

# Report of the Special Committee on Federal 340B Drug Program to the 2022 Kansas Legislature

**CHAIRPERSON:** Representative Susan Concannon

**VICE-CHAIRPERSON:** Senator Renee Erickson

**OTHER MEMBERS:** Senators Beverly Gossage, Richard Hilderbrand, Kristen O’Shea, Jeff Pittman, and Mary Ware; and Representatives John Barker, Will Carpenter, Brenda Landwehr, Vic Miller, Sean Tarwater, and Kathy Wolfe Moore

## **CHARGE**

The Committee is directed to review the federal 340B Drug Pricing Program, with the objective of gaining a better understanding of how the program is implemented in Kansas and the experience of participating entities.

Topics for review should include:

- Federal requirements of the program;
- The role qualifying 340B providers, pharmacies, and pharmacy benefit managers play in the program;
- The fiscal impact of such program on all participants;
- Any federal or state law changes affecting such program;
- Any recent marketplace developments of interest; and
- The impact of such program on health care payers.

[*Note:* Provisions in 2021 SB 159 [Section 20 (c)] directed the Legislature to create an interim study committee on the federal 340B program. The law specified the Legislative Coordinating Council would appoint a special committee composed of 13 members, with its chairperson appointed by the Speaker of the House of Representatives.]



# Special Committee on Federal 340B Drug Program

## REPORT

### Conclusions and Recommendations

The Special Committee on Federal 340B Drug Program (Committee) recognizes the complexity of this topic and the varied ways legislation affecting the program could impact stakeholders, including 340B covered entities, pharmacies, pharmacy benefit managers (PBMs), drug manufacturers, and the communities in which covered entities operate. The Committee also notes the importance of ensuring the program and any related legislation direct resources in a way that supports the program's intended outcome of increasing the availability and accessibility of care for uninsured and underinsured individuals and communities.

To enhance the understanding of how this program impacts Kansans, the Committee recommends the following requested information be presented to any standing committees in which 340B legislation may be scheduled for hearing:

- A comparison of outcomes for providers in 340B covered entities prior to the start of the 340B program and currently;
- A comparison of prescription drug costs prior to the start of the 340B program and currently;
- A summary of legislation passed by other states concerning the 340B program; and
- Updated fiscal notes for pending Kansas legislation relating to the 340B program (2021 HB 2260) and, more generally, the licensure of PBMs (2021 HB 2383).

The Committee recommends that its chairperson submit a request to the Legislative Post Audit Committee for the Legislative Division of Post Audit (LPA) to perform an audit to better understand the impact of the 340B program in Kansas and on Kansas hospitals. Suggested topics include:

- The number of prescriptions prescribed by 340B covered entities;
- Whether patients served by these entities are receiving prescriptions at a discounted price; and
- How hospitals are using their 340B savings.
  - The Committee also suggests LPA could work with the University of Kansas Medical Center to learn more about how the 340B program works in a hospital system.

The Committee does not make a specific recommendation on the 2021 legislation it reviewed: HB 2260, currently assigned to the House Committee on Health and Human Services (mirror bill, SB 128), and HB 2383, currently assigned to the House Committee on Insurance and Pensions (mirror bill, SB 244).

***Proposed Legislation:*** None.

## BACKGROUND

The Special Committee on Federal 340B Drug Program (Committee) was established by provisions in 2021 SB 159, the 2021 omnibus appropriations bill, Section 20. The Legislative Coordinating Council later affirmed its establishment and appointed the Committee members, with the Speaker of the House of Representatives designating the chairperson. The stated purpose of the Committee is to review the federal 340B Drug Pricing Program (generally referred to as 340B or Program). This review must include:

- Requirements of the federal law;
- The role of qualifying 340B providers, pharmacies, pharmacy benefit managers (PBMs), and pharmaceutical drug manufacturers in such program;
- The fiscal impact of such program on all participants;
- Any recent federal or state law changes affecting such program;
- Any recent marketplace developments of interest; and
- The impact of such program on health care payers, including insureds, self-insureds, and government programs.

## COMMITTEE ACTIVITIES

The Committee met October 20 and December 9, 2021. During these meetings, the Committee received testimony on the background and history of the 340B, including how stakeholders such as participating medical facilities (covered entities), pharmacies, PBMs, and drug manufacturers work together under this program. Representatives of these stakeholders presented testimony on their experience with 340B, and legislators from two other states provided information on their experience passing 340B-related legislation in their respective states. In addition, the Committee

received information about pertinent federal legislation and the relationship between Medicaid and the 340B program and a briefing on 2021 HB 2260 and 2021 HB 2383.

## Overview of 340B

Analysts from the Kansas Legislative Research Department provided resource documents including an overview memorandum of 340B, a summary spreadsheet detailing recent 340B pricing and reimbursement laws in other states, and a chart outlining the 340B process and flow of revenue.

On October 20, 2021, a doctor of pharmacy (Pharm.D.) from Sentry Data Systems (Sentry) and a lawyer from the law firm of Powers, Pyles, Sutter, and Verville PC (Powers) presented information on a range of topics to provide the Committee with a foundational knowledge of 340B. Topics addressed included program intent, program history, key stakeholders, federal requirements, and challenges facing the program, such as discriminatory reimbursement rates and duplicate discounts. On December 9, the Sentry representative provided additional requested information about the program's history.

## *340B Process and Key Stakeholders*

The Sentry representative noted 340B was established by 1992 law (the Veterans Health Care Act of 1992, adding section 340B to the Public Health Service Act) with a stated purpose to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services” by reducing the amount covered entities spend on outpatient drugs. The presentation outlined the roles key stakeholders (*e.g.*, covered entities, drug manufacturers, insurers, pharmacies, and drug wholesalers) play in the 340B process, the flow of revenue to the covered entities, and the ways this revenue may be used to increase the accessibility of health care in their communities.

The Sentry representative described the federal requirements to qualify as a 340B covered entity and provided a list of covered entity types, which include federally qualified health centers, state AIDS drug assistance programs, critical access hospitals, and disproportionate share

hospitals. The representative noted the role of PBMs is not addressed in the statutes that established 340B.

### ***340B Timeline***

The Sentry representative provided a historical timeline outlining the key developments in the evolution of the 340B program. Two highlighted events were the enactment of the Affordable Care Act in 2010, which expanded the definition of covered entities to include more programs (*e.g.*, certain children’s hospitals and rural referral centers); and the addition of Health Resources and Services Administration (HRSA) audits in 2012.

At the December meeting, the Sentry representative provided a more detailed timeline outlining key events by decade. She noted 340B-related events in the 1990s included the creation of important guidance such as eligibility criteria for covered entities and audit guidelines for both drug manufacturers and the federal government. The representative noted that, in order to be considered an eligible patient, an individual must meet three criteria: receive services from an eligible location, receive services from an eligible provider, and receive services from a covered entity with responsibility for their care. Other noted events were the increase of educational activities and a new requirement that child sites be registered separately (early 2000s), the start of HRSA audits (2012), and increased regulatory authority by HRSA over civil monetary penalties (2019) and alternative dispute resolution (2020).

### ***Discriminatory Reimbursement and Duplicate Discounts***

The Powers representative also noted the purpose of 340B is to help covered entities stretch scarce resources to reach more patients and provide more comprehensive care. This is accomplished through the provision of discounted prescription drugs. The discounted drugs allow covered entities to lose less money when providing care to under- or uninsured patients and generate revenue through third-party reimbursement of outpatient drugs for insured patients (revenue often referred to as “340B savings”). The representative commented this process is disrupted if PBMs or other third-party payers reimburse covered entities at a rate lower

than a rate offered to non-covered entities, a practice the representative labeled as “discriminatory reimbursement.”

The Powers representative provided information on legislation created by other states to prohibit discriminatory reimbursement practices in state 340B programs. Legislation enacted in Arkansas and Tennessee was highlighted, as well as the proposed federal PROTECT 340B Act (described later in this report). The representative also noted the challenge of “duplicate discounts” for drugs prescribed to Medicaid patients. This refers to cases when a state Medicaid program receives a rebate for a drug that a covered entity received at the 340B discount price. The representative noted that while covered entities are responsible for protecting manufacturers from duplicate discounts for fee-for-service drugs, states are responsible for ensuring duplicate discounts are not being taken for drugs paid for by a managed care organization.

### ***Rutledge v. Pharmaceutical Care Management Association, 141 S. Ct. 474 (2020) (Rutledge)***

The Powers representative described *Rutledge* and the decision’s implications for 340B at the October 20 meeting. The representative called this an important ruling for states that are considering legislation to prevent discriminatory pricing because it supports the states’ rights to legislate in the area of PBM regulation.

The decision was formally reviewed by staff from the Office of the Revisor of Statutes at the December 9 meeting. The Assistant Revisor noted the *Rutledge* opinion issued by the U.S. Supreme Court on December 10, 2020, considered an Arkansas law that regulates the price at which PBMs reimburse pharmacies for drugs covered by prescription drug plans. Among the findings highlighted was that the Court determined the Arkansas law merely sets minimum prices and “does not require plans to provide any particular benefit to any particular beneficiary in any particular way.” Also, the court found the Arkansas law has no impermissible connection to an Employee Retirement Income Security Act of 1974 (ERISA) plan and does not preempt increased costs associated with state-specific enforcement mechanisms, even if an ERISA plan

chooses to limit benefits in response to increased costs.

### **Actions of Kansas Officials**

Representatives from the offices of U.S. Representative Jake LaTurner and the Kansas Attorney General provided information on how their offices have been active in 340B legislation and oversight at the October 20 meeting. Communication with HRSA was provided by the office of U.S. Senator Jerry Moran.

#### ***PROTECT 340B Act of 2021; Communication with HRSA***

The representative of Congressman LaTurner's office addressed H.R. 4390, the PROTECT (Preserving Rules Ordered for The Entities Covered Through) 340B Act of 2021. He noted the PROTECT 340B Act (Act) was a response to concerns expressed by safety-net providers, particularly those in rural areas, that their 340B savings are being put at risk through discriminatory reimbursement practices. The Act would prohibit health insurers and PBMs from treating 340B providers and their contract pharmacies in a manner that differs from the way health insurers and PBMs would treat a non-340B entity. This prohibition would apply to reimbursement terms and fees, dispensing fees, audits, and inventory management systems. Other provisions in the Act include civil monetary penalties for PBMs that violate the Act and increased data collection to help reduce the opportunity for duplicate discounts. [Note: At the time of this report, H.R. 4390 was assigned to the Subcommittees on Health of the House Committee on Energy and Commerce and the House Committee on Ways and Means, to which it was separately referred.]

A September 17, 2020, jointly-signed letter from 28 U.S. senators, including Senator Moran, to the Secretary of Health and Human Services (HHS) submitted by the office of Senator Moran was distributed to the Committee. The letter called on HRSA (an agency within HHS) to “take appropriate, prompt enforcement action to address violations of the Public Health Service Act.” This action is needed, the letter continued, “to ensure the 340B program continues to support access to

quality health services with proper oversight and transparency.”

#### ***Multistate Letter Signed by State Attorneys General***

The Medicaid Inspector General, from the office of the Kansas Attorney General, provided information on the efforts of a bipartisan coalition of attorneys general of 27 states and the District of Columbia. This group produced a letter, dated December 14, 2020, urging HHS to “hold accountable drug manufacturers that are unlawfully refusing to provide discounts to federally qualified health centers, hospitals, and other providers that serve vulnerable patient populations through the 340B Drug Pricing Program.” It was noted that the attorneys general argue, in the letter, that by withholding or threatening to withhold 340B discounts, drug manufacturers put low-income patients at risk of losing access to affordable medications while communities continue to battle the COVID-19 pandemic.

### **Stakeholder Experiences**

Representatives of various stakeholders provided their perspectives at the October 20 and December 9 meetings.

#### ***Hospitals***

The 340B Program Director from Ascension Via Christi and the 340B specialist from Labette Health provided testimony on the experience of hospitals with 340B. The testimony described how hospitals use their 340B savings to offer charity care for uninsured patients, for community health improvement services, and to expand access to care in underserved areas.

The representative from Ascension Via Christi highlighted a concern regarding PBM efforts to lower reimbursement rates and require additional reporting requirements that apply only to 340B providers and pharmacies, which she said hurt hospitals by reducing the 340B savings hospitals receive. Both representatives requested consideration of legislation that would protect Kansas hospitals and pharmacies from PBM practices that are discriminatory to 340B providers.

### ***Safety-net Clinics***

Representatives from Community Care Network of Kansas and Health Ministries Clinic and the Director of Pharmacy Services at Salina Family Healthcare Center provided testimony on the experience of safety-net clinics with 340B. The representatives each noted concerns about discriminatory practices on behalf of PBMs that hurt safety-net clinics by diverting 340B savings away from clinics and toward out-of-state entities. This results, the representatives noted, in an increase in health care costs and a decrease in available health care services, particularly in rural communities. The representatives encouraged the Legislature to pass legislation that would prohibit discriminatory contract practices with 340B entities and thus protect Kansans' access to care and ensure the original intent of 340B.

### ***Rural Providers***

A pharmacist from Community Health Care System (CHCS) and the Senior Vice President of Community Health Center of Southeast Kansas (CHCSEK) commented on the experience of 340B providers in rural communities. The CHCS representative noted that the counties served by their clinic have been designated as a Health Professional Shortage Area by HRSA and have some of the lowest health outcomes of all Kansas counties. Both conferees noted 340B allows them, in practice, to stretch limited resources to increase access to care in their communities and sustain providers in areas where there is a provider shortage. The representatives stated the discriminatory practices of PBMs are putting their programming at risk, and they urged the Legislature to follow other states in enacting legislation to protect 340B.

### ***Pharmacists***

Testimony was provided by a representative of the Kansas Pharmacists Association (KPhA) and a Kansas pharmacist who co-owns several pharmacies in Kansas and provides contracted 340B services for eight 340B entities. The pharmacist noted that community pharmacies establish relationships within their communities and become familiar locations where community members are comfortable receiving their outpatient medication. In this respect, it was noted, pharmacists play an important role as 340B

covered entities. The KPhA representative noted that in recent years, there have been several attempts by PBMs and pharmaceutical companies to reduce payments to pharmacies that contract with 340B covered entities or reduce access for patients receiving 340B medications.

### ***Pharmacy Benefit Managers***

The Government Affairs Principal for Prime Therapeutics provided testimony on the experience of PBMs with 340B. It was noted that drug manufacturers must agree to participate in 340B for their drugs to be covered by Medicaid and Medicare Part B. The representative reviewed recent federal activity and noted that the biggest pharmacy beneficiaries of 340B are large pharmacy chains (*e.g.*, Walgreens, CVS Caremark, and Walmart) rather than small community pharmacies. In addition, the Prime Therapeutics representative noted the number of unique covered entity sites and unique contract pharmacies has significantly increased since 2010.

**State regulation of PBMs.** Information submitted by a representative of the Kansas Insurance Department outlined the current statutes governing PBMs in Kansas and the role of the Department plays in enforcing those statutes. The Kansas Pharmacy Benefit Manager Registration Act (KSA 2020 Supp. 40-3821 through KSA 40-3828) requires each PBM to register with the Department by paying an application fee of \$140 and subsequently renewing every March 31 by paying a \$140 renewal fee. The testimony stated 49 PBMs are currently registered in Kansas. The testimony also noted that any PBM that holds a certificate of registration as an “administrator” as outlined under KSA 2020 Supp. 40-3810 is not required to register (and, therefore, not included in the 49 registered PBMs). It was further noted that under KSA 2020 Supp. 40-3826, a fine of \$500 per violation may be levied on a PBM found to be in violation of KSA 2020 Supp. 40-3821.

### ***Drug Manufacturers***

A pharmacist from PhRMA reviewed the changing purpose of the 340B program from 1992 when it was envisioned as a safety-net program to more recent times, stating that “overly broad guidance, historically weak oversight, and a lack of transparency have contributed to the program

often failing patients most in need.” The representative indicated that discounted 340B purchases have grown dramatically since 1992 and noted the number of contract pharmacy arrangements has grown more than 4,000 percent since new guidance was issued in 2010. It was also noted that discounted 340B purchases in 2020 amounted to \$38 billion, an increase of 27 percent over 2019. In addition, the representative provided information on the contract pharmacies for Kansas, stating there are 489 contract pharmacies, of which 347 are in state (71 percent) and 142 are out of state (29 percent).

### **Relationship of Medicaid and 340B**

At the December 9 meeting, the State Medicaid Director, Kansas Department of Health and Environment, described how a 1990 federal law requires drug manufacturers to pay states a mandatory rebate for each prescription issued to a Medicaid beneficiary. Additionally, the 340B law includes language that prohibits duplicate discounts (both a 340B discount and a Medicaid rebate) for one prescription. At this time, Kansas excludes covered entity-owned pharmacy claims and physician-administered drug claims from rebate invoicing. This practice resulted in a rebate loss of approximately \$8.0 million in 2020.

The Medicaid Director also noted that changes negatively impacting the State’s ability to collect rebates on 340B drugs could have a “significant fiscal impact.” For example, the conferee noted, using 2020 data, a 10.0 percent decrease in rebates would result in a \$21.1 million loss in revenue for that year. The Medicaid Director estimated that while the amount of drug rebates coming into the Medicaid program differs each year, it is generally around \$200.0 million.

### **Experience of Other States in Creating and Passing Legislation**

A state representative from Indiana and the Utah Senate Majority Leader provided testimony on their states’ experiences passing 340B-related legislation at the December 9 meeting.

#### ***Indiana***

The State Representative from Indiana provided information about 2021 HB 1405, a bill

that, among other things, included language to prevent discriminatory reimbursement rates, fees, or limiting an individuals’ choice of drug in contracts between PBMs and 340B covered entities. He indicated the bill was intended to refocus 340B savings on uninsured and under-insured populations and that it received broad bipartisan support. The representative provided fiscal information associated with the bill during Committee discussion.

#### ***Utah***

The Senate Majority Leader from Utah described his experience with 340B both as a pharmacist and as a legislator. The Majority Leader noted health clinics in his state had recently received notice from CVS/Caremark that it was no longer going to reimburse the clinic on the full amount of the prescription drug. He noted the responding legislation was passed in Utah to protect the ability of the clinics to be reimbursed at the full rate. The Majority Leader noted the Utah legislation excludes drugs that are reimbursed by the state Medicaid program.

### **Review of Kansas Legislation**

Staff from the Office of the Revisor of Statutes provided a briefing on two bills that relate to the 340B program and, more broadly, the regulation of PBMs. Both bills were introduced during the 2021 Legislative Session and remain active for consideration by the 2022 Legislature. Neither bill received a formal hearing during the 2021 Session.

#### ***HB 2260 (Short Title: Prohibiting disparate treatment by pharmacy benefits managers of certain pharmacies and pharmaceutical services providers.)***

HB 2260 was introduced by the House Committee on Health and Human Services and referred to the same committee. The bill would prohibit a PBM from disparately treating any pharmacy or pharmaceutical services provider based on the pharmacy or provider’s designation as a 340B covered entity. PBMs would be prohibited from imposing or requiring different terms for 340B covered entities than those imposed or required for other pharmacies or providers. Additionally, the bill would prohibit a PBM from discriminating against a 340B covered entity in any way that interferes with a person’s



choice to receive a covered drug from the 340B covered entity. Under the bill, a PBM would be limited in the amount that it could collect as a cost-share amount from a pharmacy, pharmacist, or covered person. [Note: Mirror legislation, SB 128, has been referred to the Senate Committee on Financial Institutions and Insurance.]

***HB 2383 (Short title: Providing for enhanced regulation of pharmacy benefits managers and requiring licensure rather than registration of such entities.)***

HB 2383 was introduced by the House Committee on Insurance and Pensions and referred to the same committee. The topic of the bill, the Assistant Revisor noted, extends beyond the 340B program and would restructure the legal environment governing PBMs in Kansas. The bill would, among other things, require PBMs to apply for and receive licensure. A PBM license could be revoked, suspended, or limited; a licensee could be censured or placed under probationary conditions; or an application for licensure or renewal could be denied for a variety of conduct relating to fraud, misrepresentation, violation of state or federal statutes or rules and regulations, consumer complaints, and failure to provide required information to the Commissioner of Insurance. The bill also includes anti-retaliation provisions that would protect any pharmacy or pharmacist who provides information requested by the Commissioner related to any complaint or concern. The Commissioner of Insurance would be authorized to establish fines and other penalties as enforcement. The bill also would require PBMs to annually submit transparency reports to the Commissioner containing data from the prior calendar year relating to covered entities and plan sponsors doing business in Kansas. [Note: Mirror legislation, SB 244, has been referred to the Senate Committee on Financial Institutions and Insurance.]

### CONCLUSION AND RECOMMENDATIONS

Following discussion, the Committee made the following conclusions and recommendations:

- To enhance the understanding of how this program impacts Kansans, the Committee recommends the following requested

information be presented to any standing committees in which 340B legislation may be scheduled for hearing:

- A comparison of outcomes for providers in 340B covered entities prior to the start of the 340B program and currently;
  - A comparison of prescription drug costs prior to the start of the 340B program and currently;
  - A summary of legislation passed by other states concerning the 340B program; and
  - Updated fiscal notes for pending Kansas legislation relating to the 340B program (HB 2260) and, more generally, the licensure of PBMs (HB 2383).
- The Committee recommends its chairperson submit an audit request to the Legislative Post Audit Committee for the Legislative Division of Post Audit (LPA) to perform an audit to better understand the impact of 340B in Kansas and on Kansas hospitals. Suggested topics include:
    - The number of prescriptions prescribed by 340B covered entities;
    - Whether patients served by these entities are receiving prescriptions at a discounted price; and
    - How hospitals are using their 340B savings.

The Committee also suggests LPA could work with the University of Kansas Medical Center to learn more about how the 340B program works in a hospital system.

- The Committee did not make a specific recommendation on the 2021 legislation it reviewed: HB 2260, currently assigned to the

House Committee on Health and Human Services (mirror bill, SB 128); and HB 2383, currently assigned to the House Committee on Insurance and Pensions (mirror bill, SB 244). The Committee

noted it would like to leave the decision on whether a bill receives a hearing in the hands of the chairperson of each standing committee.