, Senior Director, State Affairs for the Pharmaceutical Care Management Association (PCMA)

RE: Senate Bill 2378
White Bagging/Clinician-Administered Drugs and Anti-Mail
Opposition

Good Afternoon Chair Lee and members of the Human Services Committee. My name is Michelle Mack, and I am a Senior Director, State Affairs at the Pharmaceutical Care Management Association (a/k/a "PCMA"). PCMA is the national trade association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 275 million Americans with health coverage provided through employers, health insurance plans, labor unions, Medicaid, Medicare, Federal Employees Health Benefit Programs, and other public programs.

Thank you for the opportunity to provide testimony to SB 2378, a bill which would prohibit plans from the specialty drug delivery practice known as white bagging as well as prohibit preferred pharmacy networks and mandating plan design for heal plans and employers in North Dakota. PCMA respectfully opposes SB 2378.

PBMs and their health plan and employer clients use specialty pharmacies to deliver high quality, accessible pharmacy services while promoting product affordability. Flexibility to continue contracting with these select pharmacies is the key to ensuring access and promoting affordability in North Dakota. When an employer or health plan decides to contract with a PBM to administer their pharmacy benefit, they maintain authority over the terms and benefit plan design, including how drugs should be obtained by or delivered to beneficiaries. The employer or plan— not the PBM—makes decisions regarding cost-sharing requirements, formularies, and networks (which this legislation creates havoc on), including the use of mail delivery of a drug to a patient or provider.

While the vast majority of shipped prescriptions do not require special handling or packaging, for those that do, mail-service pharmacies use U.S. Pharmacopeia guidelines to determine handling needs and leverage proprietary software to map out the ideal packaging journey, which accounts for the acceptable temperature range, forecasted weather conditions, and destination temperatures. Proprietary software is used to map out a delivery path for those prescriptions that

must stay within a specific temperature range. Such software accounts for the acceptable temperature range for each prescription, forecasted weather conditions, and destination temperatures. Based on this information, the appropriate shipping time frame and packaging are determined specific to that prescription. For example, a mail-service pharmacy may package prescription drugs in temperature-protective coolers with gel packs to ensure that the prescriptions stay within a safe temperature range — even accounting for if the package is sitting outside for hours after delivery.

Specialty prescription drugs, including injectable drugs with special handling requirements, are usually shipped through commercial mail and shipping carriers, such as UPS and Federal Express. Specialty drugs requiring refrigeration are typically shipped for overnight delivery, often through common carriers other than the United States Postal Service.

The safety and efficacy of mailed prescriptions is of utmost importance and is well reflected in the level of precision and planning undertaken by mail-service pharmacies in the mailing of prescription drugs, including those with special handling requirements. The precision also reflects the needs and preferences of consumers not only for safe, high-quality products, but also to know when their prescription will be shipped and received[1]. For example, as required by CMS, Medicare Part D plan sponsors require their network mail-service pharmacies to provide enrollees an approximate shipping date range, of within two-to-three days, prior to delivery.[2] Mail-service pharmacies offer enhanced safeguards for safety and accuracy. Before shipping a prescription to a patient's home, mail-service pharmacies' staff pharmacists electronically review the patient's medications to detect adverse drug reactions, especially any potentially harmful drug-to-drug interactions — even when the patient uses several pharmacies. This information may not be available to a patient's physician without an interoperable health record system.

Specialty pharmacies and mail delivery are tools used in pharmacy networks because they ensure high-quality drug delivery service, avoid waste, and ensure appropriate use of the medications. In limiting the choice to allow white bagging, this bill is likely to substantially increase costs for both North Dakota consumers, health plans and employers.

This bill will also prohibit employers and health plans from designing an employee benefit plan that relies on preferred pharmacy networks to increase pharmacy quality and access and reduce costs to consumers. We appreciate the idea of patient choice, but we cannot ignore the cost to both health plans and more importantly patients. A recent North Dakota State University report indicated that "in 2019 North Dakotans spent nearly $1.5 billion on prescription drugs…[which] ranks amongst the highest per capita expenditures in the country"[3].

In addition, our research shows that in the first year alone, restricting white bagging and the use of preferred pharmacy networks and mail-order pharmacies will cost North Dakotans $50 million in excess drug spending and $600 million over the next 10 years. We all want to do something about the high cost of prescription drugs, the question we have is why would you add more

[1] CMS, "Clarifications to the 2014 Policy on Automatic Delivery of Prescriptions" (December 12, 2013).
[2] Op. cit, CMS (December 12, 2013).
[3] March, Raymond J. "Pharmaceutical Price Controls Destroy Innovation and Harm Patients". Challey Institute for Global Innovation and Growth at North Dakota State University. (December 2022).

restrictions or mandates that would increase costs to the already high prescription drug prices for the residents of North Dakota?

It is for these reasons we respectfully request that you reject SB 2378.

Thank you. I appreciate the Committee's time and attention to our concerns and am available for questions.

North Dakota SB 2378 Will Cost the State Over $600 Million In Increased Prescription Drug Costs

The core mission of pharmacy benefit managers (PBMs) is to reduce prescription drug costs for health plan sponsors so that consumers have affordable access to needed prescription drugs. PBMs offer a variety of services to their health-plan-sponsor clients and patients that improve prescription adherence, reduce medication errors, and manage drug costs.

The proposed North Dakota legislation will seriously undermine the ability of PBMs to control drug costs, and as a result drug spending in North Dakota will soar. Although some of the provisions are subject to interpretation, enacting just the bill provisions discussed below could cost the state of North Dakota **$50 million in excess drug spending** in the first year alone, and **$607 million** over the next 10 years.

SB 2378 would restrict the use of preferred pharmacy networks and mail-order pharmacies.

- PBMs require pharmacies to compete on service, price, convenience, and quality to be included in preferred networks. Pharmacies that agree to participate in such arrangements are designated as 'preferred' and become members of a preferred pharmacy network. These types of networks have gained traction among plan sponsors and deliver tangible out-of-pocket savings for patients.
- Nearly 80% of employers believe that mail-order specialty pharmacies are the lowest-cost site of service compared with retail community pharmacies and other options.[1] This bill guts the ability for health plans and PBMs to create preferred pharmacy networks for plans by mandating an "any willing provider" requirement. According to the FTC and academic analysis, this type of mandate leads to less competition and higher prices for consumer.[2]

SB 2378 would ban white bagging

- Under a white bagging model, a specialty pharmacy ships the drug for a given patient directly to the health care provider rather than the provider buying the drug and billing the insurer. The cost of these drugs through specialty pharmacies is lower than through the traditional "buy-and-bill" model.
- Legislation that would bar health insurers from implementing white bagging will seriously undermine the ability of health plans and PBMs to manage their medical specialty pharmacy expenditures, and as a result, drug spending in North Dakota would soar. Use of white bagging has real benefits for patients, providers, and health plan sponsors.

Projected 10-Year Increases in Prescription Drug Spending In North Dakota, 2023–2032 (Millions)

	Self-Insured Group Market	Fully-Insured Group Market	Individual Direct Purchase Market	Medicaid	**Total**
Restrict preferred pharmacy networks and mail-order pharmacies[3]	$136	$132	$37	$8	$313
Restrict White Bagging	$116	$112	$31	$35	$294
Maximum Costs – Two Provisions	**$252**	**$244**	**$68**	**$43**	**$607**

Methodology: The methodology used to create these cost projections for adopting pharmacy restrictions was that used by Visante in the January 2023 paper "Increased Costs Associated With Proposed State Legislation Impacting PBM Tools." The methodology used to create the white bagging cost projections is described in "Appendix: White Bagging Dispensing."

1. Trends in Specialty Drug Benefits, PBMI, 2018
2. "Contract year 2015 policy and technical changes to the Medicare advantage and the Medicare prescription drug benefit programs," FTC letter to CMS, Mar. 7, 2014.
3. Note: North Dakota may already use some form of AWP rules. Estimated cost increases are based on comparing "with vs without AWP."

Chairwoman Lee
1822 Brentwood Court
West Fargo, ND 58078

Re: Healthcare Distribution Alliance (HDA) Statement on SB 2378

Dear Senator Lee,

On behalf of the Healthcare Distribution Alliance (HDA), representing the nation's primary healthcare distributors, I am writing to thank you to urge your support of SB 2378. If successfully enacted, this legislation would limit the ability of certain entities (Payers) to create restrictions relating to insurance coverage for and access to physician-administered drugs, most notably, the growing practice of "white bagging" which has the potential to disrupt patient care and is increasingly being required by insurers and pharmacy benefit managers (PBMs).

HDA's distributor members serve as the critical logistics provider within the healthcare supply chain, adding efficiency, security and keeping the healthcare system functioning every day. HDA members work 24 hours a day, 365 days a year to ensure approximately 10 million healthcare products per-day, including specialty drugs, are safely and securely delivered to more than 180,000 providers across the country.

As referenced above, the practice of "white bagging" is an arrangement between insurance companies and designated specialty pharmacies that they contract with, or own themselves, to ship physician-administered medications directly to sites of care (i.e., hospitals, clinics, doctors' offices) after they have been prescribed by the attending physician. Most U.S. hospitals and physician offices maintain inventories of medications their patients need which can be immediately available when the patient arrives for treatment based on that patient's real-time needs. When a patient's insurance provider interjects and stipulates the drug prescribed by their attending physician and available at the site of care must instead be dispensed and shipped from an off-site specialty pharmacy, this practice has the potential to delay access to treatments.

While delaying treatment is burdensome on the patient as well as the physician providing care, white bagging practices introduce additional concerns as well. Such concerns include ensuring the proper storage and handling of these products which in turn may increase provider liability. The creation of increased drug waste due to the product being specified for a specific beneficiary. Most notably for many patients, the process of "white bagging" may increase costs to the patient as well due to treatment typically being switched from a patient's medical benefit to his/her pharmacy benefit which often includes higher cost-sharing responsibilities.

Complex drug therapies for rare diseases require timely access and enhanced physician oversight of storage, dosing, and administration. Patients trust their doctors to care for them. Any policies that prevent physicians from delivering timely access and safe administration of medically necessary drugs should be opposed. If you have any questions, please contact me at 716-307-4022 or tbutchello@hda.org.

Thank you,

Travis Butchello

1275 Pennsylvania Avenue NW, Suite 600, Washington, DC 20004 • **Main** (202) 963-1200 • **Web** www.hda.org

Director, State Government Affairs
Healthcare Distribution Alliance

CC:

Vice Chair Ruby

Representatives:
Dobervich
Fegley
Kiefert
Mitskog
Rohr
Sanford
Schneider
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February 8, 2023

Chairman Judy Lee
Senate Human Services Committee
North Dakota State Capitol
600 East Boulevard Avenue
Bismarck, North Dakota 58505

Re: AHIP Concerns on SB 2378, *Relating to clinician-administered drugs*

Dear Chairman Lee and Committee Members,

America's Health Insurance Plans (AHIP) appreciates the opportunity to share our concerns with the Senate Human Services Committee on SB 2873. As proposed, this legislation will undermine affordability and access to care and coverage for the people of North Dakota by prohibiting the tools health insurance providers use to put downward press on the price of prescription drugs.

Specialty drug prices are high and growing. Everyone should be able to get the medications they need at a cost they can afford. But drug prices are out of control, and hardworking families feel the consequences every day. Health insurance providers are fighting for patients, families, and employers for more affordable medications, and this work is particularly critical when it comes to specialty drugs.

Specialty and clinician-administered drugs generally are high-priced medications that treat complex, chronic, or rare conditions and can have special handling and/or administration requirements. These specialty drugs are given at a variety of sites of care including hospitals, medical provider offices, infusion centers, and by medical professionals during home visits. Both the number and the price of these drugs have rapidly increased in recent years and, as a result, specialty drugs are a leading contributor of drug spending growth. Specialty drug share of net spending across institutional and retail settings has grown from 27% in 2010 to 53% in 2020.[1]

Physician markups on specialty/clinician-administered drugs are excessive. SB 2378 would attempt to prohibit health insurance providers from structuring benefits and requirements for costly clinician-administered drugs that provide substantial cost savings for North Dakotans without sacrificing product safety or the quality of care.

Patients, families, and employers are exposed to not only the high price of specialty drugs, but they are subjected to physician markups and fees. These physician markups and fees are well documented and *significant*.

AHIP recently released a new study[2] where AHIP researchers analyzed the cost of 10 drugs that are stored and administered in a health care setting, such as a hospital, but could also be safely delivered through a specialty pharmacy for provider administration. The study examined data from 2018-2020 and found:

[1] IQVIA, The Use of Medicines in the U.S., May 27, 2021
[2] AHIP, Hospitals Charge Double for Drugs – Specialty Pharmacies More Affordable, February 16, 2022

- Costs per single treatment for drugs administered in hospitals were an average of **$7,000 more** than those purchased through pharmacies. Drugs administered in physician offices were an average of **$1,400 higher.**
- Hospitals, on average, **charged double the prices** for the same drugs, compared to specialty pharmacies, and
- Prices were **22% higher in physicians' offices** for the same drugs, on average.

These markups on the price of the drug were in addition to what hospitals and physicians were reimbursed to administer the drug to the patient. AHIP's findings confirm similar studies by the JAMA Internal Medicine[3], AllianceBernstein[4], Health Affairs[5], and the Moran Company[6].

Using lower-cost specialty pharmacies saves money for patients and helps to make premiums more affordable. Health insurance providers have developed many innovative solutions to make prescription drugs more affordable, including leveraging lower-cost pharmacies – called specialty pharmacies – to safely distribute certain drugs (sometimes called either "white bagging" or "brown bagging").

Specialty pharmacies can deliver drugs directly to a physician's office or to a patient's home right before a patient's appointment. This means that patients can avoid inflated fees and other costs that hospitals and physicians charge to buy and store specialty medications themselves. It is important to understand that specialty pharmacies offer patients access to the same drugs, from the same places, using nearly identical shippers who must adhere to the same strict chain of custody and FDA requirements.

Specialty pharmacy programs are designed to be safe and seamless to the patient. Thousands of patients successfully and safely receive their drugs through brown and white bagging each year without issue.

Specialty pharmacies are only used for certain prescription drugs that may be safely delivered in this way. Specialty pharmacies must abide by all state and federal legal and regulatory requirements, in addition to meeting extra safety requirements for specialty drugs imposed by the Food and Drug Administration (FDA) and drug manufacturers.

In addition to the extremely stringent safety requirements for specialty pharmacies, health plans routinely have exception processes in place to address the rare circumstances of quality, safety, medical necessity, and/or care interruption. Health plans develop their specialty pharmacy programs with all potential dosing and treatment dispensing scenarios in mind. In fact, medications are routinely shipped with enough additional supply so that facilities can adjust a dose as required at the time of administration.

The processes for delivering these medications through specialty pharmacies are the same as those used when hospitals acquire the drugs themselves. In fact, many hospitals and physician groups obtain these medications from the same specialty pharmacies.

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[3] JAMA, Hospital-Administered Cancer Therapy Prices for Patients With Private Health Insurance, April 18, 2022; JAMA, Payer-Specific Negotiated Prices for Prescription Drugs at Top-Performing US Hospitals, November 8, 2021. 3

[4] STAT, How much? Hospitals mark up some medicines by 250% on average, January 20, 2021; Axios, Hospitals are making a lot of money on outpatient drugs, February 15, 2019. 1

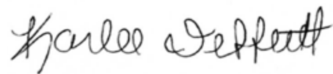
[5] Health Affairs, Price Differences To Insurers For Infused Cancer Drugs In Hospital Outpatient Departments And Physician Offices, September 2021.

[6] The Moran Company, Hospital Charges and Reimbursement for Medicines: Analysis of Cost-to-Charge Ratios, September 2018.

The proposed provisions of the bill would create an anti-competitive, high-cost clinician-administered drug market in North Dakota. If passed, this legislation effectively removes any competitive incentive for providers to offer lower prices and higher quality care because health plans would be prohibited from using utilization management tools for these drugs and services. Plans would not be able to employ benefit design to reward patients for seeking out care at high-quality, lower-cost sites. Overall, the provisions reveal an attempt to redirect clinician-administered drugs to hospital-based settings and away from specialty pharmacies. Eliminating this important cost saving tool will create a statutory monopoly on physician-administered drugs to hospital-owned pharmacies and leave patients, families, and employers exposed to out-of-control specialty drug prices and excessive physician markups.

Thank you for your consideration of our comments. AHIP and our members plans are eager to continue working to fight for more affordable medications for the residents of your state and patients, families, and employers across the country. We strongly urge the Senate Human Services Committee to protect competition and reject policies that will take away lower-cost choices from patients.

Sincerely,



Karlee Tebbutt
Regional Director, State Affairs
AHIP – Guiding Greater Health
ktebbutt@ahip.org / (720) 556-8908

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. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

Wolf, Sheldon

From: Lee, Judy E.
Sent: Wednesday, February 1, 2023 9:52 PM
To: Wolf, Sheldon
Subject: FW: SB2378

Please load this in testimony, when the bill comes up.

Senator Judy Lee
1822 Brentwood Court
West Fargo, ND 58078
Home phone: 701-282-6512
Email: jlee@ndlegis.gov

From: Mark J. Hardy <MHardy@ndboard.pharmacy>
Sent: Wednesday, February 1, 2023 7:50 AM
To: Lee, Judy E. <jlee@ndlegis.gov>; Howard <NDBOPh@ndboard.pharmacy>
Subject: RE: SB2378

Hi Senator,

Carolyn is a Board member on the Board of Pharmacy and a great Pharmacist. She is articulating concerns that many pharmacists are having about this practice and the concerns for patient care that they are faced with (mostly) the large PBM owned pharmacies forcing patients to get services through this method. Mike at the Association put together the bill draft on behalf of his membership to address the practice. Sounds like quite a few other states have taken legislative action on this practice.

Thanks
Mark

** Our office has moved, please note the new address and contact numbers below**

Mark J Hardy, Pharm D
Executive Director
North Dakota Board of Pharmacy
1838 E Interstate Ave Suite D
Bismarck, ND 58503
Phone (701) 877-2404
Fax (701) 877-2405
www.ndboard.pharmacy

From: Lee, Judy E. <jlee@ndlegis.gov>
Sent: Tuesday, January 31, 2023 9:27 PM
To: Mark J. Hardy <MHardy@ndboard.pharmacy>; Howard <NDBOPh@ndboard.pharmacy>
Subject: FW: SB2378

Any thoughts?

Senator Judy Lee

1822 Brentwood Court
West Fargo, ND 58078
Home phone: 701-282-6512
Email: jlee@ndlegis.gov

From: Carolyn & Jim Bodell <jbodell@min.midco.net>
Sent: Tuesday, January 31, 2023 1:29 PM
To: Lee, Judy E. <jlee@ndlegis.gov>
Subject: SB2378

January 31, 2023

I am writing to you regarding Senate Bill 2378 (White Bagging).

For the past several years of my career as a pharmacist, I practiced in an oncology center. We served the cancer patients, as well as rheumatology and gastrointestinal infusion patients.

The practice of white bagging has grown over the years. I know the costs of many treatments are very expensive. White bagging often results in insurance companies shifting costs to prescription plans that generally have higher out of pocket expenses for the patient. Insurers will say the white bagging practice will help ensure appropriate medication use, help avoid unwarranted drug expenditures, optimize adherence to medication therapy, and ensure patients experience a high level of care and satisfaction. I did **not** see any of these benefits to our patients.

Concerns I have with the white bagging process are many:

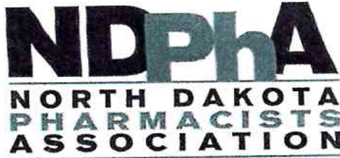
- Non-reimbursed time of practice site staff:
  - I often had to make 6-10 phone calls, along with faxing various forms to set up initial shipment of product. With hold time and transfers to multiple people, I have spent at least eight hours on the phone to get one case processed. If the patient needs a dose change for any reason, a year has passed, or at the beginning of a new calendar year, this process starts over. Since most cancer treatments are weight based and/or impacted by side effects, dose changes are common.
  - Time spent tracking shipments
  - Admixture of medications
  - Pharmacist regimen reviews
  - Destruction of wasted products
  - System to manage ordering and receipt of product.
- Non-reimbursed supplies:
  - Admixture and administration supplies (infusion bags, administration tubing, syringes)
  - Additional storage area because these products cannot be placed in the general inventory
- Medication waste:
  - The patient regimen may change due to side effects or disease changes after their medication has shipped. The medication cannot be returned to the specialty pharmacy and has to be wasted. The patient has probably paid their co-pay for a medication they will not use.
  - This medication was provided for a specific patient and cannot be used for anyone else.
- Treatment Delays: (Time is crucial for cancer patients)
  - It can take 10-15 days to schedule an initial shipment.
  - The Specialty Pharmacy can have a maximum number of prescriptions they will ship in a day, so that can cause a delay in shipping the medications for a patient, and ultimately, a delay in the patients treatment.
  - Shipment delays due to weather delays
- Legality of white bagging:
  - Admixture of a white bagged product can be considered redispensing which is not legal

- Drug supply chain management is a requirement for pharmacies. Because the products are sent for a specific patient, the supply chain information is not provided. Pharmacies have no way of knowing if the product is safe for patient use.

- Practice sites retain responsibility for storage and handling of the products, liability issues, patient safety, continuity of care, and meeting regulatory requirements. All of this without reimbursement for the services provided.

The traditional practice of buy and bill eliminates the problems I have listed. It allows for more flexible provision of product for the patient. We know the pedigree of the products, eliminates storage issues, allows for reimbursement of all services provided, decreases waste of products and decrease the chance and cost of waste. I hope that you will consider all of my information and vote in favor of this bill.

Sincerely,
Carolyn Bodell, R.Ph



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Senate Human Service Committee – SB 2378
Madam Chair - Senator Judy Lee
Wednesday February 8, 2023

Madam Chair and members of the committee, for the record, my name is Mike Schwab, Executive Vice President of the North Dakota Pharmacists Association. We are here today in support of SB 2378.

SB 2378 is looking to address a number of problems and concerns many healthcare providers are experiencing as it relates to clinician administered drugs and the patient care process. Prior to last session, our office was approached with a request to address what we in the world of pharmacy call "white bagging" and "brown bagging" issues. We had enough on our plates last session, the request came late and we ran out of time. However, since last session, we have heard from members in all parts of the state regarding an increase in insurance mandates requiring patients to have their therapies/medications exclusively dispensed by an insurer or pharmacy benefits manager (PBM) mail order pharmacy or PBM mail order affiliates.

It is important to note, the big three insurance companies are all now vertically integrated and control 80% of the health plan pharmacy benefit market. The big three are CVS/Caremark/Aetna (#4 on Forbes), United Health/Optum Rx (#5 on Forbes) and Cigna/Express Scripts (#12 on Forbes). They are all in the business of pharmacy owning mail order pharmacies, brick and mortar pharmacies and specialty mail order pharmacies.

What is "white bagging"? This process happens when a PBM or insurer mandates certain drugs are to be delivered to a healthcare practice setting which are then supposed to be administered to the patient. The drugs have to come from an external source which is most often the PBMs mail order pharmacy or PBM affiliate pharmacies. This process causes numerous issues and concerns for healthcare providers and patients. While PBMs argue that white bagging lowers healthcare costs (more on this later), healthcare providers say the practice captures more revenue for the PBMs and may violate patient standards of care.

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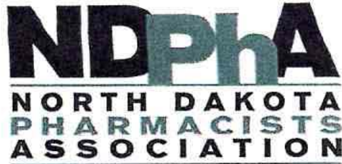
White bagging can also bypass pharmacy safety checks, health system planning, supply chain integrity and interferes with the care planning processes. There is a high level of coordination and timing that has to take place with white bagging policies as well. In addition, dosing errors, delivery delays, lost shipments and receiving the wrong drug happens which negatively impacts patient outcomes, delays patient care, may require another appointment and can create drug waste. There are a whole host of other patient and clinical considerations to think about as well. Those considerations include the inability to adjust drug dosages in response to urgent laboratory or clinical findings. When these types of issues happen due to the insurer mandated requirement, we are actually increasing costs.

What is "brown bagging"? This process is similar to white bagging with one main difference. In this case, the drug comes directly to the patient and is in the patient's custody. The many reasons listed above related to white bagging apply to brown bagging as well. However, there are a couple of additional important points worth noting. Under this process, there are elevated safety and product integrity concerns. A provider's liability risk is also elevated under these types of patient steering arrangements.

Now, let's circle back to claims made by the PBMs that these types of mandated requirements save money. In 2018, the Auditor of the State of Ohio produced a State Report which found discriminatory reimbursement practices because the PBMs compensated their affiliate pharmacies at a higher rate than other providers. This same type of practice has been found to be taking place in many other states as well. Arkansas for example found the PBMs were steering patients to its wholly owned affiliate so that it could pay itself more and was in fact paying itself more. An analysis in Florida in 2020 showed PBM affiliated pharmacies were making 18x to 109x more profit over the cost of the drugs than the typical pharmacy. The State of Oklahoma also found PBM owned and affiliated pharmacies were reimbursing themselves at higher rates. Minnesota, Wisconsin and other states have expressed concerns over the practice of PBMs steering patients to PBM-owned pharmacies.



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There are others who would like to testify today so let me conclude by asking once again for your support of SB 2378. When it comes to clinician administered drugs, they should be dispensed as close to the patient point of care as possible. We should do our best to support product integrity and minimize as many risks and safety concerns as possible for patients. Thank you for your time. I will try to do my best to answer any questions.

Respectfully submitted,

Mike Schwab

Mike Schwab
NDPhA - EVP

February 8, 2023

Sen. Judy Lee, Chair
Human Services Committee
North Dakota Senate

Re: SB 2378

Chair Lee and members of the Senate Human Services Committee:

Thank you for the opportunity to comment on SB 2378. I represent Prime Therapeutics, a pharmacy benefit manager (PBM) owned by 19 not-for-profit Blue Cross and Blue Shield health insurers, including Blue Cross Blue Shield of North Dakota. SB 2378 would substantially increase health care costs for North Dakotans without providing any additional benefit. For that reason and those below, we oppose this bill and request the Committee recommend a Do Not Pass.

Prime helps people get the medicine they need to feel better and live well by managing pharmacy benefits for health plans, employers, and government programs, including Medicare and Medicaid. We manage pharmacy claims and provide clinical services that help people with complex medical conditions access the drug therapies they need at the best possible price. Our business model relies on transparency and advocating for simpler, lowest-net-cost pricing for drugs.

"White bagging" is the practice of an in-network specialty pharmacy dispensing and distributing a clinician-administered medication to the patient's health care provider for administration. The health plan reimburses the specialty pharmacy for the medication and reimburses the provider for the administration of the drug. Another practice, "Buy and bill" is when a health care provider purchases the product from a supplier and bills the health plan sponsor for dispensing the drug and for administering the drug, frequently resulting in double the cost over specialty pharmacy dispensing.[1]

White bagging is a way for payers to get patients the treatment they need, when they need it, at a substantially lower price. The scope of drugs potentially subject to white bagging is relatively narrow, but the cost of these specialty drugs is incredibly high and growing rapidly each year. In 2021, 55% of drug expenditures were for specialty medications, which represent 3% of defined daily doses.[2] Despite claims to the contrary by some hospital industry advocates, white bagging has an excellent patient safety track record. According to URAC, one of the main accrediting bodies of specialty pharmacies, 99.8% of prescriptions are accurately dispensed, and 99.7% accurately distributed.[3] While the cost of banning or restricting white bagging is hard to quantify, a fiscal note attached to a white bagging restriction bill in Missouri in 2022 estimated that such a bill would cost the Missouri Consolidated Health Care Plan, and thus taxpayers, $18 million in additional prescription drug expenses.[4] That cost would have been for the same drug therapies already being administered, nothing additional other than the dollars paid.

Notably, this bill takes aim at not just clinician-administered drugs and white bagging, but rather alternative models of delivery and treatment. The drug supply chain is constantly innovating to lower

1 HOSPITAL PRICE HIKES: Markups for Drugs Cost Patients Thousands of Dollars – AHIP, Accessed November 22, 2022
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the cost of drugs and leveraging competition to make health care more affordable. A notable example is integrated dispensing networks where hospitals and payers negotiate a fair rate of reimbursement for physician-administered drugs. This allows providers to maintain control of their drug supply chain while providing savings to payers over traditional buy and bill methods. That is one “channel management” method payers use in addition to white bagging. However, increased state restrictions on cost savings tools reduce competition and incentives for participation in innovative payment models that provide benefits to all stakeholders.

Passing SB 2378 would handcuff North Dakota health plans to an expensive benefit design mandate that would ultimately drive up the cost of health care for all North Dakotans. The alternative to passing this bill is not a white bagging mandate – it is allowing North Dakota health plans to retain white bagging as one tool to fight against one of the fastest growing cost centers in health care, specialty drugs. Our job is to make sure patients get the medications they need to feel better and live well, which means the right medication at the right time and place and for the best possible price. Removing white bagging as an option would ensure North Dakotans only have access to the treatment they need at a price best for the hospital.

Thank you for your consideration of my testimony and I urge the Committee to recommend this bill as Do Not Pass. Please contact me if you have any questions regarding this written testimony or my oral testimony.

Sincerely,

Alex Sommer, J.D.
Prime Therapeutics

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Wolf, Sheldon

From: Lee, Judy E.
Sent: Wednesday, February 8, 2023 10:22 PM
To: -Grp-NDLA Senate Human Services; Wolf, Sheldon; Lahr, Pat; NDLA, Intern 02 - Pouliot, Lindsey
Subject: FW: SB 2378 - Pharmacy Choice

Sheldon, please load this and Mr. Askew's other message in 2378 testimony.

Senator Judy Lee
1822 Brentwood Court
West Fargo, ND 58078
Home phone: 701-282-6512
Email: jlee@ndlegis.gov

From: Askew, Andrew <Andrew.Askew@EssentiaHealth.org>
Sent: Wednesday, February 8, 2023 10:11 PM
To: Lee, Judy E. <jlee@ndlegis.gov>; Clemens, David <dclemens@ndlegis.gov>; Cleary, Sean <scleary@ndlegis.gov>; Roers, Kristin <kroers@ndlegis.gov>; Hogan, Kathy L. <khogan@ndlegis.gov>; Weston, Kent <kweston@ndlegis.gov>
Cc: Mike Schwab <mschwab@nodakpharmacy.net>; Bartuska, Chrystal A. <cabartuska@nd.gov>
Subject: SB 2378 - Pharmacy Choice

Greetings, committee members:

I write to follow up on today's hearing on SB 2378 in hopes of addressing some of the assertions made in testimony today. As you probably are now well aware of, this is a very complex and contentious debate that can cause a lot of confusion.

Most importantly, SB 2378 **does not prohibit the practice of white bagging**. Senate Bill 2378 restricts insurance plans from **mandating or forcing patients** to exclusively receive medications through white bagging. In other words, SB 2378 gives patients the choice to receive medications through white bagging or their preferred local providers, which is why it is being described as "pharmacy choice." Below is the operative language, which begins at page 1, line 21:

> "A pharmacy benefit manager . . . **may not [r]equire** a patient as a condition of payment or reimbursement, to purchase pharmacist services, including prescription drugs, exclusively through a mail-order pharmacy or a pharmacy benefit manager affiliate . . . ." (Emphasis added).

While we believe it is clear that this provision bans insurance plans from mandating which pharmacy patients must use, the supporters of SB 2378 are amendable to amending the bill if additional clarity is needed.

There was also a lot of focus on the cost of receiving these expensive clinician administered drugs in a hospital or clinic setting. What was not made clear to the committee was that the amounts "**charged**" by hospitals and clinics are actually **negotiated** between insurance payers and care providers. In other words, hospitals and clinic are reimbursed according to the negotiated rates agreed to by the insurance plans. Hospitals and clinics do not simply charge whatever amount they want – they charge the amount agreed to by the insurance plans.

Another question was raised about whether ERISA preempts the state from preventing patients from being forced to obtain medications through out of state specialty pharmacies. In 2020, the Supreme Court of the United States unanimously held that ERISA **does not preempt** all state regulations of PBMs. In the wake of the *Rutledge* decision, the

Eighth Circuit Court of Appeals held in *Wilke v Pharmaceutical Care Management Association* that North Dakota's 2017 laws regulating PBM practices, such as limiting the fees they may charge pharmacies, limiting copayments, and regulating drug benefit provisions and plan structures, **was not preempted by ERISA**.

Since *Rutledge* and its progeny, there is increasing and considerable interests from state legislations to reign in payers and PBMs on various front, including white bagging mandates. For example, Essentia and Mayo Clinic have brought similar legislation in Minnesota this year. In 2021, three states enacted white bagging laws (AR, LA, VA). Keeping with this trend, at least 10 states were actively considering white-bagging legislation so far in 2022. Two additional states, Florida and Wisconsin, considered white-bagging bills that ultimately failed in committee. Of the 10 states debating white bagging legislation, at least two, West Virginia and Oklahoma, have passed their bill through at least one legislative chamber.

Finally, we think it is important to underscore that the patient safety and care concerns are not hypothetical. These are concerns playing out throughout North Dakota that present daily challenges for our providers and patients. Attached please find a testimonial from an Essentia pharmacist in Fargo, highlighting the patient impacts of white bagging. As referenced in the document, the other large health system in Fargo (i.e., Sanford Hospital) **does not** allow white bagging. As a result, patients who are unable to obtain medications through Sanford because of mandatory white bagging requirements mandates, are often sent to Essentia, which has a more lenient policy toward white bagging in order to ensure patients are not deprived access to what is often life-saving care.

As I mentioned, this is a complex – and often confusing – issue. What isn't complex or confusing is the fact that when patients are forced to receive white bagged medications, their out-of-pocket costs drastically increase and their access to timely, safe medications is reduced. As the committee deliberates, we respectfully ask that you support a DO PASS recommendation for SB 2378. Thank you for your time and consideration!

Sincerely,

Andy Askew

Andrew L. Askew, J.D.
Vice President, Public Policy
Essentia Health
Corporate Office I MDMC120
502 E. 2nd Street
Duluth, MN 55805
P: 701-351-2326 I F: 218-720-6406
andrew.askew@essentiahealth.org

Wolf, Sheldon

From: Megan Houn <Megan.Houn@bcbsnd.com>
Sent: Thursday, February 16, 2023 9:14 AM
To: NDLA, S HMS
Subject: FW: 2378

Thank you!

Megan Houn
Vice President, Government Affairs and Public Policy
BLUE CROSS BLUE SHIELD OF NORTH DAKOTA
701-255-5548 (work)
701-255-5595 (fax)
megan.houn@bcbsnd.com | www.BCBSND.com

From: Megan Houn
Sent: Wednesday, February 8, 2023 9:46 AM
To: Lee, Judy E. <jlee@ndlegis.gov>; scleary@ndlegis.gov; dclemens@nd.gov; Hogan, Kathy L. <khogan@ndlegis.gov>; Roers, Kristin <kroers@ndlegis.gov>; kweston@ndlegis.gov
Subject: 2378

Good Morning, Senate Human Services Committee,

I wanted to share with you (below) a few studies that have been done on anti-white bagging legislation. The end result in all cases is higher costs. While we can appreciate the patient safety components, frankly, this is an anti-choice bill that leaves BCBSND members with only one option… their local pharmacist and higher costs. We have to get out of the habit of protectionism around our local pharmacies.

BCBSND supports and partners consistently with our local pharmacy friends because our members want to receive their care with their local pharmacists. BCBSND does not on any plan, force mail order. Our members always have an option on care. We would like them also to have an option on cost given that over 26 cents of every dollar BCBSND spends is on pharmacy costs.

Please don't hesitate if you have any questions.

Megan Houn
Vice President, Government Affairs and Public Policy
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ND

BOLDER SHADE OF BLUE

Why Address the Cost of Clinician-Administered Drugs?
Clinician-administered drugs are a leading contributor to drug spending growth. **Clinician-administered drugs have high prices, which are then subject to even further, significant markups above hospitals' acquisition costs.** These markups are well-documented, including in several studies released this year:

• Bernstein (2021): This analysis found that some hospitals mark up prices on more than two dozen medicines by **an average of 250%**. For example, hospitals charged more than **five times the purchase price** for Epogen, which is used to treat anemia caused by chronic kidney disease for patients on dialysis, and **4.6 times the price** for Remicade, a drug that treats a range of autoimmune conditions. According to the analysis, administering treatments to commercially insured patients is **20 times more profitable** than administering the same drugs to Medicare patients. The analysis also showed hospitals have been slow to begin using biosimilars, which are nearly identical to brand-name biologic treatments and produce the same health outcome, but at a much lower cost.
https://www.statnews.com/pharmalot/2021/01/20/hospitals-biosimilars-drug-prices/

• Health Affairs (2021): This study examined the 2019 prices paid for by Blue Cross Blue Shield for certain drugs administered in hospital clinics versus provider offices. The study found the prices paid for hospital outpatient departments were **double** those paid in physician offices for biologics, chemotherapies, and other infused cancer drugs (99-104% higher) and for infused hormonal therapies (68% higher). Blue Cross Blue Shield – and therefore patients and employers – would have saved **$1.28 billion, or 26 percent of what they actually paid**, if the insurer had all patients receive their infusions in a provider's office instead of hospital clinics.
https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.00211

• JAMA Internal Medicine (2021): The median negotiated prices for the 10 drugs studied ranged from **169% to 344% of the Medicare payment limit**. The largest variation in markup came from Remicade, an IV drug that treats autoimmune conditions – the median rate paid by commercial insurers at Mayo Clinic's hospital in Phoenix was more than 800% of the Medicare rate. https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2785833

• AllianceBernstein (2019): Depending on the drug and type of hospital, markups ranged on average from **3-7 times more** than Medicare's average sale price. https://www.axios.com/2019/02/15/hospital-charges-outpatient-drug-prices-markups

• The Moran Company (2018): Most hospitals charge patients and insurers **more than double their acquisition cost** for medicine. The majority of hospitals markup medicines between **200-400% on average**.
https://www.themorancompany.com/wp-content/uploads/2018/09/Hospital-Charges-Reimbursement-for-Medicines-August-2018.pdf

These markups on the price of the drug are **in addition to** the amounts hospitals separately bill insurers for the professional services required to administer the drugs.

Patients, families, and employers all bear these unreasonable and growing costs through higher health insurance premiums and out-of-pocket costs. It is imperative that health insurance providers be allowed to help encourage the administration of these drugs in lower cost, more convenient settings when it is safe and clinically appropriate to do so.

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March 14, 2023

Rep. Robin Weisz, Chair
Human Services Committee
North Dakota Senate

Re: SB 2378

Chair Weisz and members of the House Human Services Committee:

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White bagging is a way for payers to get patients the treatment they need, when they need it, at a substantially lower price. The scope of drugs potentially subject to white bagging is relatively narrow, but the cost of these specialty drugs is incredibly high and growing rapidly each year. In 2021, 55% of drug expenditures were for specialty medications, which represent 3% of defined daily doses.[2] Despite claims to the contrary by some hospital industry advocates, white bagging has an excellent patient safety track record. According to URAC, one of the main accrediting bodies of specialty pharmacies, 99.8% of prescriptions are accurately dispensed, and 99.7% accurately distributed.[3] While the cost of banning or restricting white bagging is hard to quantify, a fiscal note attached to a white bagging restriction bill in Missouri in 2022 estimated that such a bill would cost the Missouri Consolidated Health Care Plan, and thus taxpayers, $18 million in additional prescription drug expenses.[4] That cost would have been for the same drug therapies already being administered, nothing additional other than the dollars paid.

Notably, this bill takes aim at not just clinician-administered drugs and white bagging, but rather alternative models of delivery and treatment. The drug supply chain is constantly innovating to lower

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the cost of drugs and leveraging competition to make health care more affordable. A notable example is integrated dispensing networks where hospitals and payers negotiate a fair rate of reimbursement for physician-administered drugs. This allows providers to maintain control of their drug supply chain while providing savings to payers over traditional buy and bill methods. That is one “channel management” method payers use in addition to white bagging. However, increased state restrictions on cost savings tools reduce competition and incentives for participation in innovative payment models that provide benefits to all stakeholders.

Passing SB 2378 would handcuff North Dakota health plans to an expensive benefit design mandate that would ultimately drive up the cost of health care for all North Dakotans. The alternative to passing this bill is not a white bagging mandate – it is allowing North Dakota health plans to retain white bagging as one tool to fight against one of the fastest growing cost centers in health care, specialty drugs. Our job is to make sure patients get the medications they need to feel better and live well, which means the right medication at the right time and place and for the best possible price. Removing white bagging as an option would ensure North Dakotans only have access to the treatment they need at a price best for the hospital.

Thank you for your consideration of my testimony and I urge the Committee to recommend this bill as Do Not Pass. Please contact me if you have any questions regarding this written testimony or my oral testimony.

Sincerely,

Alex Sommer, J.D.
Prime Therapeutics

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House Human Services Committee
SB 2378
March 14, 2023

Chairman Weisz and Committee Members, I'm Courtney Koebele, executive director of the North Dakota Medical Association. I present this testimony on behalf of the North Dakota Medical Association. The North Dakota Medical Association is the professional membership organization for North Dakota physicians, residents, and medical students. NDMA supports SB 2378.

The practice involves insurance companies forcing medications that are administered in a clinic to be purchased through an insurer's exclusive pharmacy of choice. The medications, specifically for one patient, are then sent to a physician's office or a hospital where they are administered to patients. This new practice is being used for chemotherapy medications, certain ophthalmologic medications, and other physician administered drugs. The practice adds unnecessary complexity to the physician/patient relationship, raises patient safety issues, and may cause delays in patient care.

The required use of "white bagging" replaces the current system where a clinic has a supply of needed medications in stock that can be used to address the patient's needs. When the insurer requires the drug to be ordered for the patient from their pharmacy, it limits the physician's ability to adjust the medications as needed when treating the patient.

With white bagging, drugs are not always delivered in time for the patient's appointment. If medications aren't available when needed, the patient must reschedule, which may result in less adherence and scrambled treatment plans. The unintended consequence is the impact on patients, such as wasted travel time, time off work, and frustrations of navigating a more complex system.

Another inefficiency created in white bagging is that the medication arrives in time, but the physician changed the treatment. The drug is now wasted, and the needed therapeutic isn't available. Using the existing model of care, it's easier for the onsite pharmacy to make that change.

This bill does not mandate the use of local pharmacies and allows the patient and provider to choose if white bagging is appropriate for them or not.

NDMA requests a DO PASS recommendation on the bill. Thank you for the opportunity to testify today. I would be happy to answer any questions.

3-13-2023

Dear Representatives,
I will keep my comments brief. I am a pharmacist in rural ND, Stanley, and I just wanted to write and express my support of this bill. I am constantly bombarded with requests from mail order patients that run out of their meds and I have to fill gap prescriptions. If we weren't here to fill in the gaps these patients would have gaps in continuity of care that could put them at risk. A lot of my customers only choose to use mail order because they are forced to either with no coverage or larger copayments. It is very important that we end this risk for ND residents and allow them to choose there pharmacy provider.
Thank you for your time.
Terry Dick, Rph

I am writing in support of SB 2378. As a rural community pharmacist, my patients have had to go mail order for their specialty medications. These could be injectable or oral medications.
The PBMs direct the prescriptions for these specialty meds to their own mail order pharmacies. So the PBM is the pharmacy and the insurance. Conflict of interest?? These are the same entities that negotiate the contracts showing what I am reimbursed for medications for their patients also. They would prefer their patients would go completely mail order and close up the rural pharmacies in North Dakota.
Im also writing as a mom of one of the patients who had to go mail order for her specialty medication. When it is mailed to her- she must be home due to storage of this medication- must be refrigerated- not frozen or over heated. If its stolen from her steps - she is liable. She has resorted to having it delivered to her work place to make sure it is safe.
There is absolutely no reason we could not dispense these medications through a retail pharmacy. We used to dispense them before the PBMs changed their contracts to demand mail order.
Please consider voting in favor of this bill.

Thank you,
Kathleen Nelson RPh. Owner
Casselton Drug and Arthur Drug
Casselton. ND. Arthur, ND

House Human Services Committee
SB 2378
March 14, 2023

Chair Weisz and committee members, thank you for this opportunity to weigh in on this important issue to health care in North Dakota. My name is Maari Loy, and I serve as the Essentia Health Pharmacy Operations Senior Manager in Fargo. Prior to joining Essentia, I worked as a pharmacist in other health-systems in Fargo after graduating from NDSU's Pharmacy School. I am a Central Cass High graduate, and my family and I continue to live in Casselton.

Essentia Health is an integrated health system serving patients in the Midwest. We employee roughly 15,000 employees who serve patients and communities through our 14 hospitals, 77 clinics, six long-term care facilities, three assisted living facilities, three independent living facilities, six ambulance services, and one research institute. Essentia Health is an accredited accountable care organization by the National Committee for Quality Assurance and is focused on the triple aim of better health, improving patient experience, and lowering costs.

A trend is growing in infusions centers that threatens the timeliness and safety of medication administration to patients. Increasingly, insurance payers are demanding that clinics "white bag" medications. White bagging — called this because of the white bags in which pharmacies traditionally deliver medications — is a process in which the patient's insurance company dictates which pharmacy can be used to dispense the drug. These specialty pharmacies are often owned by or affiliated with the insurance companies' pharmacy benefit manager (PBM). This requirement to use the PBM designated specialty pharmacy is fraught with issues that impact patient safety and the timeliness of therapy.

White bagging can cause delays in medication administration. For example, patients may arrive to their clinic ready for their chemotherapy infusion only to be told that their medication has not arrived from the specialty pharmacy. While the clinic infusion pharmacy routinely stocks this drug and has a supply ready for patients, white bagging can cause a delay in shipment because the clinic has not received the medication in time for the patient's scheduled infusion. This is because of the demands of the insurance company. A delay in shipment can also occur if a patient has a change in medication dosage or therapy. To make things worse, if the original drug has already been shipped, the white bagging process can prevent the drug from being returned. In this case, the patient must pay for both the original drug as well as the new prescription. Situations like this could be prevented if the insurance company allows the clinic infusion pharmacy to dispense the drug. What's more, these are not hypothetical situations occurring in some distant state. They are occurring here in North Dakota for our neighbors on a regular basis.

The added burden of managing the white bagged drugs creates several potential safety issues. The provider must know when the medication needs to be reordered from the specialty pharmacy, especially if the order is changing for any reason. It can be difficult to know the exact timing needed for the reordering process when the provider has to work with an unfamiliar pharmacy and shipping, temperature storage, and supply chain challenges. Then, the clinic infusion pharmacy must assure the orders have arrived, potentially from one of multiple specialty pharmacies, ensure that the arrival of

the shipments matches the patient's treatment dates, and that the correct drug and dose have arrived. Medication that is white bagged must be stored separately because these drugs can only be given to that specific patient. Since these white bagged medications are shipped to the clinic infusion pharmacy outside of the normal supply chain process, there is a large potential for error and patient safety concerns.

So why are insurance companies trying to push the white bagging method? One reason insurance companies give for supporting white bagging is cost savings. Unfortunately, they mean cost savings for themselves – not the patients seeking what is often life-saving drugs who are forced to pay more out-of-pocket for these drugs. Simply put, when white bagging occurs, the insurance company can shift the drug from the patient's medical benefit coverage to the pharmacy benefit coverage, where there are increased co-pays or other out-of-pocket costs and there may be no out-of-pocket maximum for drugs. So, while white bagging may have cost savings to the payer, patients are stuck with increased cost, significant barriers to care, and disruptions to the patient-provider relationship.

This is why SB 2378 has been introduced to prohibit insurance companies from demanding white bagging of medications that are typically administered in a clinic infusion center. This bill will prevent this process that can ultimately cost additional money and cause harm to patients. Support for this bill will be crucial to allow physicians and patients to make the choice that is best for patients — rather than being dictated by insurance companies.

Thank you for your time and consideration.

Sincerely,

Maari Loy, PharmD, BCPS, MBA
Operations Senior Manager - Essentia Health Fargo

Home address: 1052 Morningside Ct; Casselton, ND 58012

Date: March 13, 2023

To: Members of the House Human Services Committee

From: Michelle Mack, Senior Director, State Affairs for the Pharmaceutical Care Management Association (PCMA)

RE: Senate Bill 2378
White Bagging/Clinician-Administered Drugs and Anti-Mail
Opposition

Good Afternoon Chair Weisz and members of the Human Services Committee. My name is Michelle Mack, and I am a Senior Director, State Affairs at the Pharmaceutical Care Management Association (a/k/a "PCMA"). PCMA is the national trade association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 275 million Americans with health coverage provided through employers, health insurance plans, labor unions, Medicaid, Medicare, Federal Employees Health Benefit Programs, and other public programs.

Thank you for the opportunity to provide testimony to SB 2378, a bill which would prohibit plans from the specialty drug delivery practice known as white bagging as well as prohibit preferred pharmacy networks and mandating plan design for heal plans and employers in North Dakota. PCMA respectfully opposes SB 2378.

PBMs and their health plan and employer clients use specialty pharmacies to deliver high quality, accessible pharmacy services while promoting product affordability. Flexibility to continue contracting with these select pharmacies is the key to ensuring access and promoting affordability in North Dakota. When an employer or health plan decides to contract with a PBM to administer their pharmacy benefit, they maintain authority over the terms and benefit plan design, including how drugs should be obtained by or delivered to beneficiaries. The employer or plan— not the PBM—makes decisions regarding cost-sharing requirements, formularies, and networks (which this legislation creates havoc on), including the use of mail delivery of a drug to a patient or provider.

While the vast majority of shipped prescriptions do not require special handling or packaging, for those that do, mail-service pharmacies use U.S. Pharmacopeia guidelines to determine handling needs and leverage proprietary software to map out the ideal packaging journey, which accounts for the acceptable temperature range, forecasted weather conditions, and destination temperatures. Proprietary software is used to map out a delivery path for those prescriptions that

must stay within a specific temperature range. Such software accounts for the acceptable temperature range for each prescription, forecasted weather conditions, and destination temperatures. Based on this information, the appropriate shipping time frame and packaging are determined specific to that prescription. For example, a mail-service pharmacy may package prescription drugs in temperature-protective coolers with gel packs to ensure that the prescriptions stay within a safe temperature range — even accounting for if the package is sitting outside for hours after delivery.

Specialty prescription drugs, including injectable drugs with special handling requirements, are usually shipped through commercial mail and shipping carriers, such as UPS and Federal Express. Specialty drugs requiring refrigeration are typically shipped for overnight delivery, often through common carriers other than the United States Postal Service.

The safety and efficacy of mailed prescriptions is of utmost importance and is well reflected in the level of precision and planning undertaken by mail-service pharmacies in the mailing of prescription drugs, including those with special handling requirements. The precision also reflects the needs and preferences of consumers not only for safe, high-quality products, but also to know when their prescription will be shipped and received[1]. For example, as required by CMS, Medicare Part D plan sponsors require their network mail-service pharmacies to provide enrollees an approximate shipping date range, of within two-to-three days, prior to delivery.[2] Mail-service pharmacies offer enhanced safeguards for safety and accuracy. Before shipping a prescription to a patient's home, mail-service pharmacies' staff pharmacists electronically review the patient's medications to detect adverse drug reactions, especially any potentially harmful drug-to-drug interactions — even when the patient uses several pharmacies. This information may not be available to a patient's physician without an interoperable health record system.

Specialty pharmacies and mail delivery are tools used in pharmacy networks because they ensure high-quality drug delivery service, avoid waste, and ensure appropriate use of the medications. In limiting the choice to allow white bagging, this bill is likely to substantially increase costs for both North Dakota consumers, health plans and employers.

This bill will also prohibit employers and health plans from designing an employee benefit plan that relies on preferred pharmacy networks to increase pharmacy quality and access and reduce costs to consumers. We appreciate the idea of patient choice, but we cannot ignore the cost to both health plans and more importantly patients. A recent North Dakota State University report indicated that "in 2019 North Dakotans spent nearly $1.5 billion on prescription drugs…[which] ranks amongst the highest per capita expenditures in the country"[3].

In addition, our research shows that in the first year alone, restricting white bagging and the use of preferred pharmacy networks and mail-order pharmacies will cost North Dakotans $50 million in excess drug spending and $600 million over the next 10 years. We all want to do something about the high cost of prescription drugs, the question we have is why would you add more

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[1] CMS, "Clarifications to the 2014 Policy on Automatic Delivery of Prescriptions" (December 12, 2013).
[2] Op. cit, CMS (December 12, 2013).
[3] March, Raymond J. "Pharmaceutical Price Controls Destroy Innovation and Harm Patients". Challey Institute for Global Innovation and Growth at North Dakota State University. (December 2022).

restrictions or mandates that would increase costs to the already high prescription drug prices for the residents of North Dakota?

It is for these reasons we respectfully request that you reject SB 2378.

Thank you. I appreciate the Committee's time and attention to our concerns and am available for questions.

North Dakota SB 2378 Will Cost the State Over $600 Million In Increased Prescription Drug Costs

The core mission of pharmacy benefit managers (PBMs) is to reduce prescription drug costs for health plan sponsors so that consumers have affordable access to needed prescription drugs. PBMs offer a variety of services to their health-plan-sponsor clients and patients that improve prescription adherence, reduce medication errors, and manage drug costs.

The proposed North Dakota legislation will seriously undermine the ability of PBMs to control drug costs, and as a result drug spending in North Dakota will soar. Although some of the provisions are subject to interpretation, enacting just the bill provisions discussed below could cost the state of North Dakota **$50 million in excess drug spending** in the first year alone, and **$607 million** over the next 10 years.

SB 2378 would restrict the use of preferred pharmacy networks and mail-order pharmacies.

- PBMs require pharmacies to compete on service, price, convenience, and quality to be included in preferred networks. Pharmacies that agree to participate in such arrangements are designated as 'preferred' and become members of a preferred pharmacy network. These types of networks have gained traction among plan sponsors and deliver tangible out-of-pocket savings for patients.
- Nearly 80% of employers believe that mail-order specialty pharmacies are the lowest-cost site of service compared with retail community pharmacies and other options.[1] This bill guts the ability for health plans and PBMs to create preferred pharmacy networks for plans by mandating an "any willing provider" requirement. According to the FTC and academic analysis, this type of mandate leads to less competition and higher prices for consumer.[2]

SB 2378 would ban white bagging

- Under a white bagging model, a specialty pharmacy ships the drug for a given patient directly to the health care provider rather than the provider buying the drug and billing the insurer. The cost of these drugs through specialty pharmacies is lower than through the traditional "buy-and-bill" model.
- Legislation that would bar health insurers from implementing white bagging will seriously undermine the ability of health plans and PBMs to manage their medical specialty pharmacy expenditures, and as a result, drug spending in North Dakota would soar. Use of white bagging has real benefits for patients, providers, and health plan sponsors.

Projected 10-Year Increases in Prescription Drug Spending In North Dakota, 2023–2032 (Millions)

	Self-Insured Group Market	Fully-Insured Group Market	Individual Direct Purchase Market	Medicaid	**Total**
Restrict preferred pharmacy networks and mail-order pharmacies[3]	$136	$132	$37	$8	$313
Restrict White Bagging	$116	$112	$31	$35	$294
Maximum Costs – Two Provisions	**$252**	**$244**	**$68**	**$43**	**$607**

Methodology: The methodology used to create these cost projections for adopting pharmacy restrictions was that used by Visante in the January 2023 paper "Increased Costs Associated With Proposed State Legislation Impacting PBM Tools." The methodology used to create the white bagging cost projections is described in "Appendix: White Bagging Dispensing."

1. Trends in Specialty Drug Benefits, PBMI, 2018
2. "Contract year 2015 policy and technical changes to the Medicare advantage and the Medicare prescription drug benefit programs," FTC letter to CMS, Mar. 7, 2014.
3. Note: North Dakota may already use some form of AWP rules. Estimated cost increases are based on comparing "with vs without AWP."

PCMA

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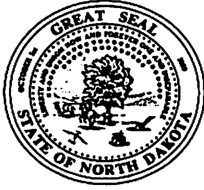

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State of North Dakota
Doug Burgum, Governor

Mark J. Hardy, PharmD
Executive Director

Senate Bill No 2378 – Clinician Administered Drugs

House Human Services Committee – Pioneer Room
2:45 PM - Tuesday – March 14, 2023

Chair Weisz, Members of the House Human Services Committee for the record I am Mark Hardy, Executive Director of the North Dakota State Board of Pharmacy. Thank you for the opportunity to testify on this important legislation.

The Board of Pharmacy is aware of the business model this legislation is focused on when the dispensing and administration of medications are completed by different practitioners. This practice is labeled as "*white*" or "*brown*" bagging models. These models have been increasing in nature given the rising number of medications that have significant costs associated with them. In many cases the patient's healthcare plan dictates requirements to use a specific pharmacy on these medications, often owned by the Pharmacy Benefit Manager for the plan, which restricts the patient's ability to utilize the pharmacy of their choice.

The nature of many medications requires special handling, storage and shipping challenges. In these models, the burden falls on the practitioners and dispensing pharmacists to ensure each medication is safe and effective for administration. As the drug supply chain moves to implement the federally enacted Drug Supply Chain and Security Act these "bagging" models may be scrutinized, given the unique chain of custody.

There are many patient safety concerns around these practices, which is the forefront of the Board's support of this legislation. We have had several complaints and concerns from patients about delays and issues with the delivery of pharmaceuticals into the state. If a patient desires their services to be obtained from a mail order pharmacy, then that is understandable, and they are accepting of the services they receive. However, when forced into using models of care that they do not desire it creates consternation, especially when things do not go as expected.

The nature of these delivery models puts healthcare professionals in an uncomfortable position, where they do not know how drugs were stored or handled and are unable to assure that they were not adulterated or misbranded in some way prior to administering them to a patient. This is why some health systems have not allowed these models of care to occur in their facilities, which leads to patients trying to determine where they can get their care. Also, these models lead to fragmentations in the patient's prescription services which prevents pharmacists from having a full picture of the patient's therapies to ensure optimal therapeutic outcomes.

This could result in missing drug interactions, duplicative therapies or other safeguards the patient should be afforded in their care.

The Board would always advocate for patient's choice to assure the patient has the opportunity to choose the pharmacy they feel best meets their pharmaceutical care needs and not be required to use a location based on the third party's requirements.

Another consequence which occurs when a patient choice is lost is when their insurance changes the patient's consistency of pharmacy services are disrupted. This causes much unnecessary stress and difficulty in reestablishing their models of care.

We appreciate the opportunity to testify on Senate Bill 2378.

I'd be happy to answer any questions.

2023 Senate Bill no. 2378
House Human Services Committee
Representative Robin Weisz, Chairman
March 14, 2023

Chairman Weisz and members of the House Human Services Committee, I am Erik Christenson, CEO, Heart of America Medical Center, in Rugby, North Dakota. I testify on behalf of the North Dakota Hospital Association (NDHA). NDHA represents hospitals and health care systems across the state. I testify in support of Senate Bill 2378. We ask that you give the bill a **Do Pass** recommendation.

I wish to share with the house members of the State of North Dakota my experience and knowledge as a pharmacist and administrator in a rural health care setting as it pertains to this legislation. I have practiced as a pharmacist in this state since 1999 and I have been a hospital CEO since 2020. Much of my professional life has been dedicated to providing health care to rural North Dakotans and I have a passion to assure that these patients continue to have viable access to good health care.

In order for rural health care to be able to continue in North Dakota, hospitals will need resources. In particular, human, and financial resources. This legislation will help to assure both of these resources are available to our patients in our communities.

One of the main points made by the insurance companies and their pharmacies is that they can save the health care system and, therefore, our patients and businesses, money. That statement makes sense if it were their goal or mission. However, why is it that they are stepping into the care delivery model in the form of providing medications? One must ask if there is a profit motive in trying to corner this part of the health care delivery model.

Over the past ten years, in which insurance companies and their pharmacies have continued to expand services and force people to their care, the cost of drug expenditures continues to skyrocket. From 2012 to 2022, the annual prescription drug expenditures for Medicare have increased from $67.5 Billion to $143.2 Billion. (CMS, 2023) The narrowed networks created by the large pharmacies, pharmacy benefit managers, and insurers are not allowing for a competitive environment that would help reduce costs. Instead, these

large companies are cornering the market and forcing our communities to pay more for needed medications.

Hospitals are not the bad guys in this equation. In 2010, hospitals and clinical services accounted for 51 percent of the national health care expenditure. (Martin, 2010) In 2020, hospitals and clinical services accounted for 45 percent of the expenditures. (AMA, 2023) In raw dollars that is pay cut of $247 billion. The hospitals are doing their part to cut costs and still provide excellent care. Where is the money going?

In 2022, half of all hospitals had a loss in operations. (Muoio, 2023) This past year, Kaiser Permanente posted a $4.5 billion loss in operations. (Glaidkovskaya, 2023) Over this same year, the big payers or insurance companies had record profits. United Health Group profited $20.6 billion, Cigna profited $6.7 billion, CVS Health profited $4.2 billion, and Humana profited $2.8 billion. (Thomas & Emerson, 2023) The data does not support the premise that these companies will save our communities money. Instead, it appears that they will cherry pick the most profitable parts of the health care delivery model and push those profits to their companies. In the wake of this practice, they will leave the small rural hospitals with scraps to care for the complex health needs of our communities.

One of most critical programs for vulnerable hospitals is the 340B drug pricing program. This program provides significant dollars to rural hospitals allowing them to continue to provide lifesaving services to low-income patients and those living in rural communities. This is a budget neutral program when administrated correctly that is very successful. However, when insurance companies are allowed to corner the medication market and remove the ability of hospitals to purchase medications, these 340B dollars are no longer available to these same hospitals. Instead, the insurance company and their own mail order pharmacies are able to capture these drug rebates. In fact, a recent analysis indicated that pharmacy benefit manager-controlled pharmacies operated by Walgreens, Caremark, Express Scripts, and OptumRx have siphoned away $2.58 billion from the 340B program. (Okon, 2022) That is $2.58 billion that will not be used to help vulnerable or rural patient populations.

You will hear the insurers talk about the increased charges by hospitals for these medications. However, they are not comparing apples to apples. What a hospital charges has little to do with the final costs of health care. What determines the costs of health care is the contractual agreement with the payer. The vast majority of hospital bills are paid through a payer such as Medicare or commercial insurance. These insurance companies have contractual agreements that determine the reimbursement for products and services rendered. It does not matter whether a hospital charges $5,000 or $500 for a drug. If the

insurance company pays the hospital $350, that is what the hospital will get. Contractual write-offs are a big part of the hospital financial system. When an insurance representative is complaining that the hospital is getting paid too much for medication, they are complicit with that payment.

Finally, I want to highlight the problem of allowing insurers to enforce limited access to medications in the form of mail order delivery by summarizing the experience of a North Dakota hospital infusion center. In many cases, the process set up by the insurance company requires the hospital to get prior authorization 10-15 days before initial shipment. It then takes another 3-5 days to process the order. Finally, there must be an authorization of shipment with the patient. It generally requires the hospital to contact the insurer 6-10 times during this set up process and about 8 hours of time on the phone to complete. In many cases, the medication shipment is delayed or interrupted during this process. There are documented cases of treatments being delayed due to this inefficient and unnecessary process. In the end, this process costs the patient in time due to rescheduled appointments and quality in delayed care. The hospital must spend more resources to accomplish this process. A recent survey found that the white bagging process increases hospital expenditures by $310 million. (Vizient, 2021) The insurance company makes extra profit by cornering the medication market and drug rebates, but they are not ultimately responsible for the patient. The hospital must pay more to provide the appropriate care for their patients.

In summary, I support the passage of this legislation as I feel that it is important to assure that our citizens have access to good care and that large out of state companies do not inhibit that access. This bill will support rural hospitals and help assure that we have access to the medications we must provide to our patients. This access must be readily available under normal supply chains and not limited in order to support the bottom lines of big business. There is good reason to believe that limited drug delivery models do not save money for the patients or the community as a whole and, in fact, can hamper affordable care. Good health care is important to North Dakotans, and I feel this bill will help to assure good health care in our state.

Please give the bill a **Do Pass** recommendation. I would be happy to respond to questions.

Respectfully,

Erik Christenson, CEO
Heart of America

References:

AMA (2023). Trends in health care spending. *American Medical Association.* Retrieved from: *https://www.ama-assn.org/about/research/trends-health-care-spending*

CMS (2023). National Health Expenditure Data. Centers for Medicare and Medicaid Services. Retrieved on February, 5 2023. https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet

Gliadkovskaya, A. (2023) Kaiser Permanente posts $4.5B net loss in 2022, driven by rising costs, investment losses. *Fierce Healthcare.* Retrieved from: https://www.fiercehealthcare.com/providers/kaiser-permanente-posts-45b-net-loss-2022-driven-rising-costs-investment-losses

Martin A.B. et al. (2010). Growth in US health spending remained slow in 2010. *Health Affairs, 2012.* Retrieved from: https://www.nlm.nih.gov/nichsr/stats_tutorial/section1/mod4_costs.html

Muoio, D. (2023) Hospitals faced worst financial year since the start of the pandemic in 2022, Kaufman Hall data show. *Fierce Healthcare.* Retrieved from: https://www.fiercehealthcare.com/providers/approximately-half-us-hospitals-end-2022-negative-operating-margin

Okon, T (2022). Hospitals and for-profit PBMs are diverting billions in 340B savings from patients in need. *Statnews.com* Retrieved on February 6, 2023 from: https://www.statnews.com/2022/07/07/for-profit-pbms-diverting-billions-340b-savings/

Thomas N. & Emerson J. (2023). Large health system vs. payer profits in 2022. *Becker's* Retrieved from: https://www.beckerspayer.com/payer/large-health-system-vs-payer-profits-in-2022.html

Vizient (2021). Survey on the patient care impact and additional expenses of white/brown bagging. Retrieved from: https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/noindex/whitebaggingreport.pdf

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House Human Services Committee – SB 2378
Chairman Robin Weisz
March 14, 2023

Chairman Weisz and members of the committee, for the record, my name is Mike Schwab, Executive Vice President of the North Dakota Pharmacists Association. We are here today in support of SB 2378.

SB 2378 is looking to address a number of problems and concerns many healthcare providers and facilities are experiencing as it relates to clinician administered drugs and the patient care process. Prior to last session, our office was approached with a request to address what we in the world of pharmacy call “white bagging” and “brown bagging” issues. The request came late and we ran out of time. However, since last session, we have heard from members in all parts of the state regarding an increase in insurance mandates requiring patients to have their therapies/medications exclusively dispensed by an insurer or pharmacy benefits manager (PBM) mail order pharmacy or PBM mail order affiliates.

It is important to note, the big three insurance companies are all now vertically integrated and control 80% of the health plan pharmacy benefit market. The big three are CVS/Caremark/Aetna (#4 on Forbes), United Health/Optum Rx (#5 on Forbes) and Cigna/Express Scripts (#12 on Forbes). They are all in the business of pharmacy owning mail order pharmacies, brick and mortar pharmacies and specialty mail order pharmacies.

What is “white bagging”? This process happens when a PBM or insurer mandates certain drugs are to be delivered to a healthcare practice which, are then supposed to be administered to the patient. The drugs have to come from an external source which is most often the PBMs mail order pharmacy or PBM affiliate pharmacies. This process causes numerous issues and concerns for healthcare providers and patients. While PBMs argue that white bagging lowers healthcare costs, healthcare providers say the practice captures more revenue for the PBMs and may violate patient standards of care. White bagging can also bypass pharmacy safety checks, health system formularies,

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supply chain integrity and interferes with the care planning processes. There is a high level of coordination and timing that has to take place with white bagging policies as well. In addition, dosing errors, delivery delays, lost shipments and receiving the wrong drug happens which negatively impacts patient outcomes, delays patient care, may require another appointment and can create drug waste. There are a whole host of other patient and clinical considerations to think about as well. Those considerations include the inability to adjust drug dosages in response to urgent laboratory or clinical findings. When these types of issues happen due to the insurer/PBM anti-competitive mandate requirements, we are actually increasing costs.

What is “brown bagging”? This process is similar to white bagging with one main difference. In this case, the drug comes directly to the patient and is in the patient’s custody. The many reasons listed above related to white bagging apply to brown bagging as well. However, there are a couple of additional important points worth noting. Under this process, there are elevated safety and product integrity concerns. A provider’s liability risk is also elevated under these types of patient steering arrangements.

In 2021, Vizient, Inc released a survey of hospital respondents titled “Survey on the patient care impact and additional expense of white/brown bagging”. There are a number of highlights worth noting from the survey. It was estimated that health systems are spending $310 million annually in estimated labor required to manage the additional clinical, operational, logistical and patient care work associated with these kinds of PBMs mandates. It was also noted in the survey that 92% of the respondents experienced patient care issues due to problems with medication received through these PBM mandates. The top issues respondents reported:

- 83% - Product did not arrive in time for administration to the patient.
- 66% - Product delivered was no longer correct due to updated patient treatment course or dose needing to be changed.
- 42% - Product delivered is inappropriate or the wrong dose.

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You will hear PBMs state that these types of mandated requirements save money. The Auditor of the State of Ohio produced a state report which found discriminatory reimbursement practices because the PBMs compensated their affiliate pharmacies at a higher rate than other providers. (Candisky, Cathy – Columbus Dispatch - April 30, 2019). This same type of practice has been found to be taking in many other states as well. Arkansas for example found the PBMs were steering patients to its wholly owned affiliate so that it could pay itself more and was in fact paying itself more. (Arkansas Study and Arkansas Department of Insurance Report – October 2020). An analysis in Florida in 2020 showed PBM affiliated pharmacies were making, 18x to 109x more profit over the cost of the drugs than the non-affiliated pharmacies. In Florida, specialty drugs are not only steered to PBM-affiliated pharmacies, but they are also more expensive at the PBM affiliated pharmacies. (3 Axis Advisors - January 2020). The State of Oklahoma also found PBM owned and affiliated pharmacies were reimbursing themselves at higher rates. Minnesota, Wisconsin, Florida and other states have expressed concerns over the practice of PBMs steering patients to PBM-owned pharmacies.

States, such as Louisiana, Virginia, Arkansas, Georgia, and others have already passed laws in an attempt to stop PBM steering and mandated mail order practices by the PBMs. Other states (like ND) are attempting to do the same. In January of 2023, Governor Ron DeSantis and the State of Florida announced an aggressive comprehensive PBM reform platform. He announced many PBM reforms but two specific reforms deal with consumer protections just like SB 2378. Two main reforms protecting small businesses and patients deal with (1) prohibiting PBMs from mandating consumers use a PBM mail-order pharmacy while allowing consumers to opt-into the service and (2) prohibit anti-competitive PBM practices such as mandating a narrow network that only includes PBM owned or affiliated pharmacies.

In 2022, the Federal Trade Commission (FTC) launched an inquiry into PBM business practices, contracting practices and potential anticompetitive behavior and its impact on the industry and consumers/patients. The FTC has a number of topics they are looking into and some of those topics speak to what we are talking about today.

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- FTC Topic – The impact of PBM rebates and fees on formulary design and patients' ability to access prescribed medications without endangering their health, creating unnecessary delay, or imposing administrative and other burdens on patients and providers.
- FTC Topic – PBMs use of methods to steer patients away from non-affiliated PBM pharmacies and methods of distribution towards PBM-owned and affiliated pharmacies.
- FTC Topic – PBMs policies and practices related to specialty drugs and pharmacies, including criteria for designation and practices for encouraging the use of PBM affiliated specialty pharmacies, and practices relating to dispensing high-cost drugs over alternatives.

This year, in March 2023, the U.S. House Oversight and Accountability Committee announced it is launching an investigation into PBMs over alleged anti-competitive tactics according to a press release by Chairman James Comer (R-KY). Committee members previously analyzed PBMs in a December 2021 report, and found that PBM consolidation has raised costs for consumers and has negatively impacted patient health. Chairman Comer sent letters to all the major PBMs and the letters are worth the read. (March 2023 – House Oversight Committee).

There are others who would like to testify today so let me conclude by asking once again for your support of SB 2378. When it comes to clinician administered drugs, they should be dispensed as close to the patient's point of care as possible. We should do our best to support product integrity and minimize as many risks and safety concerns as possible for patients. SB 2378 gives patients the right and choice to determine which participating provider they want providing their care and the right to determine from whom they purchase services. Thank you for your time. I will try to do my best to answer any questions.

Respectfully submitted,

Mike Schwab
NDPhA – EVP

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References:

Source: 3 Axis Advisors. (January 2020). Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis. https://www.3axisadvisors.com/projects/2020/1/29/sunshine-in-the-black-box-of-pharmacy-benefits-managemen

Candisky, Cathy. (April 30, 2019). Ohio Medicaid officials to crack down on PBM specialty drug practice. Columbus Dispatch. https://stories.usatodaynetwork.com/sideeffects/ohio-medicaid-officials-crack-pbm-specialty-drug-practice/

Source: Rowland, Darrel. (October 27, 2021). Medicaid chief quietly drops bombshell: Millions obtained by PBMs unaccounted for by state. Columbus Dispatch. https://www.dispatch.com/story/news/2021/10/27/health-care-monopoly-rais es-drug-costs-consumers-pharmacists-say-pbms-prescription-cvs-united-cy gna/8513593002

Arkansas study: Reimbursements are higher for national chains | NCPA – Link to Arkansas Department of Insurance report included as a link as well.

Vizient, Inc. – 2021 Survey on the Patient Care Impact and Additional Expense of White/Brown Bagging: Survey on patient care impact (vizientinc.com)

Florida Governor Ron DeSantis - Lower Prescription Drug Prices_ (flgov.com)

July 2022 - FTC Launches Inquiry Into Prescription Drug Middlemen Industry | Federal Trade Commission

March 8, 2023 - Comer Launches Investigation into Pharmacy Benefit Managers' Role in Rising Health Care Costs - United States House Committee on Oversight and Accountability

Support Updates to SB 2378 to Protect North Dakotans from High-Cost Drugs, While Providing Choice

Everyone should be able to get the medications they need at a cost they can afford. But drug prices are out of control, and hardworking families feel the consequences every day. Health insurance providers are fighting for patients by developing innovative solutions to make prescription drugs more affordable. One of these solutions is leveraging the use of lower-cost pharmacies – called specialty pharmacies – to safely distribute clinician-administered drugs (sometimes called either "white bagging" or "brown bagging").

As proposed, SB 2378 limits consumer choice and will increase health care costs for North Dakotans. SB 2378 eliminates the tools utilized by health plans to address high-cost clinician-administered drugs by narrowing and eliminating efforts to cut wasteful spending within the drug cycle. Of greatest concern is the restriction on where health plans can purchase clinician-administered drugs, which are typically the most expensive drugs, and treat diseases such as cancer, multiple sclerosis, and Rheumatoid arthritis. Data illustrates hospitals include exorbitant markups on clinician-administered drugs:

> **Costs per SINGLE treatment for drugs administered in hospitals were an average $7,000 more than purchased through pharmacies. Hospitals, on average, charged DOUBLE the prices for the same drugs, compared to specialty pharmacies.**

Health plans utilize specialty pharmacies (pharmacies that meet specific and rigorous standards to handle very sensitive drugs, such as cold storage) to ship drugs directly to hospitals to bypass their profit markups. Cost savings are then utilized to lower consumer's out of pocket costs or premiums.

Amendment Language Is Needed:

Amendment language for SB 2378 provides:

- Specialty pharmacies will work closely with hospitals and patients to deliver medications effectively and safely, while providing consumers protections from hospitals' exorbitant markups, saving patients thousands of dollars.
- The ability for pharmacies to be considered a vendor of specialty drugs if they meet rigorous safety standards to protect patient safety, while providing a seamless experience for patients.
- Limiting the circumstances when health plans may purchase clinician-administered drugs from specialty pharmacies and ship them to hospitals.
- Requiring health plans and PBMs to include appeals and exceptions within their programs, such as when a drug prescription changes, and on-site drugs are required to be used.

Myth v Fact:

Myth: SB 2378 is necessary to protect pharmacists from health plans and PBMs circumventing their services.
Fact: This is false. North Dakota law includes an "Any Willing Pharmacy" which requires payors to add any pharmacy to join a payors network if they can be credentialed and meet specified cost, quality, and service requirements.

Myth: There are safety concerns when drugs are mailed to a hospital or patient from an outside source.
Fact: This is false. Specialty pharmacies employ sophisticated supply chain processes to ensure products shipped are equipped with packaging specific to the safety standards required with each individual drug.

Myth: Health plans/PBMs use these methods to favor specific pharmacies.
Fact: This is false. If hospitals charged the same price as other suppliers, payors would reimburse them directly.

AHIP strongly urges the Human Services Committee to support updates to SB 2378 to support competition among providers and to not take away lower-cost choices from patients.

Prepared by the Legislative Council staff for
Senator K. Roers
March 13, 2023

PROPOSED AMENDMENTS TO SENATE BILL NO. 2378

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to create and enact a new section to chapter 26.1-36 of the North Dakota Century Code, relating to health insurance coverage of clinician-administered drugs; and to amend and reenact section 26.1-36-12.2 of the North Dakota Century Code, relating to freedom of choice for pharmacy services.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 26.1-36-12.2 of the North Dakota Century Code is amended and reenacted as follows:

26.1-36-12.2. Freedom of choice for pharmacy services.

1. ~~No~~A third-party payer, including a health care insurer as defined in section 26.1-47-01, providing pharmacy services and prescription drugs to any beneficiary may not:
    a. Prevent a beneficiary from selecting the pharmacy or pharmacist of the beneficiary's choice to provide pharmaceutical goods and services, provided that pharmacist or pharmacy is licensed in this state;
    b. Impose upon any beneficiary selecting a participating or contracting provider a copayment, fee, or other condition not equally imposed upon all beneficiaries in the plan selecting a participating or contracting provider; ~~or~~
    c. Deny ~~any~~a pharmacy or pharmacist the right to participate as a preferred provider under chapter 26.1-47 or as a contracting provider for ~~any~~a policy or plan, provided the pharmacist or pharmacy is licensed in this state, and accepts the terms of the third-party payer's contract; or
    d. Require a patient to purchase pharmaceutical goods and services, except specialty drugs as defined under section 19-02.1-16.2, exclusively through a mail order pharmacy or a pharmacy owned by a pharmacy benefits manager.
2. Notwithstanding the provisions of subsection 1, the department of health and human services may exclude, from participation in the medical assistance program administered under chapter 50-24.1 and title XIX of the Social Security Act [Pub. L. 89-97; 79 Stat. 343; 42 U.S.C. 1396 et seq.], as amended, any provider of pharmacy services who does not agree to comply with state and federal requirements governing the program, or who, after so agreeing, fails to comply with those requirements.

3. ~~Any~~A provision in a health insurance policy in this state which violates the provisions in subsection 1 is void.

4. ~~Any~~A person ~~who~~that violates this section is guilty of a class A misdemeanor and each violation is a separate offense. The commissioner may levy an administrative penalty not to exceed ten thousand dollars for a violation of this section.

5. The commissioner may not require a third-party payer that is a self-insurance plan governed by the federal Employee Retirement Income Security Act of 1974 [Pub. L. 93-406; 88 Stat. 829; 29 U.S.C. 1001 et seq.] to comply with this section.

6. The ~~insurance~~ commissioner shall enforce ~~the provisions of~~ this section.

SECTION 2. A new section to chapter 26.1-36 of the North Dakota Century Code is created and enacted as follows:

Clinician-administered drugs.

1. As used in this section, "clinician-administered drug" means an outpatient prescription drug, other than a vaccine that:
   a. Cannot reasonably be self-administered by the patient to whom the drug is prescribed or by an individual assisting the patient with the self-administration; and
   b. Is typically administered:
      (1) By a health care provider authorized to administer the drug, including when acting under a physician's delegation and supervision; and
      (2) In a physician's office, a hospital outpatient infusion center, or other clinically supervised setting.
2. A third-party payer, including a health care insurer as defined under section 26.1-47-01, may not require a clinician-administered drug to be dispensed by a pharmacy selected by the third-party payer and delivered to a participating or contracting provider for administration.
   a. This subsection does not apply if the third-party payer has offered a participating or contracting provider administering a clinician-administered prescription drug the ability to participate in the third-party payer's network on the same terms and conditions the third-party payer offers to the third-party payer's preferred providers.
   b. A third-party payer that requires a clinician-administered drug to be dispensed by a pharmacy selected by the third-party payer under subdivision a shall provide a process by which a provider administering a clinician-administered drug may request an exception if:
      (1) A delay caused by the pharmacy makes it impossible for the patient to receive the drug as scheduled; or

(2) Damage to the drug occurs which causes the drug to be unsafe to administer to the patient.

c. A pharmacy that dispenses a covered clinician-administered drug:

(1) Must be properly licensed in the state as a pharmacy and be accredited by a nationally recognized accrediting body for specialty pharmacy as a specialty pharmacy.

(2) Must have policies in place for safety recalls which are consistent with national accreditation standards for safety recalls issued by a nationally recognized accrediting body for specialty pharmacy.

(3) Shall provide tracking details to the prescribing provider for the shipment of a covered clinician-administered drug and shall require a signature upon receipt of the shipment when shipped to a physician's office to the extent required to do so by the nationally recognized pharmacy accreditation body by which the pharmacy is accredited.

(4) Shall require advance confirmation of the date, time, and place of delivery of a covered clinician-administered drug by the prescribing provider's office or the member.

(5) Shall employ appropriate packaging or other environmental safety controls to ensure clinician-administered drugs remain at the appropriate temperature, as indicated by the manufacturer, through all stages of supply and shipping to the extent required to do so by the nationally recognized pharmacy accreditation body by which the pharmacy is accredited.

(6) Shall maintain at all times pharmacist or nurse availability for prescribing clinicians and patients to ask questions.

d. A third-party payer that requires a clinician-administered drug to be dispensed through one or more designated pharmacies shall establish a process to allow for appeals and exceptions to these limitations.

3. A third-party payer, including a health care insurer as defined under section 26.1-47-01, may offer, but may not require, the use of a pharmacy to dispense a clinician-administered drug directly to a beneficiary with the intention the beneficiary will transport the drug to a provider for administration.

4. The insurance commissioner may not require a third-party payer that is a self-insurance plan governed by the federal Employee Retirement Income Security Act of 1974 [Pub. L. 93-406; 88 Stat. 829; 29 U.S.C. 1001 et seq.] to comply with this section."

Renumber accordingly