

HEALTH CARE COMMITTEE

Monday, August 18, 2025 Roughrider Room, State Capitol Bismarck, North Dakota

Representative Carrie McLeod, Chairman, called the meeting to order at 10:01 a.m.

Members present: Representatives Carrie McLeod, Karen Grindberg, Karen Karls, Lisa Meier, Jon O. Nelson, Mitch Ostlie*, Karen M. Rohr, Mary Schneider; Senators Judy Lee, Tim Mathern, Kristin Roers, Desiree van Oosting

Others present: Sarah Aker, Laura Anderson, Brendan Joyce, and Kodi Pinks, Department of Health and Human Services; Brooke Borlaug and Alyssa Wolden, Sakakawea Medical Center and Coal Country Community Health Center; Erik Christenson, Heart of America Medical Center; Dan Conrad and Megan Hruby, Blue Cross Blue Shield of North Dakota; Jon Godfread, Insurance Commissioner; Mark Hardy, State Board of Pharmacy; Bharath Krishnamurthy*, American Hospital Association; Gretchen Schilling, Sanford Health Plan

See <u>Appendix A</u> for additional persons present *Attended remotely

Ms. Katie Carpenter, Counsel, Legislative Council, presented a memorandum entitled <u>Supplementary</u> Rules of Operation and Procedure of the North Dakota Legislative Management.

PRESCRIPTION DRUG TRANSPARENCY REPORTING STUDY

Ms. Carpenter presented a memorandum entitled <u>Prescription Drug Transparency Reporting Study - Background Memorandum.</u>

Mr. Jon Godfread, Insurance Commissioner, provided testimony (<u>Appendix B</u>) relating to an overview of the federal Drug Discount Program. He noted:

- The federal Drug Discount Program, commonly called the 340B Program, was established in 1982 to allow certain health care providers, called covered entities, to purchase outpatient drugs at reduced prices.
- The original purpose of the program was to support safety net providers like federally qualified health centers, critical access hospitals, and rural clinics.
- Concerns raised regarding the program include providers potentially using the program as a revenue stream, savings not reaching patients and underserved communities, and a lack of accountability for manufacturers or providers.
- In 2010, federal guidance allowed covered entities to contract with an unlimited number of external pharmacies. Calls for reform fall into three categories: strengthened federal oversight, clearer definitions and enforcement, and greater transparency and accountability.
- A growing number of states require hospitals and other covered entities to report revenue from the program and how the funds are being used.
- Courts are split on whether states may regulate the 340B Program or if state regulation is pre-empted by federal law.

In response to questions from committee members, Mr. Godfread noted:

 The Insurance and Securities Department has not received direct complaints from consumers about the 340B Program.

• If reporting requirements are enacted by the Legislative Assembly, the department could collect the data and generate reports, provided the data reported is clearly defined.

Dr. Brendan Joyce, Pharmacy and Clinical Services Director, Medical Services Division, Department of Health and Human Services, provided testimony (<u>Appendix C</u>) relating to the relationship between Medicaid and the 340B Program. He noted:

- The federal Medicaid Drug Rebate Program requires a drug manufacturer to sign a drug rebate agreement to have the manufacturer's drugs covered under Medicaid.
- These agreements require manufacturers to provide Medicaid programs with rebates based on 340B Program pricing for qualified entities.
- When non-340B Program health care providers bill drugs to Medicaid, Medicaid reimburses for the drugs, and the Medicaid member receives the drug. After, Medicaid invoices the manufacturers for rebates quarterly and manufacturers pay the rebates within 38 days. The average drug rebate is 49 percent.
- If a provider uses drugs purchased through the 340B Program, Medicaid may not invoice the manufacturer for rebates.
- Medicaid programs are required to pay for drugs at the acquisition cost.

In response to questions from the committee, Dr. Joyce noted the use of 340B Program drugs is not permitted for Medicaid Expansion because managed care, which works on behalf of Medicaid, does not have access to the ceiling price due to confidentiality restrictions. However, Medicaid may use rebates to offset drug costs.

In response to questions from the committee, Ms. Sarah Aker, Executive Director, Medical Services Division and Medicaid Director, Department of Health and Human Services, noted the Department of Health and Human Services prioritizes following the federal regulations of the Medicaid Drug Rebate Program and the 340B Program.

Mr. Nathan Svihovec, Director of North Dakota Government Relations, Essentia Health, introduced Dr. Nick Sharrow, Pharmacy Business Services Director, Essentia Health, to the committee. Dr. Sharrow presented information (Appendix D) regarding the 340B Program reporting requirements and access to comprehensive care. He noted:

- 340B Program eligible hospitals must register for the program and comply with program requirements.
- Eligible outpatient clinics associated with eligible hospitals also may qualify for the program.
- Many hospitals reinvest 340B Program savings into their communities to address gaps in specific patient populations and patient's access to health care.
- Hospitals must take steps to ensure Medicaid does not claim rebates for manufacturers on drugs purchased by the hospital through the 340B Program.
- Hospitals also must take steps to ensure 340B Program drugs are not sold, resold, or otherwise transferred to anyone other than 340B Program patients.
- Hospitals must maintain records for audit purposes to demonstrate compliance, including contract pharmacy data.
- Essentia Health conducts in-house audits each month to ensure compliance.

• Federal government audits cover distinct data points across multiple operational, clinical, and compliance categories, including policies and procedures, eligibility documentation, and associated cost reports. The results of these audits are publicly available.

Dr. Alyssa Wolden, Director of Pharmacy, Sakakawea Medical Center and Coal Country Community Health Center, provided testimony (<u>Appendix E</u>) relating to the relationship between the 340B Program and federally qualified health care centers. She noted:

- Coal Country Community Health Center is a federally qualified health center with clinic locations in Beulah, Hazen, Center, and Killdeer. The health center has participated in the 340B Program since 2004.
- The savings the health center receives are used to support patient care through programs, including the health center's Integrating Mental Health Physical Health and Continuity of Care Together Program, Substance Abuse Program, and Sliding Fee Drug Discount Program. Savings also are used to provide patient transportation and uncompensated care.
- A portion of the 340B Program savings are used to support a third-party administrator that assists in compliance and manages inventory across contract pharmacy locations.
- Reporting requirements that are too cumbersome pull resources away from patient care.

Ms. Kim Kuhlmann, External Affairs Manager, Community HealthCare Association of the Dakotas, provided testimony (Appendix F). She noted:

- The goal of the 340B Program is to stretch resources to best serve low-income and uninsured populations.
- The 340B Program operates without taxpayer funding.
- Federally qualified health centers are required to reinvest 340B Program savings into services that expand access for medically underserved patients.
- Federally qualified health centers are required to provide care regardless of ability to pay. For uninsured and low-income patients, a sliding fee scale frequently is used.
- At federally qualified health centers, savings from the 340B Program are passed directly to patients. In most cases, patients pay about one dollar above acquisition costs for a drug. Without the 340B Program, these drugs would not be affordable for many patients, even when a sliding fee scale discount is applied.
- Legislation to add reporting requirements could create a significant administrative burden, strain
 resources, and distract from patient care. Many federally qualified health centers would need to
 hire additional staff or contract with an external consultant to assist with data reporting if
 additional reporting requirements are added.
- Many federally qualified health centers conduct monthly internal audits and are required to meet existing federal compliance measures for the 340B Program, which includes annual recertification, preventing diversion to ineligible patients, preventing duplicate discounts, and documenting compliance.

Ms. Melissa Hauer, General Counsel and Vice President of Advocacy, North Dakota Hospital Association, introduced Mr. Bharath Krishnamurthy, Director of Health Policy and Analytics, American Hospital Association. Mr. Krishnamurthy provided testimony (<u>Appendix G</u>) regarding an overview of prescription drug transparency reporting under the 340B Program. He noted:

- The American Hospital Association represents over 5,000 hospitals nationwide, including 2,000 hospitals that participate in the 340B Program.
- The 340B Program was established as a solution to high and rising drug prices and was

designed to support the different health care needs of communities by allowing each hospital to decide how to best expand access to health care services.

- The 340B Program is funded entirely through discounts provided by drug companies, rather than through taxpayer funds.
- Eligibility for the 340B Program is limited to six types of public or private nonprofit hospitals, including critical access hospitals and disproportionate share hospitals.
- The discounted 340B Program price is calculated by subtracting the average manufacturer price
 and the unit rebate amount. The unit rebate amount is a minimum percentage discount off the
 drug's average manufacturer price and varies based on the type of drug.
- Hospitals use the 340B Program savings based on the unique needs of patients. Many hospitals
 have programs that reduce the costs of drugs and provide charity care to patients.
- Contract pharmacies operate as dispensing sites for hospitals in exchange for a fee. Patients in rural areas may find it more convenient to receive 340B Program drugs at their local pharmacies than to travel to the hospital or clinic.

Dr. Mark Hardy, Executive Director, State Board of Pharmacy, provided testimony (Appendix H) relating to the relationship between the 340B Program and the State Board of Pharmacy. He noted:

- The 340B Program supports covered entities and contract pharmacies, and supports this state's health care infrastructure, especially in rural communities.
- The State Board of Pharmacy has not received any formal complaints or investigations into fraudulent or concerning behaviors related to the 340B Program.
- North Dakota had a similar prescription drug transparency reporting program through the Insurance Department, which was repealed.

Dr. Erik Christenson, Chief Executive Officer, Heart of America Medical Center, provided testimony (Appendix I) relating to data from rural hospitals and pharmacies with contracts with covered entities. He noted:

- The Heart of America Medical Center is a small critical access hospital in Rugby. Of the revenue the hospital receives, between \$800,000 and \$1 million is derived from the 340B Program.
- Rural critical access hospitals have limited opportunities to generate operational revenue. It is difficult to attract employees to rural areas and compensation for highly trained medical professionals is costly.
- Funds from the 340B Program are used to offset operational costs.

Dr. Gretchen Schilling, Pharmacy Director, Sanford Health Plan and Security Health Plan, provided testimony (Appendix J) relating to the relationship between the 340B Program and health insurers. She noted:

- Sanford Health Plan has a pharmacy and therapeutics committee to assist in examining new prescription drugs, determine coverage availability, review clinical efficacy of medications, and review the effect on patients physically and financially.
- Pharmacy benefit managers and health insurers are required to report prescription drug information to the Insurance and Securities Department.
- Pharmaceutical manufacturers are in the 340B Program voluntarily, and may leave the program at any time.
- Health plans are not considered covered entities under the 340B Program and do not directly participate in the reimbursements or discounts through the program.
- Brand name medication and specialty medications are often the most expensive. Discounts available under the 340B Program are not a factor used to determine coverage. Instead,

coverage of a biosimilar or generic drug may be used to reduce costs.

Health plans seek the lowest net cost price for the drug, regardless of 340B Program status.

In response to questions from committee members, Dr. Schilling noted individual case reviews are conducted for members who have tried a biosimilar drug but were unable to tolerate the medication.

Ms. Jessica Lynch, Director of State Policy, Pharmaceutical Research and Manufacturers of America, provided testimony (Appendix K) relating to the relationship between the 340B Program and pharmaceutical manufacturers. She noted:

- Pharmaceutical Research and Manufacturers of America represents biopharmaceutical research companies and has 33 member companies.
- Since 2000, member companies have invested over \$1 trillion in the search for treatments and cures. These activities have created nearly 3,500 jobs in North Dakota, provided nearly \$1 billion in economic output, and generated \$60 million in taxes annually.
- Covered entities purchase 340B Program drugs at a reduced price and are able to increase the
 drug's price to the original list price, which can be seven times the amount of the original
 discounted price. This is a form of spread pricing and the covered entity profit margin is driving
 health care costs.
- North Dakota has the second highest utilization rate of 340B Program drugs in the country.
- Traditionally, rebates have been negotiated with pharmacy benefit managers and health insurers. Instead, the 340B Program permits covered entities to keep these savings and the traditional rebates are not available.
- Growth in the 340B Program has not corresponded with an increase in charity care. In North Dakota, 88 percent of 340B Program hospitals fall below the national average for charity care.
- Between 2014 and 2022, 340B Program hospital assets increased by 55 percent and uncompensated care decreased by 36 percent.
- States including North Carolina, Minnesota, and Indiana have increased reporting requirements. Data collected from these reporting requirements helps to inform policy decisions, including costs of state employee health plans and pharmacy benefit manager reforms.
- Nationally, 68 percent of audits resulted in adverse findings. Since 2015, only 14 audits have been conducted in North Dakota, with 50 percent resulting in adverse findings.

Mr. Mike Schwab, Executive Vice President, North Dakota Pharmacists Association, provided testimony relating to the relationship between the 340B Program and pharmacies. He noted:

- Covered entities may contract with pharmacies to help dispense medications to patients who are receiving care from covered entities.
- Pharmacies that elect to participate in an agreement with a covered entity are considered contract pharmacies.
- A contract pharmacy is responsible for maintaining a separate inventory for the program.
- Pharmacies incur costs associated with the extra staff time needed to manage and run the 340B Program. The three largest pharmacy benefit managers account for 26 percent of contract pharmacy arrangements in the 340B Program.

Comments by Interested Persons

Ms. Megan Hruby, Vice President of Government Affairs and Public Policy, and Mr. Dan Conrad, President and Chief Executive Officer, Blue Cross Blue Shield of North Dakota, provided testimony relating to the study of prescription drug transparency reporting. They noted:

• Blue Cross Blue Shield of North Dakota is the largest health insurer in the state, serving approximately 400,000 North Dakotans.

• Pharmacy costs account for nearly 30 percent of the amount expended by Blue Cross Blue Shield of North Dakota on health care costs.

- For fully insured customers, the customer pays the premium and the health insurer takes on the financial risk. However, as the administrator of health care for employers, the employers bear the financial risk.
- North Dakota ranks first in the nation for 340B Program revenue per capita.
- Pharmaceutical manufacturers offer 340B Program drug pricing to facilities or rebates to insurers, but not both.
- Commercially insured and self-funded members pay the pharmacy the full price of medications and full price claims are submitted to health insurers. The health insurers pay the full price and seek a rebate from the pharmacy manufacturer that results in a net price. Pharmacies have taken more of the rebates, resulting in members paying the difference of the full price and the net price. Increased loss of rebates over time may impact affordability of health care and lead to rate increases.

REPORTS

Ms. Kodi Pinks, Division Director, Health Statistics and Performance, and Ms. Laura Anderson, Policy Director, Behavioral Health Division, Department of Health and Human Services, presented a report (Appendix L), pursuant to North Dakota Century Code Section 19-03.1-23.5, summarizing the number of deaths that occurred in the state caused by or related to fentanyl consumption. They noted:

- Two-thirds of the deaths occurred in males, and the highest number of overdose deaths occurred among individuals aged 30 to 39. Mountrail, Sioux, Benson, and McKenzie counties had the highest overdose death rates over the past 5 years.
- The toxicology reports for many of the deaths detected multiple substances.
- A decrease in deaths occurred between 2023 and 2024.
- In 2025, 75 percent of these deaths occurred at home.
- The Department of Health and Human Services is working to provide an online dashboard with drug overdose data.
- North Dakota has received almost \$23 million from opioid settlement funds and will receive an
 additional \$40 million over the next 18 years. These funds are used to support prevention and
 workforce development through opioid settlement grants. There is no statewide system to track
 individuals whose lives are saved by the use of naloxone. However, grantee reports indicate
 there were 877 successful overdose reversals between October 2024 and July 2025.
- There are over 1,200 individuals in the state who are actively receiving opioid treatment services from four licensed methadone clinics.

In response to questions from the committee, Ms. Anderson noted tribal-related entities have been grantees and tribes also have access to a similar version of the federal opioid response grant.

No further business appearing, Chairman McLeod adjourned the meeting at 3:06 p.m.

Katie Carpenter	
Counsel	
ATTACH:12	