

MINUTES

SPECIAL COMMITTEE ON FEDERAL 340B DRUG PROGRAM

December 9, 2021
Room 112-N—Statehouse

Members Present

Representative Susan Concannon, Chairperson
Senator Renee Erickson, Vice-chairperson
Senator Beverly Gossage
Senator Richard Hilderbrand
Senator Kristen O'Shea
Senator Jeff Pittman
Senator Mary Ware
Representative John Barker
Representative Will Carpenter
Representative Brenda Landwehr
Representative Vic Miller
Representative Sean Tarwater
Representative Kathy Wolfe Moore

Staff Present

Megan Leopold, Kansas Legislative Research Department
Melissa Renick, Kansas Legislative Research Department
Leighann Thone, Kansas Legislative Research Department
Amelia Kovar-Donohue, Office of Revisor of Statutes
Eileen Ma, Office of Revisor of Statutes
Scott Abbott, Office of Revisor of Statutes
Randi Walters, Committee Assistant

Conferees

Lisa Scholz, PharmD, MBA, FACHE, Sentry Data Systems
Sarah Fertig, Medicaid Director, Kansas Department of Health and Environment (KDHE)
Alex Sommer, J.D., Government Affairs Principal, Prime Therapeutics
Hali Brown, PharmD, Community HealthCare System NE Kansas
Daniel Creitz, J.D., Senior Vice President, Chief Compliance Officer, Community Health
Center of Southeast Kansas
Representative Ed Clere, Indiana House of Representatives
Senator Evan Vickers, Majority Leader, Utah Senate and Pharmacist

Others Attending

See [Attached List](#)

ALL DAY SESSION

Welcome and Announcements

Chairperson Concannon called the meeting to order at 10:03 a.m. The Chairperson welcomed members to the Committee. Four conferees participated virtually, as well as two Committee members, Senators O’Shea and Ware.

Briefing on the 340B Program Historical Timeline

Chairperson Concannon recognized Lisa Scholz, Head of Industry Relations, Sentry Data Systems to provide a briefing on the history of policy around the 340B Program. (Ms. Scholz previously presented 340B Program information at the October meeting and returned to provide further information on this topic.) Ms. Scholz noted the federal 340B law, the Public Health Service Act, was passed in 1992; she presented a timeline from 1992 to present day describing trends that have transpired decade by decade. Ms. Scholz indicated that 340B-related events in the 1990s include the creation of important guidance such as eligibility criteria for covered entities and audit guidelines for both drug manufacturers and the federal government. Other noted events on the timeline were the increase of educational activities and a new requirement that child sites be registered as 340B covered entities 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). In response to a question from a committee member, the conferee 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 the individual’s care. ([Attachment 1](#))

Ms. Scholz addressed questions from the Committee regarding the intent and history of the 340B Drug Program, the definitions for eligible 340B patients and covered entities, the processes in which covered entities are audited by the federal government, the ways in which covered entities utilize the money from the program, the role of Prescription Benefit Managers (PBMs) in the program, and the 340B legislation that has passed in other states. A Committee member requested a list of 340B hospitals in Kansas, which was provided by staff. ([Attachment 2](#))

Update on the Relationship of Medicaid and 340B Program

Chairperson Concannon next recognized Sarah Fertig, State Medicaid Director, to provide a brief overview of how the 340B Program intersects with Kansas Medicaid. Ms. Fertig discussed two laws that affect 340B and Medicaid. The first was a 1990 federal law that required drug manufacturers to pay a mandatory rebate for each unit of their product shown in state Medicaid drug utilization claims data. Ms. Fertig indicated these rebates help to offset the Medicaid program costs. The second law was the 1992 federal law that created the 340B Program. Ms. Fertig explained the provision that prohibits duplicate discounts, described how the law allows states some flexibility in how they choose to administer the 340B Program in regard to Medicaid, and provided information on the 340B Program’s financial impact on Kansas

Medicaid. The Medicaid Director indicated that, in order to avoid duplicate discounts, the Kansas Medicaid Program currently excludes rebates for claims from covered-entity pharmacies and Physician-Administered Drug claims from Medicaid rebate invoicing. Physician Administered Drugs are drugs, other than vaccines, that are typically administered by a medical professional in a physician's office or other outpatient clinical setting. These exemptions resulted in a total rebate loss of \$8 million in calendar year (CY) 2020. Ms. Fertig explained if the 340B Program is altered in Kansas in a manner that affects Medicaid, this would result in a corresponding cut to the drug rebate revenue. Ms. Fertig indicated that, based on CY 2020 data, a 10.0 percent decrease in the number of Medicaid drug claims that could be submitted for rebates would have resulted in a \$21.1 million loss of rebate revenue. ([Attachment 3](#))

Ms. Fertig addressed questions from the Committee regarding type of funds represented, proposed legislation, and how rebate funds are currently used.

Experience of Pharmacy Benefit Managers with the 340B Program

Chairperson Concannon recognized Alex Sommer, Prime Therapeutics. Mr. Sommer indicated that the federal law creating the 340B Program includes language regarding covered entities and the provision of drugs from manufacturers to those covered entities but does not include direction regarding drugs dispensed by contract pharmacies. Mr. Sommer noted the number of contract pharmacies participating in the 340B Program has expanded significantly since 2010 and he described how the contract pharmacies fit into the program and the flow of funds for a 340B contract pharmacy network. Mr. Sommer indicated there is oversight of how covered entities use their 340B savings, but there is no oversight of the way contract pharmacies use theirs. Mr. Sommer next provided information on 340B contract pharmacy locations by company as of July 1, 2020, noting that many are large pharmacy chains (e.g., Walgreens, CVS, and Walmart). Mr. Sommer indicated a solution should come from the federal government and explained that there are currently seven different lawsuits, agency action, and proposed legislation at the federal level. ([Attachment 4](#))

Mr. Sommer addressed questions from the Committee regarding contract pharmacies, covered entities, PBMs, PBM contracts, and issues with duplicate discounts.

Experience of Rural Providers with the 340B Program

Chairperson Concannon commented on the next agenda topic, stating she wanted the committee to hear the experience of conferees from a small hospital that was a freestanding facility in a rural area. Chairperson Concannon recognized Daniel Creitz, Community Health Center of Southeast Kansas (CHC/SEK). Mr. Creitz noted while healthcare services and delivery have improved over the past 100 years, southeast Kansas continues to be collectively the poorest and least healthy region in the state. The conferee explained CHC/SEK is allowed to participate in the 340B Program because of its partial funding under Section 330(e) of the Public Health Service Act. Mr. Creitz provided background for CHC/SEK noting it provides all of its 60-plus services regardless of the patient's ability to pay and with no collection agency assistance. Mr. Creitz described some of the services CHC/SEK provides and discussed why federal qualified health center (FQHC) services and the 340B Program are so important in southeast Kansas. Mr. Creitz highlighted health statistics for southeast Kansas and Cherokee County, including health outcomes, health factors, and patient statistics. Mr. Creitz provided an overview of services CHC/SEK provides to Cherokee County and how the 340B Program

supports those services. Mr. Creitz stated within Cherokee County, CHC/SEK has three contract pharmacies and one in-house pharmacy. ([Attachment 5](#)) ([Attachment 6](#))

Mr. Creitz addressed questions from the Committee regarding the experience of rural providers with the 340B Program including the relationship of contract pharmacies and in-house pharmacies, coverage and availability of medications, potential state legislation, and effects of discriminatory practices of PBMs.

Lunch

The Committee recessed for lunch at 12:55 p.m. with 1:30 p.m. as the stated time for reconvening this meeting. The meeting reconvened briefly at 1:50 p.m. and paused until technical difficulties were corrected. The meeting reconvened at 2:47 p.m.

Experience of Other States in Creating and Passing Legislation Regarding the 340B Program

Chairperson Concannon welcomed and introduced Ed Clere, Indiana House of Representatives. Representative Clere indicated he introduced Indiana HB 1393, which was amended at the end of session into Indiana HB 1405 and passed into law during the 2021 Legislative Session of the Indiana Legislature. Representative Clere focused on the section of HB 1405 related to 340B, explaining it was intended to prevent discrimination against 340B covered entities. Representative Clere explained that HB 1405 prevents discriminatory language in contracts between a PBM and a 340B covered entity. Representative Clere indicated that the legislators intentionally focused the bill language on these contracts and that it applies to contracts that are entered into, amended, or renewed after June 30, 2021. Representative Clere stated the legislature's intent with this bill was simply to refocus 340B savings to the vulnerable populations that the program was intended to serve to the extent that can be done under state law. Representative Clere noted that part of the discussion for legislators is to understand how these savings have been diverted away from the populations they were intended to benefit and ways to restore that support. ([Attachment 7](#))

Representative Clere addressed questions from the Committee regarding the Indiana legislation and law. In response to a question from a Committee member, Representative Clere provided a copy of the Fiscal Impact statement for HB 1405. ([Attachment 8](#)) Chairperson Concannon noted the respective votes for HB 1405 of 92-1 in the Indiana House and 47-0 in the Indiana Senate. Representative Clere commented that HB 1405 had broad support from covered entities who felt strongly that this legislation would help those covered entities serve their respective populations.

Chairperson Concannon recognized Evan Vickers, Senate Majority Leader, Utah Senate. Senator Vickers noted he is a pharmacist by profession, and he and his family own three retail pharmacies in Utah. He reported two of these pharmacies work directly with 340B entities. Senator Vickers addressed Utah SB 140 which he and Representative Steve Eliason (House of Representatives) sponsored. It was passed in the 2021 Legislative Session. The senator indicated this bill was fairly narrow, looking only at those pharmaceuticals provided to FQHCs and this contractual arrangement. Senator Vickers noted the purpose behind the 340B Program has been to provide medication and services to low-income people. Senator Vickers highlighted how the 340B Program works, citing a more recent issue with PBMs that are no

longer reimbursing covered entities on the full amount of the medication. Senator Vickers noted the Utah bill addresses concerns that PBMs are treating covered entities differently than other entities by prohibiting actions such as requiring pharmacies to identify 340B drugs or assessing an additional fee for using a 340B medication. Senator Vickers indicated this bill is intended to preserve the intent of the original 340B Program: to allow those low-income people to have the benefit of the medication and allow covered entities to continue to provide quality health care to the people they serve. ([Attachment 9](#))

Chairperson Concannon noted the bill passed the Utah Senate on a 27-0 vote and the House of Representatives by a vote of 67-0. Senator Vickers addressed questions from the Committee concerning Utah SB 140, issues that need to be further addressed on the federal and state levels, discriminatory practices that can occur within the 340B Program, the benefits of the 340B Program, and PBM pricing contracts.

Experience of Rural Providers with the 340B Program (Cont.)

Chairperson Concannon recognized Hali Brown, PharmD, Community HealthCare System NE Kansas (CHCS). Ms. Brown described her experience of becoming a pharmacist and working at CHCS. Ms. Brown noted that community pharmacies are vital to the health and well-being of rural communities. Ms. Brown explained CHCS does not have an in-house pharmacy, so the only way it can pass along savings on 340B discounted drugs to its patients is through contract pharmacies. Ms. Brown noted some of the manufacturers have only allowed covered entities to select a single contract pharmacy and further explained how CHCS had to decide which contract pharmacy to select. Ms. Brown indicated CHCS uses 340B savings to provide discounted prescriptions to its patients. Ms. Brown explained that covered entities select contract pharmacies, PBMs reimburse contract pharmacies, and contract pharmacies share that savings with the covered entities. The conferee indicated without these savings from the contract pharmacy, covered entities are unable to provide discounts to patients who cannot afford their medications. Ms. Brown stated the PBMs disrupt the intent of the 340B Program by transferring the benefit intended for not-for-profit safety net providers to the PBMs themselves. Ms. Brown noted this negatively impacts the health of patients in Kansas. ([Attachment 10](#))

Ms. Brown addressed questions from the Committee regarding the share of the savings between the covered entities and the contract pharmacies, discriminatory acts and transparency issues, supply chain issues, the original intent of the 340B Program, who is profiting from the 340B Program, and dual ownership of PBMs and pharmacies.

Chairperson Concannon recognized Alex Sommer, Prime Therapeutics, to address additional questions from the Committee. Mr. Sommer addressed the Utah and Indiana legislation as well as the pending Kansas legislation, pass-through PBMs, and the PBMs revenue from the 340B Program.

Review of Kansas 2021 HB 2260, HB 2383, and *Rutledge v. Pharmaceutical Care Management Association*

Chairperson Concannon recognized Scott Abbott, Office of Revisor of Statutes. Mr. Abbott noted both HB 2260 and HB 2383 were introduced in the 2021 Session and remain alive for consideration by the 2022 Legislature. ([Attachment 11](#))

Mr. Abbott first provided an overview of HB 2260 noting that, of the two bills, this bill is more narrowly constructed. Mr. Abbott stated the bill would prohibit PBMs from disparately treating any pharmacy or pharmaceutical services provider based on their designation as a 340B covered entity. Mr. Abbott further highlighted the provisions of the bill. ([Attachment 12](#))

Mr. Abbott next provided an overview of HB 2383 noting the bill is broader in scope than HB 2260. Mr. Abbott stated HB 2383 would restructure the legal environment surrounding the regulation of PBMs in Kansas. Mr. Abbott indicated the bill would replace the current regulatory scheme (registration) with licensure and have grounds for limiting, revoking, canceling, or otherwise taking action against the licensee for certain actions. Mr. Abbott further highlighted the provisions of the bill. ([Attachment 13](#))

Mr. Abbott discussed the 2020 U.S. Supreme Court decision, *Rutledge v. Pharmaceutical Care Management Association* [PCMA]. Mr. Abbott indicated PCMA filed suit against an Arkansas law, alleging that this state law was preempted by the Employee Retirement Income Security Act of 1974 (ERISA). Mr. Abbott reported the U.S. Supreme Court concluded that ERISA does not preempt that Arkansas law as it pertains to regulating PBM reimbursement rates. Mr. Abbott highlighted the findings the Court made and noted that the last paragraph of his written testimony lists the resolution of arguments that were presented by the PBMs, essentially finding that this was not the type of intrusion into the regulation of PBMs that would be preempted by ERISA.

Mr. Abbott addressed questions from the Committee regarding how the *Rutledge* opinion might impact Kansas HB 2260 and HB 2383.

Committee Discussion and Proposal of Final Recommendations for the Committee Report to the 2022 Legislature

Chairperson Concannon recognized Megan Leopold, Kansas Legislative Research Department (KLRD), to review the charge and purpose of this study committee. Ms. Leopold stated study committees may make recommendations and provide information to the Legislature and its standing committees.

Ms. Leopold reviewed the provisions in the Omnibus Appropriations bill (SB 159) creating this special committee. The provisions required the Committee to review:

- The requirements of federal law, the rule of qualifying 340B providers, pharmacists, pharmacy benefit managers, and drug manufacturers;
- The fiscal impact of such a program on all participants;
- Recent federal or state law changes that affect the program;
- Any recent marketplace developments of interest; and
- The impact of such program on health care payers including insureds, self-insureds, and government programs.

Chairperson Concannon opened Committee discussion on the Committee report. The Chairperson highlighted the issues that were presented during the two Committee meetings:

- The Committee received testimony on the history of the 340B Program and how the program was designed to function.
- The Committee received testimony from stakeholders in the 340B program, including representatives of hospitals, safety-net clinics, rural providers, pharmacies, PBMs, and drug manufacturers.
- The Committee received testimony on the relationship between Medicaid and the 340B Program.
- The Committee received testimony from legislators in two states that have passed legislation regarding the 340B Program; there are 16 states that have passed legislation and similar legislation is seeing wide support in other states.
- The Committee received testimony from the Office of the Revisor of Statutes about *Rutledge v. Pharmaceutical Care Management Association*, 141 S. Ct. 474 (2020), which supported states' rights to legislate in the area of PBM regulation.
- The Committee received a press release from Kansas Attorney General Derek Schmidt regarding a \$27.6 million settlement with Centene Corp, an example of 340B self-policing. ([Attachment 14](#))
- The Committee received testimony about H.R. 4390, the PROTECT (Preserving Rules Ordered for The Entities Covered Through) 340B Act of 2021, sponsored by U.S. Representatives Tracy Mann and Jake LaTurner, and a letter to the Secretary of Health and Human Services signed by 28 U.S. Senators, including Senator Jerry Moran, to address violations within the Public Health Service Act.
- The Committee has the opportunity to provide recommendations to the legislature, specifically committees that would be involved in legislation that may impact the 340B program: Senate Committee on Public Health and Welfare, House Committee on Health and Human Services, Senate Committee on Financial Institutions and Insurance, House Committee on Insurance and Pensions, House Committee on Appropriations, and Senate Committee on Ways and Means.

Committee discussion followed.

Representative Miller moved, Senator Pittman seconded to recommend to the appropriate chairs that formal hearings be held on HB 2260 and HB 2383. Discussion followed.

Representative Barker moved, Senator Gossage seconded, a substitute motion to make no specific recommendations on the 340B legislation and allow appropriate committee chairs in the House and the Senate to make a decision on how to proceed. Discussion followed. After a voice vote, division was called with a show of hands, the substitute motion carried. Senator

Pittman, Senator O'Shea, Senator Ware, Representative Miller, Representative Wolfe-Moore, and Chairperson Concannon voted no and requested their votes be recorded.

Senator Hilderbrand moved, Representative Carpenter seconded, to recommend KLRD research and present the following information to any standing committees in which 340B may be scheduled for a hearing: outcomes for 340B providers pre-340B Program and current; provide prescription drug costs pre-340B Program and current; a summary of all legislation other states have passed concerning the 340B Program; and updated fiscal notes for HB 2383 and HB 2260. Following discussion, the motion carried.

Representative Tarwater moved, Representative Barker seconded, to submit a request to the Legislative Division of Post Audit to request an audit be conducted 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 entities; whether patients served by 340B entities are receiving their prescriptions at a discounted price; the whole dollar amount of 340B savings how covered entities are using it. The audit should include the University of Kansas Medical Center to better understand how the 340B program works in a hospital system. Following discussion, the motion carried.

Chairperson Concannon announced the documents that have been distributed during the meeting are posted on-line on the Committee page of the Legislative website.

Approval of October 20, 2021 Minutes

Chairperson Concannon asked for the approval of the October 20, 2021, minutes. Without objection, the minutes stand approved.

Adjourn

The Chairperson thanked the Committee members, staff, and attendees for their participation in this meeting. There being no further business to come before the Committee, the meeting was adjourned at 5:53 p.m.

Prepared by Randi Walters

Edited by Leighann Thone and Megan Leopold

Approved by the Committee on:

January 21, 2022

(Date)