

**NATIONAL COUNCIL OF INSURANCE LEGISLATORS
HEALTH INSURANCE & LONG TERM CARE ISSUES COMMITTEE
NASHVILLE, TENNESSEE
MARCH 15, 2019
DRAFT MINUTES**

The National Council of Insurance Legislators (NCOIL) Health Insurance & Long Term Care Issues Committee met at The Sheraton Grand Nashville Downtown Hotel in Nashville, Tennessee on Friday, March 15, 2019 at 1:15 p.m.

Assemblywoman Pam Hunter of New York, Chair of the Committee, presided.

Other members of the Committees present were:

Rep. Deborah Ferguson (AR)
Sen. Jason Rapert (AR)
Asm. Ken Cooley (CA)
Rep. Matt Lehman (IN)
Rep. Joseph Fischer (KY)
Sen. Dan "Blade" Morrish (LA)
Sen. Paul Wieland (MO)

Rep. George Keiser (ND)
Sen. Jerry Klein (ND)
Asm. Kevin Cahill (NY)
Asm. Andrew Garbarino (NY)
Sen. Bob Hackett (OH)
Rep. Lewis Moore (LA)

Other legislators present were:

Rep. Roy Takumi (HI)
Rep. Deanna Frazier (KY)
Rep. Edmond Jordan (LA)
Rep. Daire Rendon (MI)

Sen. Vickie Sawyer (NC)
Rep. Tracy Boe (ND)
Asm. Ken Blankenbush (NY)

Also in attendance were:

Commissioner Tom Considine, NCOL CEO
Paul Penna, Executive Director, NCOIL Support Services, LLC
Will Melofchik, NCOIL General Counsel

MINUTES

After a motion was made by Rep. Deborah Ferguson (AR) and seconded by Sen. Jerry Klein (ND) to waive the quorum requirement, the Committee unanimously approved the minutes of its December 8, 2018 meeting in Oklahoma City, OK upon a Motion made by Sen. Dan "Blade" Morrish (LA), NCOIL President, and seconded by Asm. Ken Cooley (CA), NCOIL Treasurer.

DISCUSSION ON PHARMACEUTICAL VALUE BASED CONTRACTING

Rachel Licata, VP of Policy Research at the Pharmaceutical Research and Manufacturers of America (PhRMA), stated that value based arrangements, or value based contracts (VBCs), are defined as voluntary arrangements between manufacturers and private entities whether that be payers or risk based providers. This is where the payment or price for a specific medicine is linked to value or some sort of metrics. For example, "we will give you this price for this product if certain outcomes are met." The

outcome may be a certain number of patients on the drug meeting certain criteria. Other arrangements known as differential pricing say “for this condition, the price of this medicine is this, and for another condition, the price is this.”

There are many benefits to VBCs. For example, a payer may not want to immediately cover a new medicine that was just approved or may impose a variety of different restrictions like utilization management. A VBC can allow a drug manufacturer to take on a little more risk and in turn the payer can provide additional access and potentially at a lower cost so the drug can be more affordable. Additionally, engaging in VBCs can allow for additional support services to increase the likelihood that a patient would remain adherent on that medicine. From better adherence there are better outcomes in avoiding complications which can have far-reaching implications for other healthcare services.

Ms. Licata stated that PhRMA has conducted some research that highlights the benefits and opportunities of VBCs. Specifically, in state regulated exchange plans PhRMA has seen that plans that have value-based arrangements in place have subjected patients to lower copays, so patients are better able to afford the cost sharing provided to them at the pharmacy. PhRMA has also seen some research showing the potential impact savings more broadly if value-based arrangements were expanded. PhRMA has also seen incredible interest and uptake in the number of VBCs as more payers become involved. Payers are saying that VBCs reduce not only their pharmacy costs but also their medical costs. Through better adherence and better access to prescription drugs, payers are saying that they are seeing the value of VBCs more broadly.

Ms. Licata stated that state Medicaid programs want predictability and flexibility with regard to their prescription drug benefits. Medicaid is unique since it is required to cover almost all medicines when there is a rebate agreement in effect and manufacturers provide significant statutory rebates to states and the federal government. However, there are also voluntary arrangements known as supplemental rebate agreements where manufactures and states can engage for an additional level of rebating for better access in Medicaid. Thus far, three states have received federal approval to use supplemental rebates to engage in VBCs with manufactures, and another state is awaiting approval. Additionally, Louisiana and Washington have tried to use new, alternative methods such as a subscription known as a “Netflix model” to try to expand access and provide unlimited access to the new curative Hepatitis C therapies.

Ms. Licata stated that Oklahoma was the first state to receive federal approval for their state plan amendment (SPA) to engage in VBCs with manufacturers. To date, OK has 4 public contracts in place and has been finding some success in manufacturers taking on some additional risk through the contracts while the state is able to expand access and remove barriers to patients receiving those medicines. Louisiana issued an RFI in August on the creation of a subscription-based payment model for Hepatitis C medication; solicitation for offers began in January 2019. LA has made it a priority over the past few years to try and find a way to treat and eradicate Hepatitis C in that state. With the onset of the new curative Hepatitis C therapies that have cure rates above 90%, the state is trying to engage in a model that would allow them some predictability with regard to their Hepatitis C drug costs while expanding access to the medicines. Essentially the state has laid out that they would like a manufacturer to engage with them to provide unlimited access to their medicines for both the Medicaid population as well as the correctional population. The state has essentially set a ceiling of the price

they are willing to pay and are hoping that a manufacturer can use supplemental rebate agreements to provide unlimited access in the Medicaid program.

There is significant value with VBCs, but additional reform is needed to both enhance the uptake and outreach to other markets. The FDA recently ruled to clear one of the hurdles with regard to manufacturer communications with providers so that manufacturers have the ability to communicate with providers about unapproved products and unapproved uses to try to give a fair warning with regard to developing and operationalizing VBCs. However, there is a need for clear anti-kickback statute protection and updates. The federal Office of the Inspector General (OIG) has released a request for information on “ways in which it might modify or add new safe harbors to the anti-kickback statute … in order to foster arrangements that would promote care coordination and advance the delivery of value-based care…” PhRMA is hopeful that regulations will be promulgated to modernize the anti-kickback statute and provide protections. Additionally, there are several price reporting issues that PhRMA is hopeful to see reformed through regulations. A rule is pending at the federal level that will hopefully allow manufacturers some additional flexibility in giving a very low net price to a state or to a private payer that would not trigger that price being available to all Medicaid programs throughout the country.

Asw. Hunter asked how conversations relative to federal Medicaid cuts might affect predictability of rebates. Ms. Licata stated that in the age of Medicaid cuts, VBCs can be a way that states can target and pick off some of the medications that they feel may be driving some of their costs and find ways to increase their predictability. Ms. Licata stated that some of the Medicaid cuts may provide additional incentives to states to do so but it may not have a direct impact.

Sen. Bob Hackett (OH) asked if by implementing VBCs the U.S. is mirroring Japan’s healthcare system. Ms. Licata stated that she is not entirely familiar with Japan’s healthcare system, but she does not believe so. Here, instead of one entity setting the value or price for a medicine payers and manufacturers come to an agreement with regard to the price and specifics of those contracts. Ms. Licata also stated that PhRMA believes the Administration’s goal is to move from fee for service pay for volume towards value for pharmaceuticals and more broadly.

Sen. Morrish stated that with regard to contracts, those at the state level are transparent because they are done through an RFP process, but what about the individual health market. Ms. Licata stated that even PhRMA does not have access to those contracts, but some are publicly reported although they may not contain stipulations and net costs. There is some transparency at the state level with regard to the various entities engaging in those contracts but not a lot as they are private contracts.

CONTINUED DISCUSSION ON DRAFT NCOIL MODEL LAW ON DRUG PRICING TRANSPARENCY

Asw. Hunter introduced the panel and noted that Melodie Shrader, Senior Director of State Affairs at the Pharmaceutical Care Management Association (PCMA) was scheduled to appear before the committee today but she fell ill and could not make it. PCMA will be submitting comments on the model.

Rep. Tom Oliverson, M.D. (TX), Vice Chair of the Committee, stated that he and Senator Morrish are very confident that the bi-partisan framework is a great starting point for this discussion and can be built upon and modified throughout 2019. The goal is the successful adoption of an NCOIL Drug Pricing Transparency Model Law in a form that can be adopted by states across the country. Rep. Oliverson thanked those who have submitted comment letters and noted that NCOIL has a good track record with regard to developing framework-type model legislation as evidenced most recently by the NCOIL PBM Model Act. Rep. Oliverson stated that he believes there are two driving points behind any model legislation regarding drug pricing transparency. First, the model is not meant to and should not be able to be weaponized in any way to interfere with the ability of for-profit entities competing in a marketplace in fairness with one another for the best possible rates. Rep. Oliverson stated that he understands that drug manufactures, health plans, and PBMs are for-profit entities and the model law should not create an opportunity for one party to show their hand in cards before the bets are placed. This is not meant to be a punitive measure but rather a measure for transparency. Second, Rep. Oliverson stated that he believes it is abundantly clear when discussing why prescription drugs are so high there is not one person you can point the finger at. That is why the model law aims to involve the entire drug supply chain.

Alex Jung, Partner/Managing Director at EY-Parthenon, first provided some background remarks that contextualize her views on drug pricing transparency. Ms. Jung stated that she is a forensic accountant and worked for Arthur Anderson for many years doing audits of hospital systems, pharmacies, and employee plan sponsor organizations. Accordingly, Ms. Jung was able to see the financial statements of most of the organizations in the drug value chain. Ms. Jung then worked in the employee benefits space for both Mercer and Aon Hewitt as both an insurance broker and agent working on behalf of large, middle-market, small, and public agencies as their agent representative in placing benefits with large insurance companies and PBMs. Ms. Jung has negotiated hundreds of contracts and has seen firsthand what influences the terms and conditions and financial arrangements for many large corporations in the U.S. Ms. Jung then worked for Walgreens as its Senior VP of Corporate Strategy. In that role, she was exposed to the economic model of the pharmacy itself. Ms. Jung now works for a different accounting firm and represents all of the aforementioned stakeholders with regard to their corporate strategy which includes their business growth goals and their operating model re-design.

Accordingly, Ms. Jung has seen how the money moves in this system very intimately and there are many levers that are like a linear equation in algebra. There are multiple variables that are solved for by these organizations in order to back into their required return on investment and margin targets to meet, if they are a publicly traded company, Wall Street expectations for earning per share. In doing so, they must balance their costs as well as their profit. Those decisions are considerations that go into the terms and conditions of how they negotiate the money flow. The money flow begins with payroll deductions and most of that sits in a trust. However, what happens after that money hits the trust gets very convoluted. There are a lot of details that may not be openly evident.

Ms. Jung stated that what is being asked for in the Model is commendable and is, in accounting parlance, a receipt for services. Ms. Jung urged the Committee to also look at where the money began and how it got to the final price because there are a lot of adjustments that are made in the calculation by the time the net price gets to the patient

at the time of sale and the exposure of the out of pocket expense creates an affordability issue for the average American. Ms. Jung stated that throughout the past 35 years she has seen the drug supply chain economic model become completely complicated while every organization is pulling up to 6 different levers of incentives. Most of the calculations in determining the price of a drug come in the form of incentives. The incentives are not aligned and they are talked about in the public domain as if they are a credit but they really are a negotiation. That negotiations requires compromise between two parties to a contract and the negotiations are never going to be transparency because they are considered proprietary contract terms and conditions. However, there are ways to create accountability beyond transparency for fair negotiations. That is not going to be solved in a single model law, but Ms. Jung urged the Committee to look at the role of other parties in the value chain that inadvertently create incentives that are not necessarily aligned with the express purpose of lowering the price of drugs.

Ms. Jung stated that as she functioned as both a broker and consultant, she received a commission and incentive from the PBM to place business with them. The more volume given to the PBM the higher the commission. Ms. Jung also received a commission from her employer plan sponsor for the public health agencies she represented many of whom were state Medicaid agencies. There is a dual compensation model for not necessarily an independent role. Brokers can play agents on both sides and in order to be licensed the broker must be appointed to an agency in order to represent paper, the insurance contract, which they are signing. In the case of the PBM, that paper was the contract that Ms. Jung had with the PBM. Individual brokers do not have visibility into the aggregate commissions that are paid between large organizations. That is one example of credits in the system that work to create an economic model that is far more complicated than what is seen as the wholesale price. The wholesale price then gets manipulated again. There are differences between the amount that is billed and the amount that is allowable under the plan design. That plan design also has a major impact on affordability. What the model is trying to get to is the paid amount, i.e. the receipt, but Ms. Jung urged the Committee to also look at what was billed and what was allowed.

Saiza Elayda, Director of State Policy at PhRMA, stated that PhRMA supports NCOIL developing a drug pricing transparency model law and appreciates that the entire drug supply chain is involved. One important thing to keep in mind is why this is being done – is this transparency for transparency's sake or do we want this to be transparency that helps the patient know what they are going to pay when they are standing at the pharmacy counter. Currently, we are seeing the growth of money spent on medicines hit the lowest levels in years. IQVIA, formerly the IMS Institute, released a report looking at 2017 and the net spending on drugs only increased by 0.6%. Express Scripts' drug trending report in 2017 showed that their spending also decreased by 1.5%; CVS decreased y 1.9%; and Prime Therapeutics had a negative growth rate at -0.2%. All of those figures are down from about 2-3% from the previous year. CMS also reported that retail prescription drug spending also came down to 0.4% from 2.3% the year before. Accordingly, we are seeing historic lows in spending on prescription drugs. However, the question of "why am I paying so much at the pharmacy counter?" continues to be important and prevalent.

Ms. Elayda stated that there have been several policies that have passed in states that have tried to answer that question. A lot of those policies have been asking for a lot of data that PhRMA members believe is proprietary and confidential and should not be put

out there and could affect the marketplace and how things are priced. The data provisions are also a huge administrative burden for not just the company but also for the state to track the data and put it on a website. California's drug pricing transparency law has led to several problems in terms of compliance difficulties. PhRMA believes that requiring any disclosures from manufacturers, PBMs, or insurers need to focus on helping the patient. Part of the competitive marketplace is allowing consumers to have the information to meaningfully compare the drug benefits when they are shopping for their insurance plans. It is important that consumers are aware of their drug being covered and how much they are going to pay. It is also especially hard when consumer's see a coinsurance of 20% but they do not know what that entails – is it 20% of the WAC or list price; or 20% of something else?

PhRMA has conducted research which shows that negotiated discounts and other price concessions that manufactures have negotiated with the PBMs or insurers are not being passed down to the patient at the pharmacy counter. It is commonly heard that discounts and rebates are helping keep premiums down which is fine except for the scenario where you have sick patients who need medicines to stay healthy and active community members are subsidizing the healthy folks. Ms. Elayda stated that in 2017, the total rebates and discounts that drug manufacturers paid to PBMs was \$153 billion dollars. PhRMA believes that should be shared with the patient. By sharing those negotiated payments with the patient at the pharmacy counter versus putting it to lower premiums, research showed that commercially insured patients, especially those with high deductibles and coinsurance, can save from \$145 to \$800 dollars annually and it would only increase premiums by about 1%.

Ms. Elayda stated that while the Model does take into account the rebates on price concessions, the patient needs to be the highest priority in terms of affordability issues. PhRMA understands the want for transparency but believes that anything done in this space should be meaningful to the patient and not just resulting in throwing out numbers that patients will not understand.

Joshua Keepes, Regional Director of State Affairs at America's Health Insurance Plans (AHIP) stated that AHIP is pleased that the Committee has taken an interest in pursuing a much-needed discussion on the cost of prescription drugs and in particular how it impacts families, patients, state budgets and the country as a whole. Of the many issues facing consumers right now in the healthcare sector, the soaring costs of prescription drugs is the most critical. Data shows that overall spending on prescription drugs now represents the largest segment of your health insurance premium dollar and accounts for more than 23% of commercial premiums. The documented and substantial price increases driven by constantly increasing list prices from pharmaceutical manufacturers pose a threat to both state budgets and consumer pocketbooks. The important thing to consider throughout this discussion is that pharmaceutical manufacturers alone set list prices for prescription drugs and any attempt to lower drug costs that does not include a robust discussion on how prescription drug prices are reached will not increase transparency or benefit consumers. A meaningful discussion requires participation from all actors including PhRMA, PBMs, AHIP, and consumers so that hopefully tools for transparency can be developed for consumers.

Mr. Keepes stated that despite AHIP's ongoing concerns about rising costs and the impact on consumers, AHIP believes that each party to the drug supply chain has a role to play in shaping a better and more efficient healthcare system including those with

whom not everyone will always agree with. AHIP will be the first to say that pharmaceutical advances have brought about life saving medications that have revolutionized treatment for many diseases and dramatically improve quality of life, but that does not mean that we cannot or should not have a frank discussion about how to tackle the costs of those drugs without overly burdening pharmaceutical manufacturers or unnecessarily hindering their ability to develop and adopt new technologies and treatments. However, while an integral part of the broader health system, it is important to keep in mind that prescription drugs are only one element of patient care and that needs to be weighed and balanced with other elements of patient care and care settings. While AHIP applauds the innovation of the pharmaceutical industry, the existence of a drug and the development and putting it to market is only one element of access. Simply because a drug exists and is on the market does not mean that every patient can access it which brings us back to the cost issue and why it is so important.

Mr. Keepes stated that stakeholders and lawmakers are tasked with assessing costs, benefits, and impacts that drug costs have on consumers and other stakeholders. In assessing those costs in the medications that come to the market it is important to take into account the current state of the prescription drug market. Prescription drug spending has reached a level where it is now hundreds of billions of dollars annually. High cost specialty drugs account for a substantial part of that. Despite the many generic and cost-effective options, branded medications continue to make up 75% of drugs spent despite accounting for only 10% of prescriptions written, indicating that the development of generics to the market does not have the ability to control prices on its own. Drug spending is also a critical concern for public programs. In particular, the Medicare Payment Advisory Commission (MedPAC) which oversees and reports on issues related to Medicare, indicated that drug spending in 2016 was \$137.4 billion dollars for Medicare Part D alone, and \$29.1 billion dollars for Medicare Part B. The most obvious impact that we are seeing here, whether at the federal or state level, is the cost of healthcare coverage where prescription drug prices are having a disproportionate impact.

Mr. Keepes stated that currently, policymakers and other stakeholders do not have readily accessible information about what goes into those costs and how we are supposed to balance the benefits along with the costs. That is why AHIP believes there is a lot of value in the NCOIL project to develop a drug pricing transparency model law because it is crucial to enhancing consumer understanding power in the market. Currently, prescription drugs are developed and acquired in price with very little transparency or accountability to consumers. Conversely, health plans are subject to multiple layers of state and federal regulation that provides a picture of how premiums are earned and spent. AHIP supports greater transparency for prescription drug manufacturers because it is a vital tool to encouraging more appropriate pricing behavior. The traditional arguments regarding the burden of research and development costs as well as associated regulatory barriers are often put forth as a way of explaining dramatic increases. However, the public has very little information to validate any of those claims without transparency. Armed with new knowledge, AHIP believes that consumers will have better insight into the factors that are driving their prescription drug costs to sometimes unaffordable levels. Unfortunately, the public cannot say with any real degree of accuracy how much research and development is driving the cost of prescription drugs or what goes into any price increase. We can't say any of this because quite simply we don't have the information.

Mr. Keepes stated that it is important to also look at what AHIP is not saying. AHIP is not asking for intervention into the market to set prices for pharmaceutical drugs as AHIP acknowledges that the pharmaceutical industry has the right to price their drugs as they see fit. AHIP hopes that transparency will hope to reduce those costs a bit in the future. Instead, AHIP is supporting approaches such as this that rely on transparency and new data to help state and private purchasers better understand how drug prices are set and potentially give them the ability to negotiate more effectively. That is why AHIP has requested in its comment letters effective trigger amounts and percentage change thresholds to make the reporting requirement more robust and ensure more drugs are brought into that transparency requirement. Mr. Keepes closed by noting that AHIP submitted a comment letter on the Model on December 4, 2018, and another comment letter in conjunction with Blue Cross Blue Shield Association (BCBSA) on March 8, 2019. AHIP looks forward to being a part of these discussions going forward.

Jeremy Crandall, Managing Director – State Affairs at BCBSA, stated that BCBSA strongly endorses the spirit of the model which is to bring greater transparency to how prescription drug prices are determined. Understanding how and why drug prices are what they are is a necessary step in giving state legislators the tools to necessary to address this issue. BCBSA believes that there should be greater transparency regarding how manufacturers price their drugs and it is crucial that it includes some level of specific information related to the correlation between a drug's list price and the research, development, marketing, and other components that go into setting the cost for that specific drug. BCBSA recognizes that health plans have an important role to play in this conversation as well. Health plans are comfortable with disclosing much of the data that the model asks for related to prescription drug spending and spending trends.

Mr. Crandall stated that BCBSA's main concern with the model is how the transparency is achieved. The sponsors clearly sought to strike a balance between all of the parties that are at the table and that approach is applauded and is the right way to proceed. The concern is whether that balance is equitable. As written, the model essentially hits the "go" button for health plans to gather and distribute and reveal extensive information related to transparency immediately, regardless of whether a drug's price goes up by 40%, drops by 10% or essentially remains the same. Conversely, the model as written for manufacturers, if a drug's price never hits the 50% threshold that is listed in the model then that means that the entity that sets that list price has complete control over essentially hitting that same "go" button of determining what the ultimate cost of a drug is going to be. Health plans have a role in that as well but the price setter would never have to reveal any of the details that policymakers have said they very much need, and health plans believe they need, in order to address this issue.

In short, transparency for health plans related to drug costs with this model starts at 0% and for manufacturers it essentially starts at that 50% threshold. That is the one piece of the model that BCBSA has concerns with. Taken together, BCBSA believes that it creates an inequitable balance that inhibits the ability of the model to fully address the problem that the committee is trying to solve. Mr. Crandall stated that BCBSA believes transparency is a good thing and health plans are already called upon to provide an immense amount of information for consumers, legislators, and regulators whether it is medical loss ratios, statements of benefits, or annual rate reviews. That information is asked for the right reason – to better inform policymakers and consumers. That is why

BCBSA supports the concept of the model but asks that it be equitable when trying to get information.

The Honorable Matt Rosendale, Montana Commissioner of Securities and Insurance, stated that his office has been working on the cost of healthcare very feverishly for the past two years and upon looking to see what the cost drivers were, prescription drug prices were identified as a main cost driver. Accordingly, Cmsr. Rosendale charged his staff with finding out what was going on within the prescription drug industry to drive those costs. Since the introduction of the prescription drug benefits that were being offered by insurance companies what has occurred is the development of a delivery chain in which a lot of different players are involved, from the manufacturers of the product to the consumer who is utilizing it. There are a lot of people along the trail within that delivery system that make a lot of money off of it. Cmsr. Rosendale stated that he believes and embraces very closely the free market system but when you have different incentives being introduced by different entities, the current system has driven costs up.

Cmsr. Rosendale stated that during the past 18 months, his staff has been able to gather a lot of data about what was taking place within the delivery system. Much of that information was only able to have been obtained through the legal process because the entities were not willing to provide it voluntarily. What was found was that there are many people within the drug supply chain that are making money but the PBMs are one of the largest culprits and they are taking money from several different areas, not from just insurance companies. Transparency is no good unless you have tools to help drive the costs down. If you can see what the costs are but can't do anything about it the consumer will not benefit. Accordingly, legislation is pending in Montana that gives insurance companies the tools to reduce costs and direct additional fees that certain PBMs are taking from other parties back into the reduction of premium costs for consumers.

Derek Oestreicher, Attorney for the Office of the Montana State Auditor, Commissioner of Securities and Insurance, stated that he was tasked by Cmsr. Rosendale with finding out why drug prices are so high and what can be done at the state level to reduce the cost of prescription medications for consumers. With that very broad task, Mr. Oestreicher first had to determine what a PBM was and whether or not the Montana Insurance Department had regulatory authority over them, and how the overall drug supply chain and system works. Mr. Oestreicher stated that there are so many moving parts to the system, such as group purchasing organizations (GPOs), pharmacy services administration organizations (PSAOs), brokers, physicians, healthcare facilities, hospital pharmacies, and the 340B drug program. What states have done, and what Montana has started to do, is focus on the PBMs as the middlemen in the system.

Through Montana's regulatory authority, it was discovered that the insurance department had authority to ask for information from PBMs. On October 3, 2017, 14 separate letters were sent out to PBMs that were working in the state at the time or had worked in the state within the past 5 years. The letters asked for transaction data dating back 5 years and all associated contracts. PBMs consistently responded by saying that the information requested was protected from disclosure by trade secret, were confidential, and were proprietary algorithms. CVS Caremark responded by suing and the result was a settlement in which they produced a box of contracts to the Montana insurance department. The Montana insurance department also sued Prime Therapeutics, Express Scripts, and Aetna Health Plans in administrative actions to recover data.

Additionally, with Prime Therapeutics and Express Scripts, those entities did not have proper licensure in Montana. With Prime Therapeutics, they had not had a proper license in Montana for 6 years so that made every single transaction that they had taken part in a separate violation of Montana law.

Mr. Oestreicher stated that was the first part of the effort and the second part was to figure out what to do with it and how to create informed policy to lower consumer's costs for prescription medications. Like other states, the focus was on PBMs but the problem with that is when states have acted directly against PBMs, oftentimes they have been shut down by PCMA on ERISA preemption grounds. When a state acts in any way that relates to or makes an impermissible reference to an employee benefit plan that law is preempted by ERISA. After trying to circumvent ERISA preemption, it was decided to go back to the drawing board. What was settled on was what is already regulated and that is health insurers. The Montana insurance department knew that it had regulatory authority over health insurers and knew that individual market plans did not fall within the definition of "employee benefit plan" as defined in ERISA. Accordingly, the insurance department knew it could regulate within that sphere, no matter how small, by developing a set of best practices for health insurers in the administration and provision of their pharmacy benefit and hoped it would gain steam.

Mr. Oestreicher stated that the best practices come from some work of his colleague Marilyn Bartlett, the former director of the Montana employee health benefit plan, and she had implemented them in the pharmacy benefit for the employees in Montana and in the first year saved \$7.4 million dollars off of a \$33 million dollar spend so that is a 30-35% savings and that is continuing. The best practices include prohibiting spread pricing which is the mechanism in which, by way of example: a health insurer agrees to pay \$10 for acne medication every time it is dispensed; a PBM has a separate contract with the pharmacy that says it will be reimbursed \$5 every time acne medication is dispensed, and the PBM pockets the difference. Spread pricing was viewed as superfluous money in the system and a contractual agreement by an insurer or anyone providing a pharmacy benefit to agree to overpay for the prescription drug. That was thought not to be in the best interest of consumers and consumers premium dollars are being used to do that.

Another best practice is to disincentivize the use of rebates. It was decided that rebates could not be eliminated outright but if they could be disincentivized to the point that the PBM couldn't use them, the manufacturer wouldn't have any incentive to give them directly to a health insurer and a health insurer wouldn't want the rebate. Then the list price and starting point for negotiation would have to come down. Eliminating spread pricing and disincentivizing rebates are the two core provisions in the pending Montana legislation. A version of the Montana legislation has also been introduced in Maine and the National Academy of State Health Policy (NASHP) recently endorsed it as a model law. Mr. Oestreicher stated that he and his colleagues are very proud of the work they have done and it is unique in that they are not pointing the finger at one player in the industry and not saying that the rise in prescription drug costs is because of PBMs or insurers. Rather, the finger is being pointed at the system itself as it is broken. The system itself contains perverse incentives. Rebates in particular make formulary placement for drugs a perverse incentive and it is a pay to play system. If you don't offer a rebate you will not get on a formulary and thus you have to offer larger and larger rebates to compete with manufacturers who have similar or competing products. Accordingly, if you disincentivize rebates the list price will be reduced.

Mr. Oestreicher stated that in Montana, Kalispell Regional Hospital went with a pass-through transparency PBM and in the first year saved \$1.1 million on their pharmacy spend and in the second year saved \$1.9 million. This is a proven system. From the perspective of Mr. Oestreicher and his colleagues, other state laws, and model laws, in the area of PBMs and drug pricing are all well intentioned, but transparency alone is not going to reduce costs and is not going to price shame people into lowering their costs. Figures like \$153 billion dollars per year in rebates already exist and that is already not enough to bring drug prices down so price shaming is not an option. We are also dealing with humanity. You place an infinite value on your life so to put a price on prescription drugs that might prolong life or improve quality of life is difficult. You can't put a value on that so value based models do not work in this context when you don't know what the starting value is or when the starting value is infinite.

Mr. Oestreicher stated that the Montana legislation benefits everyone by creating more competition and a truer marketplace. Competition is also being created between PBMs as they will no longer have spread pricing and be allowed to retain rebates – they will have administrative fees for the quality services that they do provide as there is nothing wrong with a PBM administering or managing the pharmacy benefit for a health insurer. What is offensive are the nefarious things like spread pricing and rebate mechanisms and schemes. At the end of the day, the Montana approach saves money for consumers. Projections show that if just implemented in the individual market alone in Montana, \$8 million dollars in savings in the first year will be realized.

Asw. Hunter asked Ms. Jung for her thoughts on the remarks from the other panelists. Ms. Jung stated that as a rule, accounting firms must remain independent and represent the interests of all clients regardless of what role they play in the value chain. There are a lot of things that don't get discussed in the dialogue when we talk about drug prices. There are business inefficiencies that exist that also need to be addressed. For example, we have close to 10,000 licensed products on the market and the average formulary has about 2,000 products. Of those products, there is close to an 80% generic dispensing rate in the U.S. For those products that are branded, they are prescribed because there is no generic equivalent because they are protected by patent so by nature they cannot be replaced or substituted.

The other issue often run into is that the formularies are not rationalized based on clinical efficacy but rather rationalized based on incentives like rebates. Formulary placement should be prioritized based on clinical comparative effectiveness and that is not in the dialogue of any conversations Ms. Jung has been a party to. The primary task of the P&T committee is to look first at cost and second at clinical efficacy. Formularies must be addressed, and they also must be rationalized. We are paying for products that have superior replacements that are currently on the formulary because of the economic incentive and not because of their clinical efficacy. Rationalizing those portfolios will create money by nature because we are creating a more efficient inventory of available products to pay for.

Additionally, there are plan design incentives or disincentives in the way we have created exposure from an out of pocket perspective with high deductible plans. Those high deductible plans have actually functioned in some regard to create awareness of this issue as this issue is not new and these practices are ancient. What we are debating is the exposure of the practices and the terms and conditions in how the

contracts are negotiated are not going to change just because we change the algebraic variables. Ms. Jung again commended the committee in asking for transparency and a receipt, but as an accountant she asks for more – she wants to know where the money went.

Sen. Hackett stated that large corporations have not been complaining because this system saves them money and stated that what Montana is doing is trying to make the system fair for everyone and that is what everyone wants because the cost of healthcare is rising so much. Sen. Hackett asked of PhRMA that when it brings numbers back, they should be broken down per category because generics are costing more than they ever have. Sen. Hackett commended Rep. Oliverson and Sen. Morrish on the model because transparency is needed.

Ms. Elayda stated that PhRMA only represents about 37 brand name manufacturing companies and does not represent generic companies so she cannot speak on behalf of generics and how their pricing works or how they view things.

Sen. Jason Rapert (AR), NCOIL Immediate Past President, commended Rep. Oliverson and Sen. Morrish on the model and stated that the issues discussed today are not new and the more revealed represents a brick on the wall of PBM grievances that soon will crumble. Sen. Rapert asked Mr. Oestreicher if spread pricing was removed from Montana's Medicaid program. Mr. Oestreicher replied no because in an effort to avoid ERISA preemption the Montana bill only applies to the individual market. The beauty of the proposed Montana solution is that anybody can do it and it does not take legislation for somebody to voluntary conduct business in the manner called for. But because of some of the perverse incentives in the system, health plans and employer sponsored plans may not want to do it. For example, in the individual market for health insurance there is something called the minimum loss ratio for which there is an 80/20 split. That is well intentioned, but it is a perverse incentive because health plans are actually incentivized to spend more in order to make more. If your 80% medical expense goes up, then your 20% administrative costs and profit also goes up. If you disincentivize rebates to the point where rebates must be passed through directly from a manufacturer to a health insurer, that offsets the medical expense and reduces it. Health insurers don't want rebates passed through directly to them because it will offset that medical expense thereby reducing their profit.

Sen. Rapert stated that his experiences and conversations with those in the industry have made him realize that formularies revolve around pay-to-play practices which are illegal in the financial services and other industries. Sen. Rapert asked Mr. Oestreicher if he is concerned if that particular practice has not been exposed to the level to where everyone understands what it actually is. Mr. Oestreicher stated that the system is intentionally complex to the point where you must spend a year and a half to even get a basic understanding of how it operates. Montana is trying to spread the word so everyone does not have to spend a year and a half themselves. Rebates are a perverse pay to play system and Mr. Oestreicher stated that he believes they should be eliminated. Mr. Oestreicher noted that PhRMA supports the Montana legislation and in his conversations with PhRMA lobbyists in Montana, if rebates are eliminated the list price is going to come down because they must come down.

Rep. George Keiser (ND) stated that North Dakota brought the PBM function in-house for Medicaid several years ago and rebates were taken out. The difference in cost is

very significant and as a result the state is bringing Medicaid expansion in house and public employees. Workers' compensation has been in house for several years. When you bring these functions in house you can truly implement value-based initiatives because you have control. Hearings were held last summer with some of the foremost experts on PBMs on both sides of the issue and not one of them could say anything but "congratulations."

Cmsr. Rosendale stated that there are PBMs that are operating on an administrative fee and do not collect rebates or use spread pricing and they are performing a tremendous service. Rep. Keiser noted that in North Dakota's hearings there were only a couple of those types of PBMs – not several.

Sen. Morrish asked Mr. Oestreicher if he believes the model, which is a combination of Louisiana and Connecticut law, goes far enough. Mr. Oestreicher replied no and stated that a step in the right direction would be to implement some provisions from the Montana bill.

Rep. Oliverson thanked everyone for their comments and assured everyone that he is listening and will do his best to incorporate changes to the model. Rep. Oliverson noted that Section 4(a)(1) of the model requires pharmaceutical manufacturers to report WAC costs quarterly but Sections 5 and 6 require PBMs and insurers to report annually. There are triggers for additional reporting requirements for pharmaceutical manufacturers if certain thresholds are achieved but by no means is that the only report they are filing so there is some parity in terms of reporting.

With regard to Section 4(b)(1) of the model which requires supplemental reporting of the pharmaceutical manufacturer after an increase in WAC of 50% or greater for a drug with a WAC of \$100 or more for a thirty-day supply, Rep. Oliverson stated that those numbers were not randomly chosen but rather carefully negotiated in Louisiana. The issue at hand is not the ability of a pharmaceutical manufacturer to report more detailed information – the issue at hand is the ability of the state to keep up with the actual administrative cost of collating and publishing all of the data. In other words, there is definitely a cost associated at the state level with the more data you ask for, the more FTEs that department will have to dedicate to that. When introducing this bill in Texas, that was the insurance department's main concern since they would have to build a new website and there would be a lot of administrative costs. Accordingly, moving forward, it is important to realize that the lower the 50% threshold goes, the bigger the fiscal note will be when the model is introduced in states.

Lastly, Rep. Oliverson stated that the model is designed to answer the question of what forces are causing pharmaceutical prices to increase and where are the biggest increases happening within the supply chain. What emerged today is a different conversation which may be more valuable depending on how the committee wishes to proceed and that is along the lines of what are the best business practices within the health plan/PBM/pharmaceutical manufacture negotiation process, and should we be using transparency as a means to compel those practices into existence. Therefore, there seem to be two issues at play here and Rep. Oliverson sated that he may benefit from some direction from the committee as to how it wants to proceed.

**DISCUSSION/CONSIDERATION OF RESOLUTION IN SUPPORT OF AMENDING
ERISA TO ENABLE STATE PUBLIC POLICYMAKERS TO ENACT MORE
MEANINGFUL STATE HEALTHCARE REFORMS**

Asm. Kevin Cahill (NY), NCOIL Secretary, first made a Motion to adopt the resolution he has sponsored In Support of Amending ERISA to Enable State Public Policymakers to Enact More Meaningful State Healthcare Reforms. Rep. Keiser seconded the Motion. Asm. Cahill stated that at the 2018 NCOIL Annual Meeting in December, there was a terrific presentation on the role of ERISA and how it interplays with state legislators' obligation to create a meaningful system of regulation for health insurance. One of the speakers during that session, Prof. Elizabeth McCuskey of the University of Toledo Law School, opined that it may be time to ask the federal government for an ERISA waiver.

Waivers currently exist for Medicare and Medicaid and states have control over its state regulated insurance markets. However, now more than 60% of all workers with private, employer-based health insurance are in self-funded employee benefit plans and therefore governed by ERISA and out of the scope of state regulation. That creates huge problems as states attempt to bring reforms to the marketplace as states run the risk of being preempted. No one wants to do away with the real and important protections that ERISA has brought. However, when looking at the acronym of ERISA, "RIS" stands for retirement and income security and healthcare is not mentioned. ERISA was enacted with the intent of establishing uniform federal standards to protect private employee pension plans from fraud and mismanagement. It has served that purpose, but it has also allowed the growth of what is essentially an unregulated health insurance market at the state level.

Enacting a waiver system envisioned in the resolution would provide more consistency and create less confusing in the marketplace. Asm. Cahill noted that oftentimes constituents call his office and do not understand the ERISA marketplace – they just want help. Again, ERISA has been beneficial in certain respects so rather than try to dis-associate ERISA with health insurance altogether, the resolution calls upon Congress to create a waiver process similar to what exists for Medicare and Medicaid. The Committee then voted without objection by way of a voice vote to adopt the resolution.

ADJOURNMENT

There being no further business, the Committee adjourned at 3:00 p.m.