ROLL CALL

TK Keen, Chair
Laura Arp, Vice Chair
Anthony L. Williams
Lori K. Wing-Heier/
    Kayla Erickson/
    Sarah Bailey
Beth Barrington
Jessica Ryan
Paul Lombardo/
    Michael Shanahan
Howard Liebers
Andria Seip
Vicki Schmidt
Daniel McIlwain
Jeff Zewe
Chad Arnold/Joe Stoddard
Andrew Kleinendorst
Chlora Lindley-Myers/
    Amy Hoyt/Cynthia Amann
David Dachs

Oregon
Nebraska
Alabama
Alaska
Arkansas
California
Connecticut
District of Columbia
Iowa
Kansas
Kentucky
Louisiana
Michigan
Minnesota
Missouri
Montana

Ralph Boeckman/
    Erin Porter
    Renee Blechner/
        Paige Duhamel
    Robert Croom/Ted Hamby

New Jersey
New Mexico
North Carolina

Kelli Price
Ana Paulina Gomez
Carlos Vallés
Katrina Rodon
Scott McAnally/
    Brian Hoffmeister
Tanji J. Northrup
Don Beatty
Jennifer Kreitler/
    Ned Gaines
Ellen Potter/Michael Malone
Nathan Houdek/
    Jennifer Stegall
Bryce Hamilton

Oklahoma
Pennsylvania
Puerto Rico
South Carolina
Tennessee
Utah
Virginia
Washington
West Virginia
Wisconsin
Wyoming

NAIC Staff Support: Jolie H. Matthews

AGENDA

1. Consider Adoption of its July 29, June 15, April 25, and Spring National Meeting Minutes
    —TK Keen (OR)

2. Hear a Presentation from the Pharmaceutical Care Management Association (PCMA)
    —Peter Fjelstad (PCMA) and Lauren Rowley (PCMA)

3. Hear a Presentation from the Pharmaceutical Research and Manufacturers of America (PhRMA)
    —Emily Donaldson (PhRMA)
4. Hear a Presentation from the Oregon Primary Care Association (OPCA)—Marty Carty (OPCA)

5. Discuss Any Other Matters Brought Before the Subgroup—TK Keen (OR)

6. Adjournment
Agenda Item #1

Consider Adoption of its July 29, June 15, April 25, and Spring National Meeting Minutes
—TK Keen (OR)
The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met July 29, 2022. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp, Vice Chair, and Eric Dunning (NE); Kayla Erickson (AK); Anthony L. Williams (AL); Kathy Belfi and Michael Shanahan (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt (KS); Sharon P. Clark and Daniel McIlwain (KY); Jeff Zewe (LA); Joe Stoddard (MI); Chlor L. Lindley-McCoy and Cynthia Amann (MO); Andrew Kleinendorst and Victoria Bares (MN); David Dachs (MT); Tracy Biehn (NC); Erin Porter and Ralph Boeckman (NJ); Paulee Duhamel (NM); Kelli Price (OK); Ana Paulina Gomez (PA); Maggie Rosa (SC); Scott McAnally and Brian Hoffmeister (TN); Tanji J. Northrup (UT); Don Beatty (VA); Jennifer Kreitler and Ned Gaines (WA); Jennifer Stegall (WI); Jamie Taylor (WV); and Bryce Hamilton (WY). Also, participating were: Paula Shamburger (GA); and Emily Brown (VT).

1. **Discussed Questions on NCPA Presentation**

As a follow-up from its June 15 meeting, the Subgroup held a question and answer (Q&A) session on the National Community Pharmacists Association (NCPA) presentation. Ms. Price asked Matthew Magner (NCPA) if the NCPA would be in favor of state laws that require pharmacy benefit managers (PBMs) to reimburse pharmacies for filling prescriptions in amounts at or above the pharmacy acquisition costs, or has the NCPA found that such laws make it difficult for pharmacies and pharmacy services administrative organizations (PSAOs) to negotiate with PBMs with respect to other contract provisions. Mr. Magner said the NCPA has been supportive of a reimbursement benchmark. He discussed recent legislation enacted in West Virginia that the NCPA believes is a good example of a reimbursement benchmark. Mr. Keen asked about higher reimbursement and dispensing fees and the ultimate impact, if any, on consumers and/or end users. Mr. Magner said the NCPA believes the key issue is the lack of transparency in reimbursement. A pharmacist does not know how much he or she will ultimately be reimbursed even after a claim has been adjudicated because of retroactive clawbacks months later. Mr. Magner said that for consumers in the deductible phase, the amount the consumer pays at the counter for a prescription drug is based on the pharmacy’s reimbursement amount for that drug, which does not account for any retroactive clawbacks. As such, the consumer is paying an inflated amount. He said that again, the key to address this issue is transparency.

2. **Heard a Presentation on the Pharmaceutical Distributor Perspective**

Will Dane (Healthcare Distribution Alliance—HDA) presented on a pharmaceutical distributor perspective on issues related to the Subgroup’s 2022 charge to develop a white paper to: 1) analyze and assess the role PBMs, PSAOs, and other supply chain entities play in the provision of prescription drug benefits; 2) identify, examine, and describe current and emerging state regulatory approaches to PBM business practices, such as price transparency and reporting requirements, rebating, and spread pricing, including the implications of the Rutledge v. Pharmaceutical Care Management Association (PCMA) decision on such business practices; and 3) discuss any challenges, if any, the states have encountered in implementing such laws and/or regulations. He provided background on the HDA, including its role, since its founding in 1876, in helping its members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA’s members include 35 national, regional, and specialty primary distribution companies constantly envisioning new ways to move and secure the nation’s medicines, all while protecting patient safety. Mr. Dane described the pharmaceutical distribution system, highlighting the role pharmaceutical distributors play in the supplying
prescription drugs nationwide. He also illustrated what the prescription drug supply chain would look like with and without pharmaceutical distributors.

Mr. Dane summarized the role pharmaceutical wholesale distributors play in the prescription drug supply chain as follows: 1) distributors purchase health care products from manufacturers based on the wholesale acquisition cost (WAC), which manufacturers set; 2) distributors charge manufacturers fees related to their services, which are not passed on to the customer nor do they affect patients’ cost; 3) distributors sell brand medications to providers based on the WAC or WAC minus a certain percentage; and 4) for generic drugs, since they are commodities, distributors can negotiate prices typically below manufacturer WACs in exchange for sourcing certain generic drugs solely from one source or from a few specified sources. He also provided an example of supply chain profits. He explained that pharmaceutical wholesale distributors primarily use a fee-for-service model. He added that the pharmaceutical distribution model is a high-value, high-volume but low-profit margin industry. Mr. Dane said a recent analysis from Berkeley Research Group (BRG) shows the profit margin for a wholesaler is approximately 1% of the cost of brand medicines.

Ms. Brown asked Mr. Dane if providers typically purchase pharmaceuticals from one distributor. Mr. Dane said it varies depending on the type of provider, such as, for example, an independent community pharmacy versus a hospital. Mr. Hamilton asked about the extent of vertical integration between manufacturers and wholesale distributors. Mr. Dane said none. He described different approaches some wholesalers have taken regarding pharmaceuticals, such as creating repackaging and relabeling businesses, but he noted that these businesses would not be thought of as manufacturers and as such, this would not be considered vertical integration.

3. Heard Presentation on the PSAO Perspective

Scott Pace (Impact Management Group) provided the PSAO perspective on issues related to the Subgroup’s 2022 white paper charge. He discussed the role and value of PSAOs. PSAOs are service organizations that provide back-office support to independent community pharmacies and small chains, including services such as: 1) evaluation and navigation of PBM contracts; 2) help desk to assist pharmacies with communications with the PBMs; 3) credentialing and compliance assistance; 4) central payment facilitation; and 5) PBM audit support. For providing such services, PSAOs charge a flat monthly fee.

Mr. Pace explained who PSAOs are. He said that in a 2013 report, the Government Accountability Office (GAO) identified 22 PSAOs owned by a mix of wholesalers, PSAO-member pharmacies, group purchasing organizations, and other private entities. Today, it is estimated there are fewer than 10 PSAOs in operation. He said that according to one analysis, it is estimated that in 2021, the six largest PSAOs had 1,700 to 6,800 participating independent pharmacies each, with a median of 4,250 per PSAO. He said that in comparison with PBMs, the percentage of total U.S. prescription claims managed by the six largest PBMs in 2018 was 95%. The top three PBMs control 77% percent of the prescription market, and the second largest PBM accounts for approximately 90 million plan members and controlled 68,000+ pharmacies.

Mr. Pace explained that independent community pharmacies and/or small chains often do not have the infrastructure and expertise of their larger chain competitors. He said that as a result, some choose to contract with a PSAO to assist with managing their PBM interactions and “back-office” administrative duties. He described the scope of these services, including services a PSAO does not provide, such as: 1) dictating reimbursement rates; 2) setting maximum allowable cost (MAC) rates; 3) retaining any portion of the pharmacy reimbursement; and 4) creating direct or indirect remuneration (DIR) fees.

Mr. Pace provided a summary of the current landscape with respect to state policy trends and understanding of PSAOs, including misunderstandings of the services PSAOs provide and their role. He suggested that the states
when considering legislative proposals involving PSAOs, they should consider the PSAO perspective and its actual role. He also advocated the idea that “if it ain’t broke, don’t fix it.” He said PSAOs are not PBMs or insurers and should not be treated as such. He also suggested that the states remember the actual role of PSAOs and that PSAOs do not notably affect the cost of medication. PSAOs also are not responsible for patient benefit design. Mr. Pace said PSAOs are administrative support service providers. He also said not all PSAOs are wholesale distributor-owned, and not all wholesalers operate a PSAO business. He said who owns a PSAO does not affect market influence or prices. In summarizing his presentation, Mr. Pace said: 1) PSAOs are administrative service entities that charge a transparent flat fee for their services; 2) PSAOs assist with executing contracts; they do not negotiate with manufacturers, determine medication costs, nor sell medications to pharmacies; 3) pharmacies engage PSAOs to provide administrative support and expertise so pharmacists can focus on serving their patients; and 4) PSAOs do not affect the cost of pharmaceutical drug products and have no role in health benefit plan formulary design.

Ms. Duhamel asked if PSAOs file MAC appeals on behalf of pharmacies. Mr. Pace said sometimes PSAOs have filed such appeals on behalf of pharmacies. He said pharmacies like PSAOs to make such filings, but PBMs have been reluctant to accept appeals from PSAOs. He also said the reluctance of PBMs to accept MAC appeals from PSAOs is easing because some states have passed laws allowing PBMs to accept MAC appeals made on behalf of pharmacies from PSAOs. Mr. McAnally asked about the payment timeline. Mr. Pace said payment terms are usually described in the contract. He explained that in Arkansas, for Medicaid fee-for-service claims, his pharmacy is paid around seven days after the filing a claim. For other types of plans, his pharmacy is paid around 15 days after filing a claim. He noted that some states have enacted prompt pay laws that apply to pharmacy claims that set a maximum time within which a claim is to be paid. Mr. Pace noted that these reimbursements do not account for retroactive clawbacks or so-called “true ups” occurring months after the initial claim has been paid. Mr. Pace also discussed “true up” process and aggregate payments based on the effective rate. He said that a few states, including Arkansas, prohibit the use of effective rates.

Mr. Hamilton asked about vertical integration in the PSAO industry. Mr. Pace said he would consider such integration to fall into two buckets: 1) wholly owned affiliates, which is a PSAO owned by a pharmaceutical wholesaler; and 2) stand-alone entities, some of which are owned by group purchasing organizations. He said from a payment perspective, whether it is a wholly owned affiliate or a stand-alone entity, there is not much of a difference in the reimbursement rates a pharmacy receives. Ms. Shamburger asked about PSAOs’ regulatory compliance and credentialing services. Mr. Pace said one example of this would be the excluded provider list. Prescribers on this list are not eligible to write prescriptions and receive reimbursement under Medicare. He said PSAOs provide pharmacies with updated excluded provider lists on a weekly or monthly basis, which assists pharmacies with regulatory compliance.

Mr. Dachs asked if in Mr. Pace’s experience, in negotiating contract terms with PBMs, does negotiating on behalf of a larger number of pharmacies provider better leverage than negotiating on behalf of one pharmacy. Mr. Pace said that based on his experience, it makes no difference. He said, however, that for contract terms involving non-payment issues, such as audit practices and timelines, he believes PSAOs are better able to negotiate than an individual pharmacy can. Mr. Hamilton asked if pharmaceutical manufacturers are purchasing entities further down the prescription drug supply chain in an effort to possibly maintain their lists prices. Mr. Pace said he is not aware of this. He said that based on his experience, pharmaceutical manufacturers are moving in the opposite direction away from direct purchasers of the product.

Having no further business, the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup adjourned.
The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met June 15, 2022. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp, Vice Chair (NE); Kayla Erickson (AK); Anthony L. Williams, William Rogers, and Jimmy Gunn (AL); Beth Barrington (AR); Jessica Ryan (CA); Kathy Belfi, Mike Shanahan, and Paul Lombardo (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt, Tate Flott, Craig Van Aalst, and Julie Holmes (KS); Daniel McIlwain (KY); Jeff Zewe (LA); Chad Arnold and Joe Stoddard (MI); Amy Hoyt (MO); Andrew Kleinendorst and Galen Benshoof (MN); David Dachs (MT); Ted Hamby and Robert Croom (NC); Erin Porter and Ralph Boeckman (NJ); Renee Blechner (NM); Kelli Price (OK); Mike Humphreys and Ana Paulina Gomez (PA); Katrina Rodon (SC); Scott McAnally (TN); Shelley Wiseman (UT); Don Beatty (VA); Ned Gaines (WA); Jennifer Stegall (WI); Michael Malone (WV); and Jeff Rude and Bryce Hamilton (WY).

1. Heard a Presentation from the NCPA Discussing its Perspective on the Subgroup’s Charge to Develop a Whitepaper

Matthew Magner (National Community Pharmacists Association—NCPA) discussed the independent community pharmacists’ perspective on issues related to the Subgroup’s charge to develop a white paper to: 1) analyze and assess the role pharmacy benefit managers (PBMs), pharmacy services administrative organizations (PSAOs), and other supply chain entities play in the provision of prescription drug benefits; 2) identify, examine, and describe current and emerging state regulatory approaches to PBM business practices, such as price transparency and reporting requirements, rebating, and spread pricing, including the implications of the Rutledge vs. Pharmaceutical Care Management Association (PCMA) decision on such business practices; and 3) discuss any challenges, if any, the states have encountered in implementing such laws and/or regulations.

Mr. Magner provided a profile of independent community pharmacists and pharmacies. He said there are 19,400 independent community pharmacies nationwide. Of these pharmacies, approximately 80% are in areas with populations of less than 50,000 people. He said that in such areas and underserved areas, residents consider independent community pharmacists as essential health care providers and local health care problem solvers because they are the only health care providers available to them. He discussed the current business climate for independent community pharmacies and its impact on their ability to contract with PBMs. He said having three PBMs control as much as 80% if the market and the role of PSAOs in the contracting process are key factors independent community pharmacies face in contracting with PBMs. Mr. Magner suggested that such a business climate and other issues—such as the conflicts of interest in the prescription drug supply and distribution chain due to increased consolidation and integration, rising prescription drug costs, and a lack of accountability—is why regulatory oversight of PBMs is necessary. He discussed state efforts to regulate PBMs, including state PBM licensing and registration laws, state laws prohibiting mandatory mail-order, and state laws addressing reimbursements to PBM-affiliated entities.

Mr. Magner described some of the drawbacks in state PBM laws, such as overly broad exclusions and exemptions for Employee Retirement Income Security Act of 1974 (ERISA) plans and Medicare Part D plans, which create obstacles to reform. He pointed out guidance from federal courts on ERISA preemption in recent rulings, such as the U.S. Supreme Court’s ruling in Rutledge and federal circuit courts of appeal rulings in the PCMA v. Wehbi case and the PCMA v. Mulready case. He said another obstacle to reform are restrictions placed on the ability of pharmacists to alert state departments of insurance (DOIs) or other regulatory authorities about PBM business
practices that potentially conflict with state laws. He said such restrictions include state laws that only allow a state DOI to accept complaints from a consumer. Mr. Magner also said pharmacists are afraid to complain because they fear retaliation by PBMs through audits and increased scrutiny. He said another obstacle to reform related to state laws is whether the state law applies to the insurer or the PBM and whether the state law applies to plans that originate out of state. He said contractual and definitional loopholes in some state laws are also problematic. Mr. Magner urged the Subgroup to highlight these issues in the white paper to make states aware of these issues and potentially address them.

The Subgroup ran out of time for questions and agreed to invite Mr. Magner back for a question-and-answer session during one of the Subgroup’s future meetings.

Having no further business, the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup adjourned.
The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met April 25, 2022. The following Subgroup members participated: TK Keen, Chair (OR); Eric Dunning, Vice Chair (NE); Sarah Bailey and Kayla Erickson (AK); Beth Barrington (AR); Jessica Ryan (CA); Paul Lombardo (CT); Howard Liebers (DC); Andria Seip (IA); Tate Flott (KS); Sharon P. Clark and Daniel McIlwain (KY); Jeff Zewe (LA); Chad Arnold and Joe Stoddard (MI); Amy Hoyt (MO); Andrew Kleinendorst, Galen Benshoof, and Norman Barrett Wiik (MN); Troy Downing and David Dachs (MT); Ted Hamby and Robert Croom (NC); Renée Blechner (NJ); Renee Blechner (NM); Glen Mulready and Kelli Price (OK); Ana Paulina Gomez (PA); Carlos Valles (PR); Maggie Rosa (SC); Brian Hoffman and Scott McAnally (TN); Heidi Clausen (UT); James Young (VA); Jennifer Kreitler and Ned Gaines (WA); Jennifer Stegall (WI); Ellen Potter (WV); and Jeff Rude and Bryce Hamilton (WY). Also participating were: Amy L. Beard (IN); Paul Meyer (MD); and Eamon G. Rock (NY).

1. Heard Presentation on PBM Markets

Neeraj Sood (University of Southern California [USC], Shaeffer Center for Health Policy & Economics) and Karen Van Nuys (USC, Shaeffer Center for Health Policy & Economics) presented on “How Well Are PBM Markets Functioning?” Dr. Van Nuys discussed the flow of money through the pharmaceutical distribution system, which is further detailed in a 2017 research paper *The Flow of Money Through the Pharmaceutical Distribution System*, co-authored by Dr. Sood and others. She said Dr. Sood discussed this in his presentation to the Subgroup a few years ago, but she wanted to refresh the Subgroup’s memory on this subject and then provide an update on what she and Dr. Sood are currently researching related to this topic.

Dr. Van Nuys explained that at the time the research paper was published in 2017, the researchers could only examine the flow of money through the pharmaceutical distribution system for prescription drugs in the aggregate. The researchers could not single out one specific prescription drug in following the flow of money and determining the amount of money each entity along that system captured from a typical expenditure. Dr. Van Nuys said that based on this, the natural question to ask is whether the amount of money captured by some of the intermediaries along the distribution system is excessive. She said that determining whether the amount of money being captured is excessive depends, in part, on the level of risk that entity is taking to participate in the distribution system. She said Dr. Sood, along with other researchers, published a research article in January 2021 examining this question. She described the methodology used to estimate so-called “excess returns,” which is the extent to which an entity’s profits are higher than expected given the risk associated with their investments, for manufacturers, and intermediaries in the pharmaceutical supply chain to determine who is making excessive profits. She said the researchers’ findings suggest that: 1) there are excess returns in the distribution system and amongst prescription drug manufacturers and biotech manufacturers; and 2) there are potentially certain public policies, which promote competition in all areas of the pharmaceutical supply chain, that could curtail prescription drug spending. Dr. Sood noted that some aspects of the research into this question were limited due to the fact of vertical integration in the system—insurers owning pharmacies and other such consolidation in the distribution system.

Dr. Van Nuys next discussed current research as a result of changes since 2017, when the first research paper she discussed was published, which allowed researchers, such as herself and Dr. Sood, to analyze the flow of money along the pharmaceutical distribution system for specific drugs, such as diabetes drugs. One example of such a change was the enactment of state laws requiring prescription drug manufacturers to disclose certain financial...
information. She referenced a Nevada law that requires such disclosure for diabetes drugs, including insulin, and a report from the Ohio Auditor of State examining the state’s Medicaid managed care pharmacy services and spread pricing within the program. Dr. Van Nuys discussed the methodology, including the meanings of “list price,” “net price,” and “net expenditure.” She also discussed findings from a research paper published in the Journal of the American Medical Association (JAMA) Health Forum in November 2021 titled “Estimation of the Share of Net Expenditures on Insulin Captured by U.S. Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans from 2014 to 2018,” which she co-authored with Dr. Sood and other researchers that uses this new data resource to examine the money flows from insulin distribution.

Dr. Sood discussed preliminary research and findings related to the Medicare Part D market and the issue of vertical integration and market consolidation. He explained that the research in this area is continuing and as such, it has not been published. He said he hopes to be able to publish sometime in the near future. He discussed three insurer-pharmacy benefit manager (PBM) relationships: 1) in-house, where the insurer uses its own PBM—for example, CVS. This PBM also provides PBM services to other insurers; 2) rival PBMs, where the insurer uses a PBM owned by a rival health plan—for example, HealthNet contracting with CVS; and 3) standalone PBM, where the insurer uses a PBM that is not owned by a health plan, such as Catamaran, which no longer exists because it was acquired by UnitedHealthcare. Dr. Sood explained that the last insurer-PBM relationship no longer exists in the Part D market. There are no stand-alone PBMs. He discussed how the market has evolved over time with in-house PBMs taking over more and more of the market share between 2010 and 2018. He noted again that the market share for stand-alone PBMs is zero beginning in 2016 for various reasons, including their acquisition by insurers.

Dr. Sood said his preliminary research examines how these changes in market share—the increase market share of in-house PBMs, the decrease in market share for rival PBMs, and the elimination of market share for stand-alone PBMs—are potentially affecting Medicare Part D beneficiaries, health care costs, and premiums. He discussed the concept of “customer foreclosure.” He explained that because such a large share of the market, approximately 80% of the Medicare Part D market, is controlled by in-house PBMs, those customers served by these PBMs are not available to rival PBMs, which potentially reduces incentives and creates a barrier to market entry for new entrants, both PBM and insurer new entrants.

Dr. Sood next discussed the concept of “input foreclosure” and why it is relevant for understanding the impact of vertical integration. He explained that input foreclosure occurs when there is a lack of competition in the market, such as in-house PBMs holding a huge portion of the market share and lower market share for rival PBMs. This means that in-house PBMs have reduced incentives to provide high-quality PBM services at a competitive price to rival insurers—input foreclosure. He said input foreclosure could explain the increase in premium by insurers who obtain pharmacy services through a rival PBM from 2010–2018 versus in-house PBM premiums, which barely increased during the same period.

Dr. Van Nuys discussed potential policy solutions to the issues raised during the presentation: 1) enforce existing antitrust laws in key market segments; 2) encourage alternative PBM models, such as independent PBMs, to provide more market competition; 3) create full transparency within the distribution system; 4) pass prescription drug manufacturer rebates through to the patients at the point of sale; and 5) restrict PBMs to fixed fee rather than percent-of-price contracts.

Dr. Van Nuys responded to a question about what information in the reports used for the research related to insulin flow of money distribution chain was most helpful. She said that it would have been help if the Nevada report include more desegregated data and specifics related to insulin and/or specific diabetes drugs, which would also assist researchers in assessing the quality of the data. Mr. Meyer asked about the impact of pharmacy services administrative organizations (PSAOs) on the distribution system. Dr. Sood said it is unclear, but these entities could be trying to counteract the influence of such a small number of players in the prescription drug distribution system by giving pharmacies more bargaining power and leverage. He noted that it appears drug wholesalers are
acquiring more and more of the PSAOs also to get leverage over the PBMs. In addition, he noted that the drug wholesale market also is highly concentrated. He said that it seems that given the way the pharmaceutical distribution system is evolving, it is going to be just two or three large players along the prescription drug supply chain that are super vertically integrated and competing with other, which may not lead to the best outcomes for consumers.

Mr. Rock asked about the firewalls that insurers and PBMs point to when countering questions about the impact of vertical integration on access and affordability of prescription drugs. Dr. Sood said one of the reasons he wanted to research vertical integration in the prescription drug market and pharmaceutical distribution system was to determine if such firewalls are effective. He said that based on his preliminary research, it does not appear they are effective. He said that if firewalls were effective, it would not matter if an insurer used a rival PBM for its pharmacy services, but his preliminary research shows it makes a difference in premium costs. The firewalls do not appear to be a significant enough of a barrier to reduce the incentives between the insurer and the PBM it owns when that PBM is working with a rival insurer. Dr. Van Nuys, noting that the preliminary research did not study firewalls, said some insurers with in-house PBMs assert vertical integration creates efficiencies. She said that if this is true, then net expenditures should be shrinking, but that does not appear to be happening. Mr. Eamon asked if Ms. Van Nuys looked at state laws with copayment caps on insulin. She said no but explained that a cap on out-of-pocket costs helps consumers at the point of sale, but such a cap does not reduce net expenditures. Consumers could still be paying more because of increased premium because the difference must be made up somewhere to cover the cost of the prescription drug because the total expenditure for that drug has remained the same.

Mr. Keen asked Dr. Sood and Dr. Van Nuys about the Federal Trade Commission’s (FTC’s) recently released request for information (RFI) related to PBM business practices. Dr. Van Nuys said she believes this is a good thing and that she is cautiously optimistic that the FTC could start enforcing its antitrust laws against certain PBM business practices. She said that she, Dr. Sood, and other researchers have been compiling information on these issues and plan to submit comments to the FTC in response to the RFI.

Having no further business, the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup adjourned.
Draft: 5/5/22

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
Kansas City, Missouri
April 4, 2022

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met in Kansas City, MO, April 4, 2022. The following Subgroup members participated: TK Keen, Chair, Numi Griffith and Ralph Margrish (OR); Laura Arp, Vice Chair (NE); Yada Horace (AL); Alan McClain and Beth Barrington (AR); Paul Lombardo (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt and Julie Holmes (KS); Sharon P. Clark and Daniel McIlwain (KY); Chad Arnold (MI); Cynthia Amann (MO); David Dachs (MT); Ted Hamby and Robert Croom (NC); Renee Blechner (NM); Erin Porter (NJ); Glen Mulready and Kelli Price (OK); Ana Paulina Gomez (PA); Carlos Valles (PR); Scott McAnally (TN); Tanji J. Northrup (UT); Stephen Hogge and Katie Johnson (VA); Ned Gaines and Jennifer Kreitler (WA); Nathan Houdek and Jennifer Stegall (WI); Erin K. Hunter (WV); and Bryce Hamilton (WY).

1. Heard an Update from Oklahoma on Implementation of its PBM Law

Ms. Price discussed Oklahoma’s Patient’s Right to Pharmacy Choice Act, which was effective Nov. 1, 2019. The Act establishes a regulatory structure for pharmacy benefit managers (PBMs), including licensing requirements. She explained how the *Rutledge v. Pharmaceutical Care Management Association* case and the U.S. Supreme Court’s decision in that case affected the Oklahoma Department of Insurance’s (DOI’s) implementation and enforcement of the Act and its potential effect on the U.S. District Court’s ruling in the *Pharmaceutical Care Management Association v. Mulready* case.

Ms. Price said since Sept. 1, 2020, the Oklahoma DOI has received and reviewed almost 177,000 alleged violations of the Act. She said approximately 87,000 have been resolved to date. She said enforcement actions taken against PBMs include: eight cease-and-desist orders, 13 other orders, and five settlement agreements entered. Ms. Price described the specific issues the Oklahoma DOI is seeing, such as determining whether: 1) a regulation is a “cost regulation” or “central to plan administration regulation”; 2) settlement agreements made outside of the formal administrative process are confidential or are they subject to federal Freedom of Information Act (FOIA) and/or open records requests; and 3) for purposes of licensing, should a PBM and its financial status be reviewed for stability and solvency.

2. Heard a Presentation on PBM Regulation in Oregon

Mr. Griffith discussed Oregon’s current PBM laws and regulations. He highlighted a few of the law and regulation provisions, including: 1) a PBM registration requirement; 2) maximum allowable cost (MAC) appeals process requirements; 3) a prohibition on requiring patients to use mail-order pharmacy; and 4) prohibiting “claw back” claims except under certain circumstances, such as fraudulent submission or duplicate claims. He said that currently 55 PBMs have registered with Oregon. Mr. Griffith explained that the Oregon DOI’s enforcement of its PBM laws is driven by pharmacy complaints. He said that to date, the Oregon DOI has not initiated any enforcement actions because as far as the Oregon DOI knows, there have been no pharmacy complaints. He said this reflects PBMs satisfactory compliance with the law. He also highlighted that the Oregon DOI’s regulations do not apply to health carriers that directly administer their pharmacy benefits, which is a limitation on the Oregon DOI’s ability to review certain types of complaints related to its PBM law.
Mr. Griffith next discussed Oregon’s work related to prescription drug price transparency, including the work of the Joint Task Force for Fair Pricing of Prescription Drugs and its recommendations. He also noted that the Oregon Secretary of State Audits Division recently began an audit of all PBM contracts used by Medicaid managed care entities in Oregon.

Mr. Margrish, chair of the Oregon Prescription Drug Affordability Board (PDAB), discussed additional work being done in Oregon related to PBM transparency and the anticipated work of the PDAB related to PBM transparency. He said Oregon’s PDAB legislation passed in 2021, which directs the PDAB to conduct affordability reviews for the health care system for high out-of-pocket costs for residents. He explained that the PDAB will meet for the first time this summer to develop its annual work plan, which will include identifying PBM transparency issues. He said that in addition to conducting affordability reviews, the PDAB is also tasked with studying the entire prescription drug distribution and payment system in Oregon and the policies adopted by other states and countries designed to lower the list price of prescription drugs.

With respect to the drug affordability reviews, Mr. Margrish explained that in conducting the reviews, the PDAB must look at multiple factors in the purchasing and supply chain, including: 1) the estimated total amount of the price concession, discount, or rebate the manufacturer provides to each PBM registered in Oregon for the prescription drug under review, expressed as a percentage of the prices; and 2) the estimated average price concession, discount, or rebate the manufacturer provides or is expected to provide to health insurance plans and PBMs in Oregon for therapeutic alternatives. He discussed Oregon’s objectives with respect to transparency and cost, such as 1) identifying where the profits are distributed and living between industry and PBMs; 2) identifying its impact on the system and consumers; and 3) informing what drugs get presented to the PDAB for affordability reviews. He said the PDAB plans to implement through administrative rulemaking the criteria it must use to conduct the affordability reviews, which will take about four to six months. He said that means the PDAB will probably not begin conducting such reviews until the beginning of calendar year 2023. He said he would be happy to share the PDAB’s findings to the Subgroup sometime next year.

Mr. Margrish discussed the analytic opportunities the PDAB’s work will provide to inform policy because it will be examining the whole transaction and prescription drug distribution supply chain from end to end.

3. Heard a Presentation on the Subgroup’s Charge to Develop a White Paper from a Consumer Perspective

Carl Schmid (HIV + Hepatitis Policy Institute) and Anna Schwamlein Howard (American Cancer Society, Cancer Action Network—ACS CAN) provided a consumer perspective on the Subgroup’s charge to develop a white paper on PBMs and PBM business practices.

Mr. Schmid discussed the role of PBMs in prescription drug access and affordability for consumers. He discussed how PBMs are involved in formulary decisions and potential factors influencing these decisions, including which drugs will be covered, adding newly approved drugs, removal of drugs, and drug exclusions. He also discussed how PBMs affect prescription drug affordability particularly due to increased prescription drug cost-sharing and other factors affecting health care costs for consumers.

Mr. Schmid also touched on the importance of prescription copayment assistance to consumers and its role in helping to reduce out-of-pocket costs. With respect to such assistance, he discussed copayment accumulator adjustment programs, which are programs that restrict a prescription drug manufacturer’s assistance coupon from counting towards a patient’s deductible or other out-of-pocket cost-sharing requirement. He also discussed: 1) the percentage of plans in states with copayment accumulator policies and states with laws banning copayment
accumulators; 2) potential conflicts of state copayment accumulator ban laws with federal requirements related to health savings account (HSA)-qualified high deductible health plan (HDHP) and continued eligibility to contribute to an HSA in light of such a law; and 3) potential solutions to address the issue.

Ms. Howard said the Subgroup’s proposed [State] Pharmacy Benefit Manager Licensure and Regulation Act was an important first step. She said the NAIC consumer representatives strongly support the development of the white paper. She said the white paper is an opportunity for the Subgroup to build on the policies included in the proposed model’s Section 8—Regulations drafting note and when finished, it will offer a road map for states that might want to go further than what was included in the draft model. She suggested the Subgroup consider additional topics not included in the drafting note related to provisions in PBM laws that states have enacted, such as PBM network adequacy requirements, prior authorization requirements, and PBM complaint process requirements. She discussed additional items the Subgroup should consider for inclusion in the white paper, including: 1) clearly defining health carrier obligations; 2) sharing rebates with patients; and 3) the impact of the Rutledge decision and other PBM-related cases working their way through the courts.

Having no further business, the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup adjourned.
Agenda Item #2

Hear a Presentation from the Pharmaceutical Care Management Association (PCMA)
—Peter Fjelstad (PCMA) and Lauren Rowley (PCMA)
The Value of Pharmacy Benefit Management

Lauren Rowley
Peter Fjelstad
The Value of PBMs

• PBMs are Committed to Helping Patients
  – Pharmacy Benefit Managers (PBMs) are the only entity in the pharmaceutical supply chain that advocate for lower prescription drug costs for patients and payers.
    • PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors, including: commercial health plans, self-funded employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program (FEHBP), state government employee plans, managed Medicaid plans, and others.
    • PBMs will save health plans sponsors and consumers more than $1 trillion on prescription drugs over 10 years.*
    • PBMs are hired to lower prescription drug costs, and subject to the terms of the contract(s) to which they enter.

The plan sponsor always has the final say when creating a drug benefit plan.

There is no one-size-fits-all model because each plan sponsor has unique needs.
The Plan Sponsor RFP Process

Plan Issues
- Request for Proposal (RFP) dictates the terms and conditions of the PBM services, including performance guarantees, audits, controls, compensation model, etc.

PBM Bids
- Multiple PBMs bid in a highly competitive environment
- PBMs offer various design models and compensation terms, depending on plan sponsor’s specific needs

Plan Decision
- Plan sponsor may utilize benefit consultants for direction
- Plan sponsor determines its financial and care management needs

Plan Design
- Plan sponsor makes the final decision about the drug benefit plan
Pharmacy Benefit Management Services

- Claims Processing
- Price, Discount and Rebate Negotiations with Pharmaceutical Manufacturers and Drugstores
- Formulary Management
- Pharmacy Networks and Provider Education
- Mail-service Pharmacy
- Specialty Pharmacy
- Drug Utilization Review
- Disease Management and Adherence Initiatives
How PBM Tools Reduce Rx Costs for Patients and Payers:

**Negotiating Rebates from Drug Manufacturers**

PBMs negotiate rebates from manufacturers of brand-name drugs that compete with therapeutically similar brands and generics. Manufacturers typically provide a rebate if their product is “preferred,” which means it is assigned a copay lower than that of competing products.

**Negotiating Discounts from Drugstores**

Retail pharmacies provide discounts to be included in a plan’s pharmacy network. The more selective the network, the greater the discount, because each pharmacy will gain more business.

**Offering More Affordable Pharmacy Channels**

Mail-service and specialty pharmacy channels typically give plan sponsors deeper discounts than do retail pharmacies. These channels also help encourage the use of preferred products for additional savings.

**Reducing Waste**

PBMs use Drug Utilization Review and other utilization management programs to reduce over-utilization and waste, as well as reducing adverse drug events associated with polypharmacy.
How PBM\textsc{\textregistered}s Reduce Rx Costs for Patients and Payers:

**Encouraging Use of Generics and Affordable Brands**

PBMs use several tools to encourage the use of generic drugs and preferred brands. These include formularies and tiered cost sharing, prior authorization and step-therapy protocols, generic incentives, consumer education, and physician outreach. As PBMs and plan sponsors strive for greater savings, drug mix becomes even more important.

**Improving Adherence**

PBMs implement medication adherence programs and care management programs to help patients with chronic disease stick to their prescription regimens. These programs improve clinical outcomes and often increase prescription volume and expenditures.

**Managing High-Cost Specialty Medications**

PBMs combine savings from all the above categories with the unique capabilities of specialty pharmacies in safely storing, handling, and delivering complex, often injectable, medications that cost thousands per dose and in providing effective patient education, monitoring, and support for patients with complex conditions, such as hepatitis C, multiple sclerosis, and cancer.
PBM Tools

PBM Tools Will Save Health Plan Sponsors and Consumers More than $1 Trillion on Prescription Drug Costs

As prescription drug spending continues to increase, research shows PBM’s cost savings and patient care management tools should reduce prescription drug costs for health plan sponsors and consumers by an average of 20 percent.

RESEARCH SHOWS US

From 2020 to 2029, the current use of PBM tools will save health plan sponsors and consumers more than $1 trillion. PBM tools have generated significant savings for the Medicare prescription drug program. Even greater savings are expected in the future:

- **$512 B** Commercial health plan sponsors and their members will save more than $512 billion.
- **$445 B** Medicare Part D and its beneficiaries will save more than $445 billion.
- **$46 B** Managed Medicaid plans will save more than $46 billion.

**"Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers." Visante (July 2020).**
PBMs SAVE ON PRESCRIPTION COSTS FOR PATIENTS AND PLANS

**Generics**
- 86% of scripts
- 17% of costs

**Brands**
- 13% of scripts
- 47% of costs

**Specialty**
- 1% of scripts
- 36% of costs

PBM saves patients and plans $1,362 per prescription

- WITHOUT PBM: $4,844
- WITH PBM: $3,482

1 Generics include “unbranded generics” but do not include “branded generics” as reported by IQVIA.

Note: Market share estimates based on net costs. PBM = Pharmacy Benefit Manager.
Source: PCMA based on Visante analysis (2020).
Saving $$$ for Plan Sponsors

• Research Shows Us…
  • $962 – PBMs save payers and patients an average of $962 per person per year
  • $1 => $10 – for every $1 spent on their services, PBMs reduce costs by $10
  • 40% to 50% - PBMs save payers and patients 40% to 50% on prescription drug and related medical costs, compared to what they would spend without PBMs*

PBM services allow payers and patients to pay less for prescription drugs. In fact, 90% of employers are satisfied with the PBM they hire.

*“The Return on Investment (ROI) on PBM Services.” Visante (February 2020).
Overall, more than nine in 10 (93%) are satisfied with their PBM, including more than a third who are “very satisfied.”

A majority (59%) report stable costs for prescription drugs overall, including mail-order drugs.

The vast majority (81%) say that PBM programs are effective at reducing drug costs for their organization.

Methodology: The national survey was conducted online by North Star Opinion Research between June 4-9, 2020 consisting of 250 respondents drawn from a list of benefit managers and human resources directors who work for companies with 1,000 or more employees, have at least 1,000 individuals under coverage, and have an annual drug spend of over one-million dollars.
The Pharmaceutical Supply Chain
DATA SHOWS THAT MANUFACTURER DRUG PRICE INCREASES ARE UNRELATED TO PBM NEGOTIATED REBATES

Increases in Drug List Prices Not Correlated with Changes in Rebates (2016-2020)

Source: Analysis of data from CMS and SSR Health, January 2022.
Note: Xeljanz is not shown in the graphic due to graph truncation, but is included in the correlation analysis; change in list price was 9% and change in rebates was 87%.
PBM TECHNOLOGY AND EXPERTISE HELP PATIENTS LEAD HEALTHIER LIVES

In the U.S. every year, over 3.6 billion prescriptions are filled in retail pharmacies by people with insurance; nearly 10 million transactions every day happen instantly and seamlessly thanks to pharmacy benefit managers (PBMs).

HERE’S HOW IT WORKS

1. The pharmacy inputs the prescription information and sends to the patient’s PBM, in real-time and nearly instantaneously.

2. The PBM checks the patient’s benefit information, cost sharing amount, and the medication for errors and dangerous drug interactions.

3. The patient receives their medication from the pharmacy.

PBMs administer prescription drug benefits for 266 million Americans, which means immediate access to the right prescription drugs at the right time and place for thousands of patients every day. And PBMs continue to innovate, providing information on cost sharing and drug coverage through Real Time Benefit Tool (RTBT) access to 82% and electronic approval coverage for drugs that need authorization to 98% of patients who have coverage through contracted health plans and PBMs.¹

PBMs are also developing technology to directly engage with patients and enhance their lives. This direct clinical care from PBMs to patients not only improves clinical outcomes but also gives patients greater control over their own health.

“With their unique place in the healthcare supply and payment chain, [PBMs] can effectively offer direct services to their patients that other stakeholders may not have the ability to provide.”²

THANK YOU

Lauren Rowley
lrowley@pcmanet.org

Peter Fjelstad
pfjelstad@pcmanet.org
PBMs Create $145 Billion in Value Annually, a 7:1 ROI for the Health Care System

The Value of Pharmacy Benefit Management, Casey Mulligan

Pharmacy benefit managers (PBMs) provide services in the health care marketplace to patients, health plans, insurers, state, and federal governments, and even drug manufacturers. PBMs play an invaluable role lowering costs in the prescription drug payment and supply chain, and for the first time these services have been estimated using a quantitative economic model.

PBMs Create $145 Billion in Value Annually
According to The Value of Pharmacy Benefit Management the value of PBM services to society is estimated at $145 billion annually. “The value to society includes not only consumer savings net of manufacturer losses, but the values of better drug utilization, an increased pace of drug development, and government savings.” These valuable services lead to government and health payer savings, more ground-breaking prescription drugs, and healthier outcomes for patients.

Employers and Other Payers Would Forego $58 Billion in Value Each Year without PBMs
Without PBMs performing these valuable services, 40% of the $145 billion in value would be lost. The paper notes that PBM services are needed by health plan sponsors and that plan sponsors therefore would have to replicate those services if PBMs did not exist or were disbanded. In other words, if employers, labor unions, and other businesses were forced to act as their own pharmacy benefit managers they would collectively forego an additional $58 billion annually.

PBMs Generate Over $148 Billion in Savings Each Year
As a part of the value created, PBMs generate at least $148 billion in savings for the health care system annually. These savings come from PBM-negotiated rebates and discounts combined with lower expenditures on other health care services from increased drug utilization.

PBMs Create a 7:1 ROI
PBMs must expend resources in order to provide services for their health plan payer clients and patients. The value of these expended PBM resources is estimated at $22 billion annually. For every $22 billion of resources used by PBMs, they return $168 billion to the system, a 7:1 return on investment (ROI) for the health care system.

Casey Mulligan
Dr. Mulligan is currently a Professor in Economics at the University of Chicago and former Trump Administration Chief Economist of the White House Council of Economic Advisers

www.pcmanet.org
The Measured Value of Services Performed by PBMs, $Billions per Year

<table>
<thead>
<tr>
<th>PBM Activity</th>
<th>Value of PBM Services $ billions/year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer rebates tied to plan design</td>
<td>51</td>
</tr>
<tr>
<td>Promote generics</td>
<td>16</td>
</tr>
<tr>
<td>Pharmacy rebates tied to plan design</td>
<td>5</td>
</tr>
<tr>
<td>Provision of mail pharmacy</td>
<td>3</td>
</tr>
<tr>
<td>Plans’ nonpharmacy medical benefits from improved health outcomes through added utilization</td>
<td>40</td>
</tr>
<tr>
<td>External effects: lower health care costs reduce tax distortions</td>
<td>47</td>
</tr>
<tr>
<td>External effects: accelerated pace of drug innovation</td>
<td>6</td>
</tr>
<tr>
<td>Total quantified benefits, $ billion/year</td>
<td>168</td>
</tr>
<tr>
<td>SUBTRACT: Resources used by PBMs</td>
<td>-22</td>
</tr>
<tr>
<td>Total quantified value of services, net of PBM resources</td>
<td>145</td>
</tr>
</tbody>
</table>

Services Provided by PBMs

Manufacturer rebates tied to plan design - $51B/year in value created
- PBMs offer favorable placement in plan benefit designs in exchange for rebates.
- PBMs enhance competition in the drug supply marketplace by acting as group purchasers of prescription drugs – similarly to what Costco and Sam’s Club do for their members.
- Manufacturer rebates negotiated by PBMs increase utilization of brand drugs beyond what it would have otherwise been because the drugs are more affordable, which leads to greater access and drug adherence.

Promote generics - $16B/year in value created
- The work PBMs do to promote generics results in an estimated additional 15 percent of drugs dispensed are generic, bumping generic dispensing to 90 percent of prescriptions, because of PBM services.
- Generic drugs offer significant cost savings to plans, so PBMs give patients incentives to use generic drugs instead of competing brand drug.

Pharmacy rebates tied to plan design - $5B/year in value created
- PBM services are also a procompetitive force in retail pharmacies, which offer discounts to PBMs.
- In exchange for discounts, pharmacies get favorable placement in plan pharmacy networks, increasing visibility and potentially attracting additional customers.

Provision of mail pharmacy - $3B/year in value created
- Mail pharmacy services provided by PBMs can decrease patient cost sharing, while increasing convenience and drug adherence.
In addition to the added convenience of home delivery, Services provided by mail pharmacies is often cheaper than those of retail pharmacies.

**Plans’ nonpharmacy medical benefits from improved health outcomes through added utilization - $40B/year in value created**
- Proper drug utilization can prevent more serious illnesses and the more expensive healthcare associated with worse patient health.
- Health plans and PBMs can add value to insurance benefits by encouraging proper utilization of drugs that help prevent future medical claims.

**Lower health care costs reduce tax distortions - $47B/year in value created**
- PBM services reduce drug expenditures, which in turn reduce subsidies from state and federal governments.
- These government and taxpayer subsidies are known as “tax distortion” and the reduced subsidies are thus reduced tax distortions.

**Accelerated pace of drug innovation – $6B/year in value created**
- During the early-patent phase, manufacturers of unique new drugs – that add the most value – enjoy enhanced utilization due to PBM services, such as assessing them and including them on a formulary as well as negotiating the best possible price, while paying comparatively less rebate due to less competition from therapeutic substitutes.
- PBMs reduce drug expenditures through negotiations with manufacturers, while at the same time encouraging and rewarding drug innovation through increased utilization of new drugs when the financial rewards for manufacturers are the greatest.

**Resources used by PBMs - $22B/year cost to the health care system**
- The resources necessary for PBMs to provide their services including salaries, profits, and other services.

**PBM savings – at least $148B/year**
- PBMs generate at least $148 billion in savings for the health care system annually. These savings come from PBM-negotiated rebates ($99 billion) and discounts ($9 billion) combined with lower expenditures on other health care services from increased drug utilization ($40 billion).

**Additional services provided by PBMs but not included in the model**
- Prevention of medication errors: PBM drug utilization reviews and checks for unsafe interactions both help reduce premiums while improving patient health.
- Seamless technological interface between PBM-pharmacy-patient: saves patients time and effort at retail pharmacies.
- Fraud prevention: prevention of potential financial and health outcomes harms that come from misuse and improper payments.
Agenda Item #3

Hear a Presentation from the Pharmaceutical Research and Manufacturers of America (PhRMA)—Emily Donaldson (PhRMA)
NAIC PBM Regulatory Issues Subgroup

Emily Donaldson
August 9, 2022
Lack of transparency in PBM practices has led to misaligned incentives that can increase costs throughout the health system.

PBMs leverage their concentrated market power to extract large and growing payments from manufacturers, typically without direct benefits for patients.

PBMs can use their market power to compel pharmacies and employers to accept unfavorable terms that may limit access and choice and shift costs to patients.

PBM formulary decisions and utilization management restrictions can influence which medicines patients can access, and when.
PBMs Have increased their influence in the pharmaceutical supply chain through horizontal and vertical consolidation
A large – and growing – share of the rebates paid by manufacturers are not being used to reduce patient costs at the pharmacy counter.

Total Value of Manufacturers’ Gross-to-Net Reductions ($B)

Percent of Total Spending on Brand Medicines Received by Manufacturers & Other Entities

According to experts, PBMs may have incentives to prefer medicines with higher list prices and large rebates.

Public sources have noted that manufacturer efforts to reduce list prices have been met with significant headwinds by PBMs.

**Contract terms that discourage list price reductions**


**Demand letters from PBMs requiring additional payments in the event of list price decreases**


**Excluding lower list price versions of brand medicines from formularies in favor of higher list price versions**

Sources:
Many Patients Do Not Directly Benefit From Rebates and Discounts

**Cost to Patient (based on list price)**
Patient has a 25% coinsurance

\[
\text{\$400 x 25\%} = \text{\$100}
\]

**Cost to Plans (based on net price)**

\[
\text{Net Price (\$140) - Cost Sharing (\$100)} = \text{\$40}
\]

Patients can end up paying a greater share of total cost than their health insurers.
PBM actions can interrupt patient treatment continuity and provider prescribing decisions

Number of Medicines Excluded From 1 or More Formularies, by Year and PBM

Sources: Tufts CSDD; Xcenda
Lack of transparency has resulted in a shell game that lets PBMs hide the ball

Evolution of PBM Compensation Models in Response to Scrutiny

Source: Hayden Consulting Group
Policy Solutions to Address Misaligned Incentives in the Pharmaceutical Supply Chain
Anti-steering Policies can Protect Patient Access and Choice

Prohibiting PBMs from directing patients to affiliate pharmacies can:

- Improve competition
- Reduce incentives for PBMs to self-deal

Source: Hayden Consulting Group
Sharing Rebates at the Point-of-Sale Benefits Patients & Has Little Impact on Premiums

- Increases premiums only 0.6% or less
- Results in substantial patient savings – with some patients saving nearly $1,000 a year
- Improves adherence
- Reduces total annual medical spending
- Improves health equity

Cynthia Perna, Ph.D., J.D.
Perma Insights
“Delinking” PBM compensation from the price of medicines prevents PBMs from skirting regulation on rebates

Rather than receiving compensation based on the price of a medicine, supply chain entities should receive a fixed fee based on the services they provide.

Today: Current System

Compensation for supply chain entities is often tied to the price of a medicine.

When the price of a medicine goes up, supply chain payments go up.

Tomorrow: With “Delinking” Reforms

Supply chain members receive fixed fees based on the services they provide.

No relationship between supply chain compensation and the price of a medicine.
Health insurance companies and PBMs often receive sizeable rebates from brand pharmaceutical manufacturers. On average, more than half of spending on brand medicines is retained by health insurers, PBMs, the government and others in the pharmaceutical supply chain. In 2021, these rebates, discounts and other price concessions totaled $236 billion.

At the same time, many patients are being forced to pay more out of pocket for their medicines due to an increase in deductibles and the use of coinsurance. Deductibles require patients to pay in full for their medicines before insurance coverage kicks in. And unlike copays, which are a fixed dollar amount charged per prescription, coinsurance requires patients to pay a percentage of the medicine’s price.

For example, for a drug with a $100 list price, a health insurance company or PBM may negotiate a discount or rebate of $40, for a net cost to them of $60. But a patient still in her deductible pays the full $100. A patient with a 25% coinsurance pays $25 for a medicine with a $100 list price (.25X100), rather than the $15 (.25X60) she would pay if the coinsurance was based on the discounted amount being paid by her insurance company. That extra money collected from the patient may go to the health insurance company or the PBM. It does not go to the manufacturer of the medicine.

What’s worse is that this situation is unique to health insurance coverage of prescription medicines, and it penalizes patients who need medicines the most. Right now, patients receive the benefit of negotiated discounts when sharing in costs for doctor or hospital visits, but they often do not receive the same benefits for prescription drugs.

States can enact laws that would require health insurance companies and PBMs to share at least part of their negotiated savings with patients at the pharmacy counter. Despite what health insurance companies claim, this will not drastically increase premiums. One study demonstrated that, even if health insurance companies were required to share all the negotiated rebates with patients, premiums would increase at most 0.6%, while some patients could save nearly $1,000 each year on their medicine costs. Fixing this broken part of the system and sharing these savings will give patients immediate relief and help them better afford the medicines they desperately need. State legislation can make sure rebates are shared directly with patients, thus lowering what they must pay at the pharmacy.
Sharing Rebates Can Save Americans with Diabetes $500 Each Year and Improve Adherence, Especially for Black and Hispanic Americans

A new study by GlobalData looked at brand oral antidiabetic drugs (OADs) and found that sharing negotiated rebates directly with patients in commercial health plans can help lower costs, improve adherence and reduce health disparities.

Middlemen say they use rebates and discounts to lower monthly premiums, but sick patients shouldn’t subsidize costs for the healthy. Sharing negotiated rebates directly with patients in commercial health plans taking brand oral antidiabetic drugs:

<table>
<thead>
<tr>
<th>Lowers Costs</th>
<th>Savings</th>
<th>Reduce overall health care spending by $8B over 10 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helps Patients Take Their Medicines as Prescribed</td>
<td>9% Average adherence improvement</td>
<td>Patients of color would see largest adherence improvements</td>
</tr>
<tr>
<td>Hispanic patients: 16%</td>
<td>Black patients: 11%</td>
<td></td>
</tr>
<tr>
<td>Asian patients: 9%</td>
<td>White patients: 8%</td>
<td></td>
</tr>
<tr>
<td>Saves Lives</td>
<td>Avoid nearly 700 premature deaths each year</td>
<td>Patients of color would see the highest reduction in mortality</td>
</tr>
<tr>
<td>Hispanic patients: 6.7%</td>
<td>Black patients: 4.9%</td>
<td></td>
</tr>
<tr>
<td>Asian patients: 3.9%</td>
<td>White patients: 3.4%</td>
<td></td>
</tr>
</tbody>
</table>

Over 10 years, sharing negotiated rebates directly with patients could reduce patient out-of-pocket spending by $1.5B total:

- **9.8% Reduction** for the Hispanic Population
- **6.2% Reduction** for the Black Population
- **7.1% Reduction** for the Asian Population
- **3.9% Reduction** for the White Population

Prior research also shows that better adherence to diabetes medicines is associated with:

- **Improved glycemic control**
- **Lower risk of disease-related complications**
- **Fewer hospitalizations and visits to the emergency department**

It’s time for Congress to pass patient-centered solutions like sharing the savings. Doing so can improve health equity and affordability.

Learn more at [phrma.org/cost](http://phrma.org/cost).
Agenda Item #4

*Hear a Presentation from the Oregon Primary Care Association (OPCA)—Marty Carty (OPCA)*
340B Prescription Drug Program

Marty Carty
Director of Government Affairs
Oregon Primary Care Association
Who Do Health Centers Serve?

Health centers now serve more than 28 million patients including:

- 2.9 million patients 65 years and older
- Almost 8 million children
- 1.3 million homeless patients
- Almost 400,000 veterans
- 182,000 patients receiving MAT for opioid use disorder

Most health center patients are uninsured or publicly insured:

- Medicaid: 46%
- Other Public: 1%
- Medicare: 22%
- Private: 21%
- Uninsured: 10%

Most health center patients are members of racial & ethnic minority groups:

- 81% are uninsured or publicly insured
- 58% Racial / Ethnic Minority

Most health center patients have low incomes:

- 91% are low-income
- 68% at the Federal Poverty Level (100% FPL) or below
- 23% above 200% FPL
- 9% above 101% FPL to 200% FPL
**340B – History and Background**

- **340B Program established in 1992** in the federal Public Health Service Act to require manufacturers to sell drugs at a discount to “covered entity” providers.

- **Congress:** The purpose of the 340B Program is “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

- **Participating providers** include federally Qualified Health Centers (FQHC), Ryan White Clinics, critical access and DSH Hospitals; all must treat a high number of low-income or rural patients to be eligible for the program.

- **Federal Program Requirements:** All 340B participants operate under strict federal guidelines governing the program:
  - Registration and recurring recertification
  - Subject to federal audits
  - Must work to avoid duplicate discounts on a single drug
  - Ensure appropriate use of 340B savings
340B Snapshot

• “The 340B Program allows NHC to expand and stabilize underfunded programs and services. In 2021, NHC set aside $24,000 of 340B associated savings to be utilized for patient assistance which covered costs for prescription medications, medical and dental care, food, transportation, and more.” – Oregon

• “340B enables us to subsidize our school-based clinics and mobile dental unit. We are also able to provide in-home well baby visits following the birth of a child.” – Oregon
2016 - 2017

- CHCs begin fighting state-by-state to retain 340B savings on drugs reimbursed under Medicaid managed care.

- Congress holds hearing on 340B, but ultimately takes no significant action.

- “pick-pocketing” continues to expand rapidly.
22 states now prohibit PBMs from:

- Refusing to contract with,
- Reimbursing at a lower amount,
- Imposing different fees, or
- Otherwise discriminating against a 340B covered entity

- Often prohibits requiring inclusion of a modifier to indicate a drug is 340B
Agenda Item #5

*Discuss Any Other Matters Brought Before the Subgroup—TK Keen (OR)*