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Memo

Date: September 27, 2022

To: Scott Miller
Executive Director, North Dakota Public Employees Retirement System

From: Tim Egan & Dan Plante & Drew Rasmussen, Deloitte Consulting LLP

Subject: **REVIEW OF PROPOSED BILL 23.0092.01000**

The following summarizes our review of the proposed legislation as it relates to the uniform group insurance program administered by NDPERS.

OVERVIEW OF PROPOSED BILL

The proposed bill would create and enact chapter 19-25 of the North Dakota Century Code (NDCC), relating to a prescription drug reference rate pilot program; to provide for a legislative management report; to provide a penalty; and to provide an expiration date.

The bill would impose price controls on prescription drugs by implementing reference rate pricing using four Canadian provinces (Ontario, Quebec, British Columbia, and Alberta). The insurance commissioner will be required to set a list of the 25 most costly prescription drugs utilized each year. The insurance commissioner will determine the referenced rate for each drug by comparing the wholesale acquisition cost (WAC) of each drug to the Canadian drug cost in each of the identified provinces in order to choose the lowest rate. The bill requires that savings derived from the application of the reference price be used directly to reduce cost for members.

The entire supply chain, including but not limited to pharmacies in North Dakota, entities that purchase prescription drugs on behalf of members, health plans that provide pharmacy benefit management services, manufacturers, distributors, and wholesalers would be required to comply with the referenced rate prices with monetary and criminal penalties for non-compliance.

ESTIMATED FINANCIAL IMPACT

In January 2021, Deloitte Consulting ("Deloitte") reviewed the proposed Senate Bill 21.0611.01000 and was unable to estimate the actuarial impact of the bill based on the information available, the number of assumptions that would need to be made, and the uncertainty of how the bill could be implemented and administered.

Our review of Bill 23.0092.01000 shares the same considerations.

For illustrative purposes, Deloitte collected data from Sanford Health Plan for the first six months of calendar year 2022 and identified the five most costly prescription drugs on a total expenditure basis (Table 1). Deloitte compared NDPERS' average gross paid per prescription for each of the five identified prescription drug products to the Canadian benchmarks identified in the bill. The average

gross paid per prescription amount is the amount paid by NDPERS and members divided by the total number of prescriptions. This amount represents the amount paid after the application of Sanford Health Plan drug discounts but before drug rebates. The comparison illustrates that, prior to rebates, the Canadian prices are substantially lower than the price paid by NDPERS.

The legislation mandates that the ceiling price of the drug be determined by comparing the lowest cost among the Canadian benchmark sources and the wholesale acquisition cost of the drug. Of note, the wholesale acquisition cost is the price set by the manufacturer for wholesalers or direct purchasers and is not the amount that is paid by NDPERS today.

Table 1

(a)		(b)	(c)	(d)	(e)	(f)	(g)	(h) =(g)−(b)
2022 Total Cost Rank	Drug Name	NDPERS Average Gross Paid/ Prescription[1]	Canadian Benchmark Price[2] (USD)				Lowest Canadian Benchmark Price	NDPERS Gross Paid vs Canadian Benchmark
			Alberta	British Columbia	Quebec	Ontario		
1	HUMIRA	$8,680	NOT COVERED	NOT COVERED	$1,428	$1,156	$1,156	($7,525)
2	STELARA	$23,872	$3,250	$3,510	$3,138	$3,343	$3,138	($20,734)
3	OZEMPIC	$1,060	$148	NOT AVAILABLE	$142	$223	$142	($918)
4	TRIKAFTA	$31,620	$17,117	$17,117	$17,117	NOT AVAILABLE	$17,117	($14,504)
5	DUPIXENT	$3,714	$1,425	NOT COVERED	$1,366	NOT AVAILABLE	$1,366	($2,348)

1. Average Gross Paid Per Prescription is the total drug cost (including plan paid and member paid after discounts but before rebates) divided by the total number of prescriptions in the first six months of 2022
2. Canadian Benchmark Sources: Alberta Interactive Drug Benefit List (https://idbl.ab.bluecross.ca/idbl/load.do;jsessionid=fBeA3SRo_xDzSo5sX3ygGvrdeLUmYY9fqCBccjL7ui-O6M9RzsAq!2135156315?reset=true&_cid=584a3c61-954e-489b-a40c-189a197f1a9a) , British Columbia PharmaCare Formulary Search (https://pharmacareformularysearch.gov.bc.ca/SearchResults.xhtml), Quebec Régie de l'assurance maladie, List of medications (https://www.ramq.gouv.qc.ca/en/media/13896), Ontario Drug Benefit Formulary/Comparative Drug Index (https://www.formulary.health.gov.on.ca/formulary/)
3. Canadian Benchmark Price equals the Canadian unit price multiplied by the metric quantity (units) in the prescription package size. "NOT COVERED" indicates that the prescription drug was listed by the source as a non-covered product, "NOT AVAILABLE" indicates that the prescription drug was not identified on the source website or drug list.

The exercise illustrates that the proposed prescription drug reference rate pilot program would likely yield lower prescription drug costs for the most expensive drug products if the legislation can be implemented, operationalized, and complied with by the various stakeholders as proposed.

TECHNICAL COMMENTS

Deloitte's analysis of the proposed legislation generated considerations, clarifications, and potential stakeholder concerns, which are described below. In summary, there appear to be significant challenges to implementing and operationalizing a reference rate program.

Other State Examples

- The legislation is based on model language from National Academy for State Health Policy ("NASHP") https://www.nashp.org/an-act-to-reduce-prescription-drug-costs-using-international-pricing/
    - According the NASHP, there are six states (excluding North Dakota) that have introduced legislation based on the same model language: Hawaii, Maine, North Carolina, New York, Oklahoma, and Rhode Island.

- The proposed legislation failed to pass in New York but remains in committee in Hawaii, North Carolina, Oklahoma, and Rhode Island.

- Maine enacted legislation requiring an annual report on the potential savings if select drugs were subjected to a referenced rate beginning January 1, 2023. Maine's law does not include prohibitions and requirements for payors, pharmacies, manufacturers, and distributors

Methodology

- Consideration should be made for the methodology used to identify the costliest 25 prescription drugs. Each drug product has a National Drug Code (NDC), which is a product identifier used in the United States. The NDC includes information about the labeler (which may be a manufacturer, repackager, or distributor), the drug product itself (strength, dosage form, formulation), and packaging (package size and type). Some prescription drugs have many NDC numbers based on different manufacturers, strengths, and packaging. Identifying the most expensive prescription drugs based on brand-name, such as "Humira", would capture a greater percentage of cost since the methodology could be specified to include all NDCs for the brands identified. However, using brand-name could introduce additional complexity into the reference rate pricing process since the dataset would be larger and prices may need to reflect differences across product characteristics.

- Consideration should be made for the methodology used to calculate "net price" of the top 25 most expensive prescription drugs. Without definition, "net price" is unclear. "Net price" to the plan sponsor most commonly means the cost paid for a drug after discounts, dispensing fees, rebates, and member cost share. The "net price" paid by the plan may be different than that of the member. High-cost drugs may have additional patient financial assistance programs available, which are funded by drug manufacturers, and offer financial support to patients. To the extent that members receive funding from these programs, the cost of the drug may be substantially reduced or even free to them.

- The application of prescription drug rebates in the calculation of the "net price" will be an important factor in determining the "net price" since rebates can represent a significant percentage of the cost of the prescription drug.

- The methodology for calculating the savings is challenging. Drug costs may change over time based on price changes from the manufacturer, negotiated prices with pharmacies, and negotiated discounts and rebates with the health insurer.

    - A methodology that calculates the savings based on the "net price" paid by NDPERS prior to the implementation of the reference rate would likely need to be updated over time to avoid overestimating or underestimating savings.

    - The implementation of the reference rate may itself have an effect on utilization. If the drug price is lower, the product may be preferred to other alternatives and increase utilization. In this example, calculating savings based on actual utilization may overestimate savings compared to what utilization would have been had the reference rate not been in place.

- Implementation of the bill will require a process to regularly convert drug prices from the Canadian Dollar to the US Dollar and communicate the prices to all stakeholders.

Canadian Pricing

- The purpose of the bill is to reduce prescription drug costs for members in the State. Canadian drug prices are generally, although not comprehensively, lower than the prices in the U.S. One of the methodologies used in Canada to determine drug prices and coverage

determinations is the metric "quality-adjusted life-year ("QALY"). In the U.S., the Affordable Care Act prohibited the secretary of Health and Human Services from using the QALY under the Medicare program on the basis that the metric violates the Americans with Disabilities Act.

- Canada is implementing drug price reforms. On July 1, 2022, Canada implemented changes to the Patented Medicines Review Board regulations to revise the list of comparator countries used to determine drug prices (Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden and the United Kingdom). Using Canadian provincial drug prices to set the reference-price relies on Canadian pricing methodology and may be subject to change as Canada pursues additional drug price reform.

Member Savings

- The bill mandates that savings derived from reference rate pricing must be used to reduce costs directly for members. The mechanism of setting the ceiling prices for the identified drugs would create cost-avoidance and the resulting lower drug prices could result in lower premium increases from the health plan.
    - Lower aggregate drug costs should also be a factor in the development of fully-insured premium rates (however the health plan is not required to reduce premiums as a result of lower claims).
    - Members may or may not directly benefit from the reference rate pricing at the point of sale as NDPERS plan design requires members to pay a copay plus coinsurance until the member reaches an annual coinsurance maximum. Once a member meets their annual coinsurance maximum, they would no longer directly benefit from the lower drug cost at the point of sale.
    - The bill targets the 25 most costly prescription drugs utilized under the public employees retirement system health benefits. It is likely that the costliest drugs are not the most utilized drugs. The cost savings derived from the referenced drugs may reduce cost for a small portion of the NDPERS membership at the point of sale.

Penalties & Enforcement

- The bill establishes the penalty for purchasing a referenced drug for a cost higher than the referenced rate to be a class A misdemeanor. The penalty is applicable to state entities, health plans, and pharmacies licensed in the state.
    - It is important to clarify that NPDERS does not purchase prescription drugs. The pharmacies purchase prescription drugs from manufacturers or distributors, and the health plan negotiates reimbursements with pharmacies on behalf of NDPERS. The health plan may also purchase prescription drugs for mail distribution. NDPERS pays a premium to the health plan for services which include claim payments.
    - Pharmacies licensed in the state that are unwilling or unable to comply with the requirement for fear of penalty may elect to terminate participation in the pharmacy network offered by NDPERS through the health plan, which may have deleterious effects on the pharmacy and NDPERS members.
- The requirement that pharmacies licensed in the state may not purchase for sale or distribution a referenced drug for a cost that exceeds the referenced rate may create a burden on pharmacies. To the extent that the referenced drugs cannot be procured at the rate determined, pharmacies may stop stocking the referenced products. Since a majority of the 25 most costly prescription drugs are likely to be specialty drugs, it may be that the

access to some of the products is already more limited than non-specialty drugs. Specialty drugs frequently have temperature storage requirements or require special handling including clean room protocols and protective gear for pharmacists. A potential consideration during the identification of the costliest prescription drugs is to study member access to verify that the implementation will not create shortages or access constraints.

- It is unclear how North Dakota can assert jurisdiction on manufacturers and wholesalers incorporated in other states.
    - To the extent the manufacturers and wholesalers do not agree with the price controls required by this legislation, they could withdraw from the state and jeopardize access to medication for North Dakota residents.
    - Depending on the manufacturer, and the prescription drug, it may be more profitable for the manufacturers to maintain a policy of non-compliance and pay applicable penalties rather than participate in the reference-based pricing program.
    - Manufacturers may choose to participate in the reference-based pricing program and implement pricing strategies to regain revenue lost on the referenced drugs by increasing prices on other products.

Regulatory Considerations

- The reference rates required by this bill may conflict with federal most favored nation (MFN) requirements which restricts manufacturers from offering rates lower than what the federal government pays for Medicaid.
- The bill includes a prohibition of manufacturer withdrawal of referenced drugs and assesses a penalty "equal to $500,000; or the amount of annual savings determined by the commissioner under section 19 - 25 - 04, whichever is greater". Consideration should be given to the Commerce Clause of the U.S. Constitution (Article 1, Section 8, Clause 3) which gives Congress the power to regulate commerce and, in some interpretations, restrict states' authority to regulate commerce. The $500,000 could be challenged as discriminatory against interstate commerce or seen to cause an undue burden on interstate commerce. Deloitte Consulting is not licensed to practice law and NDPERS should consult with the appropriate legal representation.
- The bill does not make an explicit distinction for Medicare or Workforce Safety & Insurance ("Workers Compensation"). It is unclear if the intent of the bill is to apply the reference-rate pricing to these programs.