

NATIONAL COUNCIL OF INSURANCE LEGISLATORS
JOINT STATE-FEDERAL RELATIONS & INTERNATIONAL INSURANCE ISSUES COMMITTEE
JERSEY CITY, NEW JERSEY
JULY 14, 2022
DRAFT MINUTES

The National Council of Insurance Legislators (NCOIL) Joint State-Federal Relations & International Insurance Issues Committee met at the Hyatt Regency in Jersey City, New Jersey on Thursday, July 14, 2022 at 11:30 a.m.

Representative Brenda Carter of Michigan, Vice Chair of the Committee, presided.

Other members of the Committee present were:

Rep. Deborah Ferguson, DDS (AR)	Rep. Hank Zuber (MS)
Sen. Jason Rapert (AR)	Sen. Jerry Klein (ND)
Asm. Ken Cooley (CA)	Sen. Bob Hackett (OH)
Rep. Matt Lehman (IN)	Rep. Tom Oliverson, M.D. (TX)
Rep. Joe Fischer (KY)	

Other legislators present were:

Asm. Tim Grayson (CA)	Asm. Roy Freiman (NJ)
Rep. Stephen Meskers (CT)	Asw. Elaine Marzola (NV)
Rep. Tammy Nuccio (CT)	Asw. Pam Hunter (NY)
Rep. Roy Takumi (HI)	Rep. Brian Lampton (OH)
Rep. Rod Furniss (ID)	Rep. Forrest Bennett (OK)
Sen. Beverly Gossage (KS)	Rep. Wendi Thomas (PA)
Rep. Derek Lewis (KY)	Rep. Dennis Paul (TX)
Rep. Kevin Coleman (MI)	Rep. Jim Dunnigan (UT)
Sen. Mike McLendon (MS)	Sen. Mary Felzkowski (WI)
Sen. Walter Michel (MS)	

Also in attendance were:

Commissioner Tom Considine, NCOIL CEO
Will Melofchik, NCOIL General Counsel

QUORUM

Upon a Motion made by Rep. Matt Lehman (IN), NCOIL Immediate Past President, and seconded by Sen. Bob Hackett (OH) the Committee voted without objection by way of a voice vote to waive the quorum requirement.

MINUTES

Upon a Motion made by Rep. Deborah Ferguson, DDS (AR), NCOIL Secretary, and seconded by Sen. Jerry Klein (ND), the Committee voted without objection by way of a voice vote to adopt the minutes of the Committee's March 4, 2022 meeting in Las Vegas, NV.

CONTINUED DISCUSSION ON 340B DRUG PRICING PROGRAM

Rep. Carter stated that we'll start today with a continued discussion on the 340B drug pricing program. This topic was previously being discussed in the NCOIL Health Insurance & Long Term Care Issues Committee but at the NCOIL Spring Meeting in March it was announced that it would be transferred to this Committee. Since the 340B drug pricing program is a Federal program, it made sense to transfer the topic to this committee. Today is really about information gathering and further education on the program and after today, we will evaluate what, if any, next steps would be involved with this topic. Let's start with hearing from Asw. Pam Hunter (NY).

Asw. Hunter stated that I appreciate you letting me make a few brief remarks since we did move this topic from the Health Committee at our last session. It's been a very important conversation in New York as we've had long standing discussions about 340B and the savings. We want to make sure that any savings continue to go towards those programs and services, especially federally qualified health centers. So, I'm definitely interested in hearing how we can have a robust discussion on this, especially at the Federal level, about who is taking the savings who don't need them and are therefore putting other programs in peril.

Wayne Winegarden, Ph.D., Senior Fellow, Business & Economics at the Pacific Research Institute (PRI), thanked the committee for the opportunity to speak and stated that I think what the Assemblywoman said in terms of ensuring the program exists for those institutions, those hospitals, that it's made for is the most compelling reason why we need to reform the program. So, let me start with a very quick elevator pitch in terms of why 340B needs reform and then kind of spend the rest of my ten minutes here just trying to back this up to convince you that it's an important program. What we're trying to do is very important but we're doing it very poorly and that puts the entire program in jeopardy because right now it is completely unsustainable. The reason it's unsustainable is because when you look at the growth whether you measure the growth of dollar value of drugs going through, the number of hospitals, or "covered entities" as those that participate in the program are referred to as, or whether you're talking about the number of contract pharmacies, that growth has been out of control.

Now, if it was actually achieving its purpose, that would make sense. But it's not. So, we have out of control growth, combined with a program that's not actually doing what it's supposed to do and then it has ancillary impacts which includes incentivizing more expensive medicines to be used. You're actually raising costs for other users of drugs and you're actually incentivizing a consolidation in the medical practices which when you do it for 340B is actually inefficient as it raises costs and hurts quality of care. I think you're familiar with 340B but let me just go through it very quickly just in case some of us aren't. The purpose of 340B is to help ensure patients have the needed medicines by supporting hospitals or clinics that are serving what they call disproportionate share but basically, lower income people, particularly people without insurance. If you look at the history of it, it's actually interesting because it's a little bit of the old woman who swallowed the fly where it was once you had pharmaceutical companies provided low-cost medicines, sometimes for free, to these same types of hospitals or entities but then when Medicaid came along when they had their reform in 1990 and you had "best price". Well, "best price", if I'm giving the medicine away for free, that's your best price. That's something you can do for a small share of hospitals but you can't do that for the entire Medicaid program so you actually, from one reform trying to do something over here, you squeeze the balloon and you caused a problem over here. So, now we'll squeeze the balloon again and we created 340B and the idea for 340B is we're going to allow these covered entities to purchase the drug at a lower price. That lower price they get reimbursed at the higher rate which is in subsidy which they're

then supposed to use to expand to care. Talking about discounts, it could be 50% more and actually on average they're right now significantly more.

Here is a very simple kind of example to how this works and it's simple because I'm not including margins, markups, and all these other kind of fun things or when you talk about prices in the drug industry, we can have a whole conversation about that. But if we assume a drug with a price of \$1,000, if you have 340B discount of 50%, then that hospital when they're purchasing the drug, assume it's an infusion drug for cancer, you're actually going to pay \$500. Even though you paid \$500, the insurer, or Medicare, is going to reimburse at the full value. For Medicare it would be Average Sale Price (ASP) plus 6%, but we'll just call it \$1,000 and that means what we've now done is given that hospital \$500. Now, what's really important to remember though is that that \$500 came from the pharmaceutical manufacturer. Which when you're talking about the program when it's contained and it's part of kind of a charitable operation, it's doable but when the program grows beyond something that they can afford, you end up with restrictions, which is what we're actually seeing in the program now. Entities that deserve these types of discounts are actually finding it very hard to maintain them.

Starting with the growth very quickly, and this chart came from Drug Channels, which if you're not familiar with it, it's is a fantastic source in all things drugs. And there's two bars in this which is why this one's interesting. The light blue bar is what they guesstimate the price of the drugs are at the 340B discounted price. In this case it's the purple bar that's at the list price, or what they call wholesale acquisition cost (WAC). And what you see is you focus on the blue bar, that's a 27% average annual growth a year. So, you have the revenues in this program are growing at kind of what they're paying, 27% a year. Now, to see how excessive that is, manufacturer revenues are going up 5% a year. So, you see a huge increase in the dollar value going through this program and you can see a large part of that, that's kind of at the end of 2020 there, is through contract pharmacies which we'll come back to as that's one of the big problems in terms of why this program is having more fraud issues and is growing out of control. If you look at this graph, and this is from IQVIA, they take the WAC price data, so that bar all the way to 2021, you can see it's now going to \$94 billion, or 14% of all drug spending valued at this price. That's just an incredible growth. It's become the second largest kind of program discount in the system. So, it's supposed to be something that's kind of tailored to specific hospital's serving low-income people. Now, it's at 14% and the second largest discount program.

And why that's happened, and to me what really amazes me about this chart, and this is from IQVIA again, the light blue bar is what they call covered entities - hospitals, things of that nature. And it looks like it's not growing. But that grew 50% between 2010 to 2020. Now, why is 2010 important? Because that's when we had some changes that allowed entities to have as many contract pharmacies as they want. It's interesting about contract pharmacies as they were put in there because some of these entities, the ones that are deserving of the discount, they didn't have pharmacies internal. So, you have huge hospital systems that have their own pharmacy, then many of these entities didn't. So, you're allowed to have one contract pharmacy. In 2010, it was decided you can have as many as you want. Some institutions now have 150 contract pharmacies and so you can see in that green bar how much that's grown. It's so excessive that you can't even see the growth in the number of entities which is huge in and of itself. And then the bar in between which is also very important is entity sites because you have that incentive to consolidate, to bring independent practices into your hospital system. And this is evidence that that incentive is actually working, that we're actually buying up practices and bringing them to the hospital system. And basically the reason is for the 340B discount. So, with the relaxation of Medicaid, and with the relaxation of research and contract pharmacies all around 2010, we've seen a huge growth in this program.

In terms of contract pharmacies and why that's very important, if we're talking about almost 30,000 contract pharmacies, 70% of those, the Walgreens, the CVS', they're actually getting about 25% of the revenues from 340B because when you fill a prescription and you're a contract pharmacy, you get a higher rate than you would on a normal prescription. Seventy percent of it is going through huge big name companies. So, here's one kind of problem with the program. Contract pharmacies have exploded. They're getting a big chunk of the money and they're not the intended institutions we're trying to support. So, we have this off chute of all of the revenues going to these contract pharmacies. That's a huge problem. If we're looking at the hospitals themselves and this is now reciting some of the research I've done where we looked at a sample of hospitals in this case, this is looking at a sample of 340B hospitals and we went through 990's to see if we could get a sense of how much their revenues are growing compared to the average hospital and you can see average annual revenue growth is significantly higher in a 340B. However you measure that average doesn't matter - we have a higher revenue growth compared to your average hospital.

Not only do we have higher revenue growth, but profit growth also compared to some basic benchmarks is excessive. So, what we're seeing is growth in revenues in the hospital systems, growth in profits in the hospital systems but when you look at also the profitability, and we're able to not just do a sample, we can look at all 340B hospitals - this is for 2017 and they are actually more profitable. They're excess revenues engaged in a non-profit institution relative to revenues at 340B hospitals are significantly higher - 25% higher. So, we have incredibly profitable institutions with strong growth in revenues, strong growth in profits. The big problem is they're not spending more on charity care. If you look at how much they're spending on charity care, it's about average of 1.66% compared to a bit over 2% for your average hospital. So, we have subsidization of the program, it's expanded to the point where it's not achieving its purpose and that purpose is important but we need to reform 340B to bring it back to that issue. And why is the program having these results? Part of the problem is you're incentivizing high cost medicines and that just gets to how the markup works. Fifty percent of a higher number is a larger amount. What we actually see, and this is from a Government Accountability Office (GAO) study that they are actually prescribing more drugs and they're prescribing more expensive drugs. So, 340B is incentivizing all these hospitals that are growing to spend a lot more to use higher cost drugs. Because of that and because of the growth of the program, what we're seeing is evidence of cost shifting. And the GAO and New England Journal of Medicine stated that in fact there is cost shifting. So, non 340B patients are paying more for their drugs because of the huge discounts that are coming through the 340B program.

And we're also seeing consolidation of medical practices. When we looked at those entities cited, what you're seeing is if you were an independent cancer center, the drugs that you're using are very expensive. So, that 340B discount is worth a lot and so what you've seen is oncology practices are no longer independent; they're now part of big hospital systems. Higher costs are associated with hospital systems plus quality of care. Patients who prefer to be independent can't do it. And that leads us to why we need to reform. Some of the reforms we're talking about is most importantly transparency and restrictions on contract pharmacies as you shouldn't have 150 contract pharmacies, as it's not necessary. Boston General has a contract pharmacy in Florida - that's a bit excessive. We need to roll those back. We also need to make sure that the patients benefit and this something I hit upon but when you talk about a patient's co-insurance cost, that's typically not based in the 340B price. So, in the example I gave earlier it would be based on \$1,000. So, even though the cost to the hospital is based on \$500, a patient's paying their co-insurance on \$1,000. So, patients directly benefiting isn't part of the program but it should be. Also, restricting expansions to medically underserved areas is

important. Right now, a profitable strategy is to pick up an oncology center in the very rich neighborhood with people with lots of good insurance, and you're going to get a lot of money. But again, the purpose of the program is to serve medically underserved areas.

Miranda Motter, Senior VP, State Affairs and Policy at America's Health Insurance Plans (AHIP), thanked the Committee for the opportunity to speak and stated that she would like to spend a couple of minutes talking about 340B with particular emphasis on the parties and the disputes that I know many of you have read about in the press. I'm not going to try to duplicate any of the information that Dr. Winegarden has shared because I think some of the information that he has shared you will see here in my slides but where I talk about it there is an emphasis that I think is really important as we think about the program and we think about the disputes and the problems Dr. Winegarden talked about. And certainly we should think about if there are solutions that should be considered. So, I'm going to spend a couple minutes talking about the purpose and the participants and then really spend most of my time providing again some granularity around the disputes and where they lie and why. The purpose of the program as it was created by Congress in 1992, was to stretch scarce Federal resources to reach more eligible patients and to provide more comprehensive services to low income patients and to uninsured patients.

Here, I think it's really important to focus on who the participants of the program are and there are four main categories of participants. The Health Resource and Services Administration, referred to as HRSA. The Office of Pharmacy within HRSA is actually the administrator of the program and that's really important particularly as we talk later on about the disputes. Drug manufacturers who are participating in the Medicaid drug rebate program are participants and it's really important again to note that drug manufacturers must participate in the 340B program in order to have their drugs covered under the Medicaid program. So, that is again another really important distinction that there is essentially an exchange they receive. They provide their drugs at a discount in the 340B program and as a result their drugs then are available in the Medicaid program. We talked a little bit about covered entity and contracted pharmacies. Contracted pharmacies essentially the way I think about it is stand in the shoes of the covered entity and as Dr. Winegarden said, under Health and Human Services (HHS) guidance and HRSA guidance hospitals are utilizing contracted pharmacies in ways that are permitted under the Affordable Care Act (ACA) due to the expansion of the program.

It's also important to again focus on the eligible patients. So, the regulations at HRSA are very clear about the types of patients that should be receiving the discounts and the rebates and they're essentially those that receive care from a covered entity. So, let's talk just a quick minute again about how the program works. As I said, drug manufacturers essentially provide a discount and Dr. Winegarden talked about it being 50% or more but I think generally what we hear is the average is anywhere between 20% and 50% on outpatient drugs that are purchased by covered entities. Again, the drug discount is given in exchange for coverage of their drugs in Medicaid. The covered entities on contracted pharmacies must comply with all the 340B program requirements including making sure that the drugs are distributed and given to eligible patients. You'll hear sometimes what's referred to as a prohibition about a duplicate discount and this is really in the Medicaid context where there are duplicate discounts so discounts that result from 340B and discounts that result from the Federal rebate program are impermissible under Medicaid. That's not the case necessarily in the commercial market but you may hear references to duplicate discounts. And then lastly here and you'll see throughout my presentation there are number of links because I do think again it is very important as you are considering this issue to really go to and look at the resources that are out there whether it's the HRSA's FAQ's where it talks very specifically about covered entity requirements, contracted entity requirements, and drug manufacturer requirements. This is a slide very similar to what you

saw Dr. Winegarden present. It is simple math where you see the discounted drug, the discount being given by the drug manufacturer to the hospital or the covered entity and then what the reimbursement for that drug is. And then certainly, the difference or the delta of that goes back to the covered entity.

One of the things that I think is really important as we look at the disputes here is that this is not a health plan issue. The disputes that I'll talk about here in a minute are disputes between drug manufacturers who are essentially in some instances resisting the 340B program requirements to provide those 340B discounts. That is one situation. And then the other instance is where a drug manufacturer may be imposing certain conditions or restrictions to make sure that they get the information they need or to ensure that that drug is going to an eligible patient. And then the other sort of group of disputes that you'll see here in a minute is really by the covered entity. So, those who are seeking to protect those scarce resources to protect those funds that they are receiving under the 340B program to use for a variety of purposes. This is a high level review of where the disputes lie on the drug manufacturer side. Here, I included the materials around the 340B advocacy that you'll see PhRMA has put out and put forward and I think it's really important to see those things and their rationale of the dispute as it relates to providing the rebate to covered entities. You'll see here that initially; I think the major dispute started when notices by a small number of drug manufacturers were sent to HHS that they were going to limit and not provide the discount. Quickly thereafter, you had a number of other drug manufacturers follow suit.

This next slide really provides the backup or the additional detail of the bubbles on the prior slide. So, as I said, other drug manufacturers quickly followed suit after a couple of drug manufacturers indicated that they were not going to provide the rebate. Seventeen drug manufacturers I believe to date have indicated that they will not be providing that discount. And then as I said, about 10 of those companies have indicated that they will impose certain restrictions to make sure that they get the information back that they need from a covered entity. In December of 2020 as I mentioned HHS issued an advisory opinion that concluded that drug manufacturers are required to provide that discount under the program on covered outpatient drugs when a contract pharmacy is an agent for that covered entity. Additionally, in December of 2022, HHS issued a final rule as it related to their administrative dispute resolution (ADR) process. Drug manufacturers quickly and along with PhRMA have filed suit that challenged HRSA's advisory opinion as it related to the ADR process. And some manufacturers had, or are in, disputes as it relates to both of those things. You'll see there between 2021 and 2022 HRSA sent letters to drug manufacturers. You can see the letters there on HRSA's website to those drug manufacturers that announced they would not provide the rebate indicating that they needed to do that per HRSA guidance. And then in September of 2021 HRSA has referred a number of those cases to the Office of Inspector General within HHS.

So, again a quick high-level overview of where the disputes lie and really the perspective of the drug manufacturers as it relates to the 340B program. Let me quickly move to the disputes on the covered entity side. Again, I wanted to provide sort of the high level overview of all of the different categories of disputes that we see on the covered entity side. Again, I wanted to show and provide to you information that's publicly available on America's Hospital Association (AHA) website of what they believe the challenges are which again are really focused on the drug manufacturers. And then some resources are shown there by 340B Health which is essentially a member association of hospitals that are working on 340B advocacy and reform issues. So, let's go to the detail slide and let's start with the hospital association and the 340B providers. Quickly after those drug manufacturers announced that they were not going to provide that rebate they sent letters to those drugs companies asking them to reinstate the discounts on those products.

Thereafter, those 340B providers filed suit to really ask and to enforce HHS's obligation as it relates to drug manufacturers and enforcing the program and the drug manufacturers requirements.

Related to 340B disputes but different than the drug manufacturer issues, I did think it was also important to highlight that the Centers for Medicare & Medicaid Services (CMS) during all of this also issued a rule that would have essentially cut Medicare payments for drugs that were acquired under the 340B program. And so, as you can imagine, there were suits and litigation that followed as a result and most recently just a couple of weeks ago, the U.S. Supreme Court issued a decision in that case and you may have seen some of the press coverage as it related to that decision. In short, as you can see here there are a variety of disputes that really at its core are about the discounts that manufacturers are required to provide. And on the other side it's the covered entities and the contracted pharmacies and their role and the funding that they receive and the important resources that they receive under the 340B program. I think it is really important to note that this is not a health plan issue for all of the reasons that I just walked through and in closing I would say it is really important to be cautious against any type of legislation and policy proposals that would essentially leave the ultimate purchaser of healthcare, which is the employer and the individual patient from being left holding the bag. And when I say that I mean making sure that proposals don't relieve drug manufacturers from paying that rebate when they are required to pay that rebate under the Federal program and then also likewise making sure that any proposals don't relieve covered entities from having to comply with the program's requirements as well.

Greg Doggett, VP, Legal and Policy Counsel with 340B Health, stated that I just wanted to thank NCOIL for its continued interest in 340B. A lot of interesting information has been shared. I would like to highlight that a lot of the issues raised today are primarily Federal in nature. Going back to the NCOIL Health Committee discussions at the last two NCOIL meetings about 340B, one area that is ripe for State regulation, or I should say State legislation, is regulation of pharmacy benefit managers (PBMs). Specifically, legislation that would address discriminatory payor practices such as low reimbursement. States have already shown a tremendous interest in this issue. We have now two dozen states that have already enacted such laws. So, I would encourage the organization to continue to consider the model legislation that was discussed at those last two meetings. Also, in light of some of the information shared today, I just wanted to briefly mention a couple of research points that I think demonstrate that 340B continues to target the proper hospitals that serve a lot of low income patients, or patients in rural areas. 340B hospitals make up only 40% of the hospitals in the U.S. but they provide 60% of all uncompensated and unreimbursed care. They also provide 75% of total hospital care to Medicaid beneficiaries. And then just one last point - critical access hospitals, hospitals where healthcare access is a major issue, consistently report that 340B is one of the lifelines that just simply allows them to stay open. Especially at a time with COVID and especially when so many hospitals are facing closure in rural areas.

Asw. Hunter stated that Ms. Motter had repeated a couple different times that this is not a health plan issue - it's a drug manufacturer and covered entity issue. So, it would have been nice to actually have PhRMA here to speak on this issue. Also, we really wouldn't be needing to have this discussion if the drug prices weren't so expensive in the first place which I feel like we don't have many conversations about and that is what got us into this position in the first place. But my two question or points which I don't know if they can be addressed today or not relate to identifying the need population and what that looks like relative to safety net hospitals and their need. Because if you are talking about a situation like where I live, where I have a FQHC and a safety net hospital, this hospital has hundreds of millions of dollars for their programs and

services and the savings that they're getting benefits programs and services but the millions of dollars that come to the FQHC cannot be replaced. I think that needs to be addressed and I'd like to know how we're going to go about doing that and what is the Federal government's plan to supplant this removed money? New York is talking about, "We want our savings back" and all of a sudden it seems like a money grab from the state trying to take this savings money back but who is going to give an FQHC that money that they were using directly for programs and services that they're not going to have otherwise? So, I don't know if you all have the answers to these questions. I think that this definitely warrants more discussion than unfortunately the limited amount of time that it allows today but this is a very serious problem that I think we need to have some more people at the table to address.

Sen. Hackett stated that I agree a lot with what Asw. Hunter said. I've been involved a long time with 340B and if you look at 340B, initially you had the veterans, you had the FQHCs, and you had the disproportionate share hospitals and then President Obama allowed a lot more hospitals to get involved. So, the biggest issue is not the FQHCs and the veterans. I think if you talk to people in Washington D.C., it would destroy them and it would really be bad. And in Ohio we had some drug companies that basically said they weren't going to pay the discount and you have to realize a lot of our FQHCs are working in deserts as it is and if you cut out a Walgreens or a CVS, they have to have them if they don't have an in place pharmacy. So, the question I have is, when they set the law ten years ago or whenever they did it that the additional dollars had to be used under specific rules that the Feds dictated - has that been changed? Is that at a point where that's been strengthened? Are there any negotiations going on at the Federal level? I agree that this is a Federal issue and it's not a State issue - it's a Federal issue. And so, is there anything going on at the federal level? Because we cannot let PhRMA just dictate to us to cut this out. I understand the issue with the one set of hospitals. I'm not in the middle of that, and they can fight that how they want but is there anything being done at the Federal level to get this thing resolved so that we don't keep fighting this over and over and over?

Ms. Motter stated that from what I understand there have been attempts whether it's at the Congressional level or through HHS to try to adjust and reform the program. But it remains as it is today by the ACA and by additional laws and regulations so I am not certain it has not been changed but I would just continue to reiterate that this is a Federal program and these challenges lie at the Federal level because of the way it is currently situated. Sen. Hackett stated that if the law hadn't changed we wouldn't have this problem. If Congress would have left it alone we would have helped the ones we were helping and so adding that layer of hospitals into the system is what has created this problem from day one. And I'm not making a value judgment whether they should be in or not but the issue is we had additional hospitals that qualified for the dollars. If they hadn't had done that we wouldn't have this problem.

Dr. Winegarden stated that some of that wasn't intentional. When we created the ACA, we expanded Medicaid. When you expanded the Medicaid population you brought hospitals that weren't part of the program into the program. So, there's a lot of unintended consequences. When you're looking at the issue with 340B, nobody intended for some of these things to happen they just have happened. But to directly answer your question, there's no legislation moving right now at the Federal level that would address any of these issues.

Mr. Doggett stated that regarding the point mentioned about the contract pharmacy restrictions, in the waning days of the Trump administration they put out an opinion to say what manufacturers were doing with limiting 340B pricing for contract pharmacy was illegal and it violated the statute. The Biden administration has maintained that position. Numerous pharmaceutical manufacturers are suing the administration and there's multiple cases tied up in

courts. One thing I would mention was that the ACA did expand the number of hospitals that were in 340B but these were mostly just small rural hospitals and cancer hospitals and children's hospitals. Disproportionate share hospitals already qualified for 340B and have since the inception. Sen. Hackett stated that I'm going to argue with you on that because if you look at Ohio, the rural hospitals are all owned by the big city hospitals. So, you may say that, but that is not true in Ohio. Mr. Doggett stated that I hear what you're saying. I'm just saying if you look at the total count of hospitals, the bulk are small critical access hospitals. I'm not disagreeing with you that some of them are part of health systems and some of them are a bit larger.

DISCUSSION ON INTERNATIONAL INSURANCE ISSUES OF LEGISLATIVE AND REGULATORY CONCERN

The Hon. Dean Cameron, Idaho Insurance Director and National Association of Insurance Commissioners (NAIC) President, thanked the Committee for the opportunity to speak and stated that it's a pleasure to be here with you and we're grateful for the opportunity to provide you with an NAIC update on key international issues. Some of you may be considering why is it important for the NAIC and for you to be aware of these issues and be involved as heavily as we are? We all guard our consumers and want to protect our consumers so that they aren't hurt and with that comes the responsibility of protecting carriers who are both selling here in the United States as well as selling in other areas. We also want to be able to help those countries who have less of a robust regulatory system, or are trying to figure out their regulatory system, or what's appropriate and we can talk about some of that. And then thirdly, we know that it's important for us to build relationships as we battle some of the issues that come forward. I'm going to turn things over now to The Hon. Gary Anderson, Massachusetts Insurance Commissioner and Chair of the NAIC International Insurance Relations (G) Committee.

Cmsr. Anderson thanked the Committee for the opportunity to speak and stated that I started my career in the insurance world for a regional carrier in the Northwestern United States and then I had the opportunity to be a counsel in the Massachusetts legislature working on insurance and banking issues at the intersection of law and politics and policy. And now I have the opportunity to serve as the insurance commissioner. So, I feel very fortunate to have seen the market from a few different perspectives. As Dir. Cameron noted, this has been a critical issue for a number of years and maybe I'll just set the stage a little bit and I can do it quickly just to go back a little bit to set some context. If you go back to 2013, so this not long after the crisis and the financial stability board charged the International Association of Insurance (IAI) supervisors with creating global capital standards. And as part of that, if you recall, at that time there were nine firms that were designated as potentially systemically important insurers. Of those nine, three were from the United States. So, we have long held here in the United States that it's not just the size of these entities that may or may not pose a risk but it's what kind of activities are they engaged in? And so, when you're developing capital standards, I think it's also a challenge to think about creating one capital standard for the globe when all of our jurisdictions, particularly here in the United States, are so different from another. For example, another country in Europe, it's been the belief of Team USA that the capital standards have to account for the differing legal frameworks of the jurisdictions across the globe. I think it's fair to say that's going back to 2013 with that charge. Since then, a lot of work has been done. In 2019, we were faced with a little bit of a challenge at that time. I think there was some momentum on the side of some of our colleagues from overseas with regard to developing this single global capital standard and we had said for years that this would not be fit for purpose here in the United States. The United States had been developing our own group capital standard, which is known as the GCC, the group capital calculation.

And that leverages the structure of the United States which is, it takes the legal entities within a company and it aggregates that capital to develop a calculation at the group level. We had pushed for that. I think in 2019 we were challenged because there was no mechanism in place for us to be recognized for the work that we were doing and I would say for Team USA I think we helped to reshape the power dynamics if you will in 2019 in our favor. And what we did was, through the IAI there was being developed the international capital standard, the insurance capital standard, the ICS. We needed a framework to compare what we were developing here in the United States - the group capital calculation which is known as an aggregated method because it aggregates the capital. It's also, we've argued for years, jurisdictionally agnostic. So, if you're a jurisdiction that is a developing nation and you're looking for a capital calculation this will work for you too.

So, we were fortunate through a lot of hard work able to develop a framework to compare these two standards. That's known as the comparability assessment. So, for the past several years, since 2019 we were able to put that in place. We've then been developing areas that we needed to focus on for this comparability assessment between those two standards. We then took those areas of focus and we built them into what are known as high level principles. And throughout this process we are engaging with stakeholders, and we go through consultations. We get input from the industry and other stakeholders and we took those high level principles and now we're at a point where we're developing the last stage of what's known as criteria. That is now out for consultation so our carriers will be commenting on this last set of criteria that helped build the framework to compare these two standards.

We had an international forum in D.C. a couple of months ago. There were a few things that we needed from our international colleagues to move forward in this process. We were able to achieve those things. Those are making sure that stakeholder input is not only heard but is taken on and used in the development of this criteria and we were able to get that. We had some concerns about the comparability comparison, that it will be made at the end of 2024. We had some concerns about the makeup of the team of assessors. We got that fixed. So, I think we're on a really good path at the moment. I think that's a lot of effort that's been done over the number of years by Team USA that includes the NAIC colleagues - the Federal Reserve and Treasury that work with us as partners in our effort. So, at this point we're in a good place but we've now developed over the years, kind of a common framework, if you will, to discuss these issues with supervisors across the globe. We hold supervisory colleges. So, let's say for example, Liberty Mutual, which I am the group wide supervisor for in Massachusetts, will hold a supervisory college. Regulators from across the globe will come in and we'll discuss issues relevant to Liberty Mutual. So, we have done a lot of work to develop these common framework and common language. We assess risk across the activities that is within insurers, but also within the market. So, I'll turn it back to Dir. Cameron as I think he had a few things to say on bilateral engagements but I think we're in a very good place as far as the efforts we made over the last several years.

Dir. Cameron stated that we've also been engaging in a number of bilateral communications with other countries such as Singapore, Taiwan, and Hong Kong and Japan we met with here recently. We also met representatives from Australia, Canada, South America, South Africa, Argentina, and Brazil. And we signed a memorandum of understanding with the Conférence Interafricaine des Marchés d'Assurances (CIMA) which is the organization in Africa that most represents the majority of countries there.

Rep. Stephen Meskers (CT) stated that I want to thank you for the work you're doing for the oversight. Obviously, the regulatory framework on an international basis, on a local basis for

insurance companies is super important. In relation to your work in the NAIC, I've been reviewing and we just finished a conversation on 340B and now we're moving on. So, when we look at the regulatory framework, there's a second part of the equation which is looking at the insurance industry and its future health and sanity which is related to the cost structure and the payment structure at the insurance company. So, we're having the conversation about 340B and PBMs, etc. When I go into U.S. Government research there's a Ways and Means Committee report in 2019 mentioning that the U.S. pays about four times what the Organization for Economic Cooperation and Development (OECD) countries pay for its drug prices for the pharmaceuticals and I think for the sanity of the NAIC and our regulatory framework we have to address that elephant in the room which is what are we going to do about pharmaceutical prices and what's the potential at some point for a cap in the U.S. so we're not paying four times what OECD countries are, and what's the regulatory premium we want to see in the U.S. to keep research and development in the U.S. and at the same time give our constituents affordable healthcare? I can't explain to people why drugs are four times more expensive than in Canada and if I tell people to go up to Canada, the pharmaceuticals say they can't ship to Canada because it ends up in the U.S. and they're going to limit supplies. So, we're going to have to figure out a pricing mechanism where we guarantee a profitability, keep an industry that saves lives, and does a great job for the U.S. but I don't know where we stand on that and how important is that in terms of your regulatory oversight.

Cmsr. Anderson stated that it's not necessarily what I was prepared to talk about but I can share I think as regulators across the states we share the concern about pricing. In Massachusetts, we go through a healthcare rate review every single quarter which is a challenge and you see that the drug prices take up a little bit more each time of the chunk of overall cost relative to a premium that's paid by each of our policyholders, our consumers. There have been some efforts, I can speak only you know for Massachusetts, to address that through legislation that Governor Baker had filed and whether the legislature has the desire to take that up and the time are questions as we finish our legislative session here at the end of July for this two year session. But it's certainly on top of mind, and to your point about the value, a good friend of mine, the former Superintendent of Maine, used to say if you're not at the table you're on the table as the meal and I think that goes for these discussions but also at the international level. If we're not engaged there then things will happen to us, which happen to our carriers, which happen to our policyholders. So, it's really important that we're engaged to push our policy and particularly on this one, I wish I had a silver bullet on this one as it's been a challenge since I've been the Commissioner and before so.

Rep. Meskers stated that if I could suggest to the NAIC, I think the message to D.C. has to be the credible management of our pharmaceutical pricing. We want the industry and research here but we all need to think about where we're going with the price structure we're seeing. In Connecticut we're talking and I think it's on the order of a 20% price increase this year and that's not sustainable over time.

PRESENTATION ON DEVELOPMENTS SURROUNDING NEW TREATMENTS FOR ALZHEIMER'S DISEASE

Carter Harrison, Director of State Regulatory and Legislative Affairs at the Alzheimer's Association thanked the Committee for the opportunity to speak and stated that today I'd like to speak briefly about the new advancements that are occurring around Alzheimer's treatments and the potential impact that these treatments may have on state policy work moving forward. I'm going to start with a bit of review of the drug that has sort of kicked off this process and I'm sure you all have seen this in the news around Aduhelm which is part of a class of drugs that seeks to

remove amyloid buildup in the brain which is one of the markers for Alzheimer's type dementia. This drug has been approved to treat the early stages of dementia, so that's mild cognitive impairment or early Alzheimer's disease and this is currently the only FDA approved treatment that treats the pathology of Alzheimer's disease and it was approved under the accelerated pathway. Again, something that was noted quite a bit in the news. Also, things that were not noted but are important for policy considerations in the future is that this drug is administered by IV. It is not an oral drug and there are some very important parts of the label that deal with safety related to Amyloid Related Imaging Abnormalities (ARIA) which is very dangerous if it's not monitored and will have some future state policy impacts additionally.

So, I'd like to start with the Medicare CMS determination for the national coverage decision and I'm going to essentially break this down into a couple of different sentences although there's quite a bit more detail up here. But basically, in order to have this covered under Medicare, you'll have to be in some type of clinical trial. So, there are various options for those clinical trials which you will see up here whether they be National Institutes of Health (NIH) studies, or CMS approved studies. But in all cases, you will have to be a part of a study in order for Medicare to cover the cost of this drug. As you can see, on the last point on the slide, outside of this criteria the drug is considered not covered by Medicare. Now, this has a number of implications. Obviously, the first one I'd like to start with is on the Medicaid front. So, for those of you that are not as familiar with the Medicare program, if a manufacturer participates in the Medicaid drug rebate program, the drug has to be covered. And this was touched upon in some of the earlier presentations and of course the manufacturer for Aduhelm does participate, so therefore, the drug has to be covered under Medicaid.

Of course, states can and have restricted the use of this drug through utilization management techniques in order to make sure that the population is targeted to what exists in the label for the drug. And additionally, one of the issues that has come up as a part of this decision is that the drug when covered by Medicare is considered a Part B drug. And when not covered by Medicare is considered a Part D drug. And the reason that that's important is because Medicaid cannot pay for Part D drugs for full dual eligibles.

So, you have a circumstance where dual eligibles cannot receive this drug but other recipients in the Medicaid program, at least theoretically could if they meet the prior authorization criteria. So, as you can imagine this was pretty devastating for any person that is currently living with Alzheimer's disease but I did want to sort of highlight some of the responses to CMS's decision where there may be at least a bit of hope for the future. So, first of all while this did apply to the entire class of drugs of which there are several in the research pipeline currently, it does not mean that Medicare and CMS will not evaluate each one individually and if the data is convincing or more convincing then they may change this current national coverage determination (NCD).

In addition, they did talk about how this was promising but not quite meeting the statutory requirement for it to be covered. Again, I'm sort of taking the glass half full versus the glass half empty approach to that piece as well. And also, there are going to be future drugs that come forth and I think there's a lot of things that you as policymakers in the states will have a lot of opportunity to help impact this. And I'd like to use this chart to sort of demonstrate how I think that will happen. Now, this chart is again for demonstration purposes only but it shows how a person normally ages and gets diagnosed. And in this point, the star here represents age 65 diagnosis. And then you can see sort of a rapid cognitive decline. Also, you'll note in the chart again that the individual has been declining prior to the diagnosis that they received. This chart shows something that I hope we get to in the near future which is a place where an individual has only a mild bit of cognitive decline and is then diagnosed at an earlier age and here for this

chart's demonstration purposes, we are looking at age 45 and then they begin to receive a treatment that slows their cognitive decline. Now, when you put these two charts next to one another, you may not think there's a lot of difference between the rate of cognitive decline. However, what I'd like to point out is that there are a lot of cost savings to the healthcare system by avoiding as much healthcare needs, especially on the long-term care side, especially for Medicaid spending where you reduce the amount of time or you lengthen the runway for that individual's cognitive decline.

Not to mention the fact that the person with the disease will have more time to spend with their families, more time to plan, more time to be a part of normal society. So in the end there's a number of questions that I think states will be addressing as these treatments move forward and are starting to service the dementia population. One of those areas will deal with genetic testing and diagnosis protections. If you have individuals that are going to receive a diagnosis when they are younger perhaps when they are still working it's going to be very important that that individual that might be undergoing treatment receive the protections that are necessary in order to continue to work or be participatory in society especially if there's a genetic test. There are several forms of dementia that genetic testing does indicate that the individual may, or is more likely to develop dementia and those types of protections are going to be needed.

Additionally, testing is very important. It has also been shown in the NCD but right now these drugs, the labels want you to confirm that there are amyloid buildups in the brain and that is currently done by either spinal fluid or PET scans. Both of these, the PET scans particularly, are very expensive and they may have a certificate of public need issues related to them. There is a possibility that in the near future there will be testing that is not as expensive or does not require these types of machines which actually makes this even more complicated because providers may not be willing to invest in this equipment that would be necessary to do the treatment and to monitor it safely.

So, earlier I referenced the scans for ARIA, the label for Aduhelm currently requires constant monitoring through MRIs. It is certainly possible that future drugs will have similar requirements. So, there will be additional costs and additional needs there. The next item deals with drug delivery. You heard me state earlier that the Aduhelm was an IV drug and would be administered in a doctor's office or perhaps some other type of clinical setting and most of the drugs that are currently in the pipeline also are administered within a clinical setting and so it's going to be important to make sure that those settings are available and able to handle it.

Lastly, there's a couple of coverage implications. The reason that I went through the chart was to point out that those policymakers think about Alzheimer's as a Medicare problem, and possibly a Medicaid problem. But as these treatments come to market, the line will start earlier before an individual is likely eligible for Medicare or Medicaid. And so that will push the treatment options closer to the private insurance sector and will start to have impacts on private insurance as these treatments continue to be developed and then of course lastly, I have state employee health plans listed. I think many of you can think about other types of treatments that have come out and the policies that have gone into those whether they be cancer and the impacts they've had on the state employee health insurance plans.

Rep. Ferguson asked how many clinical trials are running right now. Mr. Harrison stated that I don't have an exact number but I'd be happy to check with our colleagues and get you the number. Rep. Ferguson asked if there is a trial in most states. Mr. Harrison replied no, not necessarily but in Arkansas, we have identified an interesting problem there and that is a lack of PET machines. So, they don't have the PET scanners available to the population there and so

they would have to go outside of state in order to participate in those types of trials so that is an issue for your state.

ADJOURNMENT

Hearing no further business, upon a motion made by Asm. Ken Cooley (CA), NCOIL President, and seconded by Rep. Tom Oliverson, M.D. (TX), NCOIL Treasurer, the Committee adjourned at 12:45 p.m.