NATIONAL COUNCIL OF INSURANCE LEGISLATORS
JOINT STATE-FEDERAL RELATIONS & INTERNATIONAL INSURANCE ISSUES COMMITTEE
2026 NCOIL SUMMER MEETING – BOSTON, MA
July 16, 2026
DRAFT MINUTES

The National Council of Insurance Legislators (NCOIL) Joint State-Federal Relations & International Insurance Issues Committee met at the Westin Copley Place Hotel in Boston, Massachusetts on Thursday, July 16, 2026 at 11:30 a.m.

New York Assemblyman Erik Dilan, Chair of the Committee, presided.

Other members of the Committee present were:

Sen. Justin Boyd (AR)
Rep. Rita Mayfield (IL)
Rep. Deanna Gordon (KY)
Rep. Michael Meredith (KY)
Sen. Kirk Talbot (LA)
Rep. Brenda Carter (MI)
Sen. Lana Theis (MI)
Sen. Paul Utke (MN)
Sen. Tim McGough (NH)
Rep. Brian Lampton (OH)
Rep. Dennis Paul (TX)
Rep. Tom Oliverson, M.D. (TX)

Other legislators present were:

Rep. Zack Gramlich (AR)
Rep. Stephen Meskers (CT)
Rep. Elijah Pierck (HI)
Sen. Adrian Dickey (IA)
Rep. Ben Fuhriman (ID)
Rep. Adrielle Camuel (KY)
Rep. Dennis Bamburg (LA)
Rep. Aimee Freeman (LA)
Rep. John Ilg (LA)
Rep. Edmond Jordan (LA)
Rep. Shaun Mena (LA)
Del. Pam Guzzone (MD)
Rep. Poppy Arford (ME)
Rep. Michelle Boyer (ME)
Rep. Bob Foley (ME)
Rep. Rolf Olsen (ME)
Sen. Bill Gannon (NH)
Asm. Jarett Gandolfo (NY)
Asm. David Weprin (NY)
Sen. Mark Mann (OK)
Rep. Kevin Norwood (OK)
Rep. Carl Anderson (SC)
Rep. Matt Morgan (TX)
Rep. Calvin Callahan (WI)
Del. Walter Hall (WV)
Sen. Cale Case (WY)
Rep. Pepper Ottman (WY)

Also in attendance were:

Will Melofchik, NCOIL CEO
Christa Rapoport, NCOIL General Counsel
Pat Gilbert, NCOIL Director of Policy, Administration & Member Services

QUORUM

Upon a Motion made by Sen. Tim McGough (NH) and seconded by Rep. Michael Meredith (KY), the Committee voted without objection by way of a voice vote to waive the quorum requirement.

MINUTES

Upon a Motion made by Rep. Brenda Carter (MI) and seconded by Rep. Brian Lampton (OH), the Committee voted without objection by way of a voice vote to adopt the minutes of the Committee's April 18, 2026 meeting.

INTRODUCTION AND DISCUSSION OF THE NCOIL STRENGTHENING TRANSPARENCY IN THE 340B DRUG PRICING PROGRAM MODEL ACT

Asm. Erik Dilan (NY), Chair of the Committee, stated we'll start today with the introduction and discussion of the NCOIL Strengthening Transparency in the 340B Drug Pricing Program Model Act. There was a great first discussion on this topic at our Spring Meeting in Louisville, KY and I know this is an issue that many of us have dealt with in our respective states across the country. And with that, I'd like to recognize Rep. Tom Oliverson, M.D. (TX), who is sponsoring this Model, for some brief remarks.

Rep. Oliverson stated it's a pleasure to sponsor this Model. You can find a copy of the Model starting on page 33 in your binders. I would point out that this Model is already state law in Indiana and other states. We all recognize the fact that the 340B Program is critically important, especially to the grantees, the Federally Qualified Health Centers (FQHCs), the Ryan White clinics, the Black Lung clinics, and those for which it was originally intended to be beneficial. However, it has grown massively. I think even the most ardent supporters of the 340B Program would agree that it's kind of gone beyond what it was originally designed to do, maybe for better, maybe for worse. So, all we're proposing to do with this Model is allow state lawmakers the opportunity to have some transparency and to be able to see how the Program is being utilized in their states with the various 340B pharmacies, participants, hospitals, facilities, medical practices, etc. That's essentially all it does. I do want to be clear that my intent here is not to do away with the 340B Program. Similarly, this is a federal program so any Model or any ideas around structurally changing the conditions of participation or the way the Program works would need to be done at the federal level. However, sunlight is a good disinfectant for everybody, and I think transparency is really important. I do want to say a special thank you to NCOIL President, Sen. Paul Utke (MN), for being a co-sponsor on this model.

Sayeh Nikpay, PhD, Associate Professor, Division of Health Policy & Management at the University of Minnesota stated thank you very much for inviting me here to be with you today. I'm so pleased to see that this Committee is thinking about 340B transparency. The 340B Program is a program that is starting to touch so many different lives and in ways that I believe were really unanticipated by the people that created it. I'm an economist and I've been doing research on this Program for over a decade, and the more you pull the threads, the more the garment sort of falls apart and you learn. I'm pleased that you're considering transparency here. I should say that I want to give a brief disclaimer. My views don't represent the University of Minnesota, which does have a 340B hospital included in it. My views also don't represent the views of the Minnesota Prescription Drug Affordability Board (PDAB), of which I am Vice Chair.

Getting started here, these figures are very fresh. Just a few days ago, the Health Resources and Services Administration (HRSA), the agency that regulates the 340B Program, came out with new numbers on the size of the Program and the discounted value of drug purchases under 340B reached $100 billion last year. Now that has grown significantly as you can see over time. To put that number in context, 340B is now a bigger program than the Medicaid drug rebate program by about 70%. It's also on its way to potentially reaching up to the Medicare Part B program net of premiums, which is about $140 billion a year. This is an important program. Maybe one of the most important statistics here is that its penetration is great. Part of that is because about half of U.S. hospitals, or if you think about it just in terms of nonprofit hospitals, it's reaching up to about two-thirds of hospitals that are participating in this Program. Now before I talk about 340B and really any

topic related to 340B, I like to talk about its history. The Program's primary beneficiaries today are nonprofit hospitals. When the Program was created in 1992, it was designed to solve a very specific problem for a narrow set of providers with a very specific solution. So, this is from some findings of a study that I just concluded this Spring. It's an open access paper, so feel free to find it. We did interviews with 20 different people who were around in 1990 to 1992 when the policy was actually being created, talked to bipartisan staff, members of the Bush Administration, advocates, lobbyists, the whole host, and we reviewed about 200 internal memos. What we learned is that when 340B was created, it was really focused on Public Health Service Act clinics. That's things like your community health centers, Ryan White programs, and then about 200 public hospitals that were members of the National Association of Public Hospitals.

And what we have seen over time is that because of some compromises that were made and some sort of loopholes, hospitals have begun to participate in it and that participation is surging. So, there are some important words when you hear about 340B. You'll hear the words like stretch scarce resources as far as possible. The stretching here was really designed for that original group of participants, those Public Health Service Act clinics and the public hospitals that had the same problem when Medicaid drug rebate got introduced. It made prices soar as manufacturers rushed to cancel their discounts with these clinics that were some of their best prices in the market. And these providers that had fixed budgets that relied heavily on federal grants or state and local funds. In the case of public hospitals, all of a sudden you go from a $100 budget when you were spending $10 on drugs and now it's blown up. Now you're spending $40 on drugs, which means you have $30 less to do other things. And so, those words were about stretching the resources for these particular types of safety net providers. So, because of issues with the way this federal policy was created, we have this program that went from this targeted population to now exploding and growing in both size and scope. As policymakers have tried to do things in their individual states, they come to me and I hear from them about this. They increasingly bump up against 340B. Minnesota enacted a 340B transparency program because lawmakers were trying to work on a policy that they thought they had no idea it interacted with 340B and the constituency that stood up in opposition to a policy was 340B hospitals and legislators were very confused. And in an effort to gain an understanding of why 340B was interacting with this other policy, they created the 340B transparency report.

I am going to show you some findings from Minnesota's transparency report and what is possible when you do transparency reporting. I've looked at your draft Model, I think it's a really great start and looks very close to what Minnesota does. I know Indiana's law is really great too. So, this is sort of the top line result from Minnesota. You can see the economics of the 340B Program pretty clear here. Largely, hospitals and clinics that participate in this Program accepted $3 billion from insurers and patients for outpatient drugs that were purchased for a cost of $1.5 billion. After you net out the, call it $160 million in fees to third parties, you get what's left on the table, which is $1.34 billion. And that money is important to providers. I am not going to say that this is not money that health care providers depend on. What I'm going to say though is that it's a lot of money. And whether you like the 340B Program or don't, understanding how the money flows and who benefits and who is potentially struggling is very important. One of the features of the Minnesota covered entity report that I think is really powerful is that they collect information on contract pharmacy fees and Third-Party Administrator (TPA) fees. What we learned from the report is that $1 in every $10 of that, you can call it savings, you can call it 340B net revenue like they do in Minnesota, $1 in every $10 of that spread is eaten up by an outside party. That's not the hospital or the clinic. When you look here across the different types of providers that can participate in the 340B Program, some of them are giving up a lot of fees. If you're talking about big hospitals, the top 10% end up giving away 25% of what they generate from 340B. For critical access hospitals, it's getting close to half gets given up in fees. And then when

you're talking about FQHCs, there are at least 10% of them that are underwater on 340B meaning 340B lowers their cost, but they're not generating any revenue from the Program.

Also in Minnesota, we were able to look at the concentration of net 340B revenue across the different types of providers that are participating, and what comes out of it is that we see that 95% of that $1.34 billion number is coming from hospitals. And when we talk about which type of hospitals, we're really talking about the large urban medical centers. So, I believe 80% of net revenue is generated by those hospitals and because Minnesota has an appendix where the top 90% of revenue generators are actually published, we can see that it's about a handful, 4 or 5 of these hospitals that account for almost half of that $1.34 billion. So, it's highly concentrated. Minnesota's covered entity report also collects data by payer, which I see the draft Model does as well. I think that's fantastic. You learn some important facts from looking at things by payer, the chief being that the largest single source of funding for net 340B revenue is commercial patients and a lot of them are going to be employer sponsored employees who are depending on an employer sponsored plan. What's the issue with this? First, I would say that we know that people who are on employer-sponsored plans, commercial plans, face a lot of cost sharing even when they're under their deductible. Typical cost sharing for drugs might be somewhere between 20-30%. That means a big chunk of this spread of this net revenue is also generated from patients who may or may not have been able to easily pay that bill even with insurance. On top of that, we know that employers spend a lot of time and a lot of money asking Pharmacy Benefit Managers (PBMs) to negotiate rebates on their behalf to lower their total expenditure at the end of the year, which helps them lower premiums and helps them grant higher wages to employees. When 340B discounts, which are given out before the transaction, stack on top of rebates that are negotiated by the PBMs, those rebates get canceled, which means that employers end up paying more for drugs at the end of the day, because a big chunk of what they were expecting in cost reductions has just gone poof. The other thing that I think is important for anyone who's regulating insurance within a state is the interactions with Medicaid. What the Minnesota Covered Entity Report also showed is that about 1 in 5 of those net revenue dollars comes from paying providers significantly more than their actual acquisition cost when they bill through Medicaid managed care. The total in Minnesota was about $260 million of extra spending relative to if they paid based on actual acquisition costs.

There are some limitations here. I'm going to skip over these because I fear that I've been talking too much. I'm glad to hear that the NCOIL Model was based on Indiana's legislation. I think Indiana's law is very good. We also have some states that have done sort of a partway version of this by doing a one-time report, and we have federal legislation and policy that's moving forward. However, I would say that it's not clear to me that these policies will pass and even if they do pass, state policymakers need some flexibility in the data in order to answer state-specific questions. And so, I would argue that passing this type of legislation at the state level can be really powerful for states to understand where the dollars are flowing. And finally, I'll just say it one more time, my research has sort of led me to believe that there's no bad guys in this world. We have among the organizations that are participating, FQHCs who my research shows, when a dollar comes in, a dollar goes back out in care. There are public hospitals. We have one public hospital in Minneapolis where I'm from whose 340B margin is essentially the same as the uncompensated care they provided in that same year. I'm not saying this is a bad program, and you shouldn't do it. I really do think it's very important. So, I appreciate your remarks, Rep. Oliverson, that it is critically important. But I do think that policymakers need to understand where the dollars are going and how they spend the next dollar.

Molly Smith, Group VP, Public Policy at the American Hospital Association (AHA) thanked the Committee for having her today. I'm definitely not going to belabor this. I think Dr. Nikpay did a great job going through at least the origins of this Program. But I think what's really important to underscore here is that truly, this started because of concerns around the high

and rising price of drugs. Those concerns persist today, and they have over the last 30 plus years of the Program. Which is actually why, after Congress initially established the Program in the early 1990s, it actually revisited the program several times just to make technical corrections, but two times to make substantive changes to the Program. And in both instances, it was either to expand the Program or to protect the participants in the Program due to kind of unforeseen situations, specifically COVID. And I just want to really underscore two points. When we talk about how many hospitals are participating in the Program, the vast majority of those are small rural hospitals, and that's who was included in one of the primary types of hospitals that was included in the expansion. So, I don't think that should be a surprise because Congress very intentionally wanted to add them to the Program. The other thing is about the high and rising price of drugs. You saw the latest figures out of HRSA that the Program has grown to $100 billion. One of the things that HRSA said, is that about 62% of that actually is flowing through really high priced drugs. So let me just give you some specific examples.

The numbers that were on the slide were from 2017 to 2025. In that time period let's think about a couple of things that have happened in the outpatient drug space. We've had CAR-T, which originally started as an inpatient therapy, now safely being able to be delivered in an outpatient setting. So, this is a six-figure cost drug. We have Keytruda, a very important cancer drug delivered in the outpatient setting, also introduced during that time, up to millions of dollars. We also have had GLP-1s come on the scene. So, we've had a lot of changes in the pharmaceutical space that have actually driven growth in the Program that have nothing to do with the behavior on the part of the covered entities. It's just that there are new drugs and there are very expensive drugs. The more the drug costs, the higher the discount. So, a lot of that growth in the Program is actually solely a reflection of drug manufacturer decisions around pricing and their introduction of new drugs. Also to underscore what the 340B Program does, this is not about changing what anyone pays in terms of a service, what an employer pays, what a public program pays, or what an individual pays. The difference here is in expenses. As Dr. Nikpay mentioned, the concern was really about more of certain providers budgets were getting eaten up by drug costs. So, this is really just trying to give them more of a cushion back into their budgets by lowering their expenses.

I appreciate that this Model Act is not touching the underlying program, but if that's what we were talking about, to be clear, making changes or scaling back of the 340B discounts would not accrue any benefit to those people who are paying for the service because it hasn't actually changed what they're paying to begin with. If you as a payer or as an employer, for example, have negotiated $100, you're paying that whether or not something's 340B and if their discount goes down, you're still paying $100. I want to be really clear that this is an expense side issue and not a payment side issue. I think there are some consistent misperceptions and I'm not suggesting you have those misperceptions, but we hear them a lot. So, I thought I would go ahead and emphasize a couple of key points. One is the one that I just made that it does not change how a covered entity is reimbursed by payers and therefore does not increase costs for payers. But the Program also very clearly does not dictate a specific use for the savings. So again, the idea here was that concern around more of providers budgets getting eaten up by drug costs wanting to free up more of those dollars so that they could expand access to care. I think that if you look at the various providers in your communities and across your state, I think it's fair to say that communities can vary quite a bit one from the other and what their needs are. Congress gave covered entities the flexibility in order to meet those needs in the way that they thought was most appropriate for their community. So, whether it's expanding access to certain preventive services and screenings, or for example, dealing with a particular gap in behavioral health services, or something else. I just want to be clear that there's no specific use dictated by the statute.

I very much appreciate that this Model is really around reporting, but I do want to be clear that there's also already a fair amount of reporting that we believe policymakers could be looking to. So, in the 340B space, all 340B covered entities report a fair amount of information to the federal government through the registration and annual recertification process. The federal government also audits providers who participate in the Program, and substantially more covered entities get audited each year than drug manufacturers. And then also there is voluntary compliance with something called the 340B Good Stewardship Principles. This is something that we facilitated several years ago within the hospital community, and we have more than 1,400 340B hospitals who are members of the AHA who have signed on to this and publicly make available their savings of the program, how they use the savings, and then, of course, just attest that they are in compliance with all program rules. But throughout this discussion what I think we've also heard is that policymakers at the state level really feel like they need a better handle on just the overall financial picture of the hospitals in your communities, particularly if you're hearing about financial stress and sort of wondering how much of this is true or where exactly that stress is coming from. Looking just at the 340B Program is not going to get you very far. It's just one piece of a very complex financing picture. So, we really do encourage policymakers to look at audited financial statements, which of course all 340B hospitals would provide federally and then of course many of you at the state level have those requirements as well. While also incomplete, but still far more robust than any reporting on 340B would offer, are the Medicare cost reports, which of course are fully publicly available.

In terms of how covered entities are using the savings, there's a lot of reporting from hospitals around the benefits that they provide to their community through the IRS 990's. The Medicare cost reports also include information, for example, on charity care through the S-10 worksheet. And then all nonprofit hospitals also do their community health needs assessments and have to publish their execution plans. And in some states, the licensure process for providers actually requires some of that same reporting, particularly around community needs. I do want to acknowledge that we should be concerned about reporting if it doesn't have a clear purpose and if it is duplicative. Right now, in the U.S. healthcare system, we spend upwards of a quarter of all healthcare spending on administrative tasks. That is more than $1 trillion. I think we're up to about $1.4 trillion this year that we will spend on things like adjudicating claims and checking insurance. Aside from managing the coverage aspects of care, the other biggest cost in terms of administrative costs in the system is reporting, whether it's quality reporting or financial reporting.

So, when we're talking about reporting, we need to understand that there is a real consequence to the healthcare system and it goes beyond financial. It also impacts staff. So, both the National Academies of Medicine and the U.S. Surgeon General several years ago found that administrative burdens on clinicians was one of the primary drivers of workforce burnout and that we all needed to do more to try to alleviate some of those burdens. When it comes to the 340B Program, certainly there are administrative staff who help support some of this reporting. But it also does involve pharmacists and pharmacy techs and people with real expertise in the drugs and how the program works. So, this is both administrative and clinical staff who need to be pulled to comply with all of this reporting. And as much as we wish that our IT systems were in some amazing state, the reality in healthcare is that a lot of this data will have to be pulled manually, compiled manually and submitted manually. So, I just want to at least underscore that we need to be conscientious of the reporting costs. With that, I will just say that our recommendations really are to look to existing reporting, particularly hospitals audited financial statements and try to avoid duplicative reporting where we can. And then frankly, if you're concerned about what benefit your 340B covered entities, including hospitals, are delivering to their communities, we strongly encourage convening them and talking with them because again unfortunately while you can definitely pull the information on that, like I said from the 990's, etc., the reality is it's just very different. And sometimes you just need to actually get in there and figure out what's going on in their

community that they feel like they are needing to address. So, we of course are always happy to facilitate that although I encourage you to work closely with your state hospital associations, which are obviously even closer to the ground in your state about what might be going on.

Sen. Mark Mann (OK) asked Rep. Oliverson if he could identify a single required data element in this Model that directly measures whether more low income individuals receive care because of the 340B Program? Rep. Oliverson stated I'll have to get back to you. That's obviously a very pointed question, and I will get you an answer.

Rep. Ellyn Hefner (OK) stated similar to Sen. Mann's question, I support meaningful transparency. Because there's so many requirements with this and all the reporting, my concern has always been what happens when we pass this legislation and what that's going to be used for, especially when this seems like more financial instead of that direct care. I serve in a city that has a big hospital that supports a lot of rural hospitals. I'm happy of how the expansion of 340B has changed because of our growth and population, and especially since our rural area has changed so much from thriving to not thriving right now. My concern is supporting the health care outcomes of Oklahomans and when we start getting this information out there it could be misunderstood. So, my question is, because you've done this research, what is the outcome that you see with this information coming out?

Dr. Nikpay responded I think there are several different outcomes. I'll give you an example from my own, and I'm speaking more as a taxpayer right now than as a researcher, although my research does inform these questions a little bit. I think that reporting of this nature gives policymakers a sense of the potential tradeoffs. So, there's an example from my market. We have a public hospital that is on the verge of failing, and we have other hospitals that are located in that same market that are benefiting a lot from 340B but have a much lower uncompensated care and community benefit, even though they are many times larger. Policymakers in Minnesota entertained the idea of a sales tax in my county, which would have landed especially on the people who use that public hospital, and then have been contemplating a statewide tax. I would as a consumer and as a taxpayer like to see policymakers grapple with the idea of, well, is it reasonable to raise taxes on me and other Minnesotans? Or should we be thinking about adjusting the way that this Program is distributed across hospitals? Is there a way to get other hospitals to participate and potentially help support that public hospital that we all benefit from and is using the Program in in a really good way? I would also say that it informs decisions about how you structure your Medicaid program. We've had several attempts in Minnesota to contemplate whether we should follow other states in paying hospitals their acquisition cost for drugs in Medicaid, potentially using that $260 million and reallocating it to some other need within the state. So, I understand that there are consequences for making this data available, but I would argue that citizens like to see that policymakers are using data in this way, and I think that it can really help understand what the Program is doing and where it's heading.

Ms. Smith stated I want to reiterate one point that Rep. Oliverson made which is that you can collect the data at the state level. Some of the changes that you just indicated would not have the authority to do at the state level. They would require federal changes to the Program. But I think that if you are concerned about understanding how the Program works and how it's impacting your state, and it might implicate policies as big as Medicaid, I would encourage you to think about ensuring that you are actually collecting all of the data that you need on the Program because right now, there's a huge gap in that there is no additional reporting for the drug manufacturers. And in fact, these are companies many of which are earning double digit margins. I think the average margin for drug manufacturers was hovering near 40% recently. Medicare and Medicaid spend a lot on prescription drugs and that is flowing to those organizations. So, I think that if you are interested in understanding the totality of the Program for making state policy, you might want to expand it to actually

ensure that you're getting that data. And I will say that a lot of the reporting that I mentioned that happens at 340B hospitals already do. That reporting does not exist in the pharmaceutical space. So, there is no current source to go for a lot of that data where it already does exist in the hospital space.

Rep. Hefner stated I think that's my apprehension for moving forward with this, because your situation in your state is so different than the one in mine and I don't think people fully understand it. If you want to change parts of the 340B Program, that is something that Congress would do, and I think there's a discussion there. But I don't think that the parts about transparency work if one side is not willing to bring them in too. Because as legislators, we need to see the full amount of what we're making decisions on, not based on where I've seen some lobbyists come into my state and given misinformation. And a lot of people are really lost. I know a ton about Medicaid having gone through the system and filling out an application, has anyone done that? So, I do know that we throw stuff around out there that people don't fully understand. And then we get a vote on it. So, my concern moving forward is if we want greater transparency, and we say that word all the time, and we're asking one side to do it, I don't think that what we have a full picture to take a vote.

Rep. Rita Mayfield (IL) stated I just want to mention that we in Illinois currently passed similar transparency legislation. It passed almost unanimously through both Houses. I believe we had 8 dissenters, but other than that it had bipartisan support on both sides. We actually had our hospital association, which is a very strong advocate against most things 340B that we try to do, and they were actually neutral on the bill. So, asking for transparency is not a bad thing, particularly when you are looking at the amount that the states are paying in 340B Medicaid costs and everything else. That is one of the reasons that we wanted to have the transparency. Yes, there are a lot of things that are available on the federal level as far as reporting but I don't know if you've ever read through those thousand page documents that were written by professors. They are not very easy to understand. They're very confusing. So, to have a simplified report actually is beneficial. Illinois HB 4327 is currently on the Governor's desk waiting to be signed. And again, it did pass with overwhelmingly bipartisan support. So don't shy away from looking at something that will provide transparency. I think this is a good thing. The goal was not to change what the hospitals are currently doing. We're not looking to reduce their benefits or anything else and yes, to your point, we do need some legislation for the pharmacy side as well. Both sides need to be looked at and have more transparency. But it was just more to give legislators a better idea. In Illinois, we actually had several bills that came through that wanted to take away 340B because people didn't understand what it does. This will at least help to solidify or validate why 340B is needed. So, don't push away from transparency because it actually stops bad legislation that may negatively impact that Program.

Rep. Stephen Meskers (CT) said there are two drivers to the 340B Program right now, which is, how are we providing subsidized health care and who's bearing the cost for that subsidized health care? But it goes back to pharmaceuticals. In the U.S. we've decided on a business model that the pharmaceutical industry can charge 3 to 4 times what it charges in the Organisation for Economic Co-operation and Development (OECD) countries for drugs. On a policy basis, I think we want to see the drugs developed in the U.S., manufactured, and sold in the U.S. And, the real question is, should they get a 20-30% premium over a profit rate on that? And should they lay off the costs on the rest of the developed world instead of us subsidizing the entire industry? So that's kind of more a statement than a question. When we go through this process, it gets very confusing to me about whether we're calling it an expense or benefit. Because ultimately, I think the important issue is we're not reducing the cost of drugs from the pharmaceutical purchase point. What we're doing is cost shifting for a benefit. I think if we're looking on a policy basis for more transparency, we do have to ask who are the beneficiaries of the policy and are we getting to the targeted audiences that we're trying to help through this policy. And it's very complicated. It's either very simple or

very complicated, depending on how you look at it. Who's bearing the cost? How do we want to drive it forward? I'm not sure that the transparency, without a full conversation, that we're going to understand the impact of the policies. It might be the best thing to start with what are the criteria for awarding the 340B benefits and are we serving the most vulnerable populations? Are we getting the benefits to reduce costs or to hospitals who are serving the most uncompensated care? And I think that really needs to be the question because I think it does become a pool of revenue and it's fungible. So, I think the question is, how do we make sure that they're doing "God's work" with the benefits?

Ms. Smith stated the first thing I would note is that uncompensated care is obviously a really important part of community benefit and how hospitals care for their communities and help some of the most vulnerable finance their care. I do want to caution that it is not the only benefit and there are others, and I'll give you some examples. For example, some of the most financially stressed hospitals are not going to be able to invest in a new behavioral health clinic or in inpatient capacity. That is something where I would say we hear the most from our members about how they use some of these savings is to bolster that gap to build behavioral health workforce and access points. So, when we think about the benefits that the community is accruing, I think we need to be very conscientious that there are things beyond charity care or financial assistance policies and it goes beyond that. Rep. Meskers stated the only thing I would say to that is everything we talk about in the legislatures that I hear suggests that it's social media that's causing our mental health crisis, and now you're suggesting that 340B should be a subsidy to take care of those mental health care issues? I'm not advocating against taking care of those issues but now we're moving from are we serving our most vulnerable population, and are we using it for other issues?

Dr. Nikpay stated my north star on this issue is always patients and one of the things I was struck by several times during this process of interviewing people who were there in the 1990s, is that several people said to us, "We never in a million years could have imagined that the 340B Program would be a source of revenue. It was never supposed to be a source of revenue." These providers I talked about, a narrow set of providers for whom this was for, those providers have requirements, and you can see those requirements today. If you go to your local FQHC's website, you will be able to find a page that gives you the sliding fee scale price menu for drugs where you can say, okay, if my income is in this range, I'm going to pay the actual acquisition cost, that 340B cost plus some amount. It's very transparent. It's really clear for patients. They're not going to leave with a bill that they don't understand. They can see upfront that they're going to get some support and same thing with our public hospitals, which also does presumptive eligibility for patients below 300% of the federal poverty level. So, they're really using the 340B Program in the way I believe Congress intended, which is access for patients. A little bit of revenue gets generated on privately insured patients, but it goes right back out the door in the form of more charity care. What I have seen myself, this is not for the state of Minnesota, but Minnesota does have this appendix where you see at a hospital level how much of 340B savings or net revenue or however you want to describe it is being generated. And when you stack that up against uncompensated care or community benefit, the line showing the relationship is basically flat. And so I think this question of are patients benefiting is a really important one. Unfortunately, the way that Congress set up this Program, even though they intended it to benefit patients, it is not set up in this way. And so, transparency is a way for you to understand how this policy is affecting your taxpayers, your constituents, and get a more nuanced picture of where the benefits are accruing.

Sen. Justin Boyd (AR) said between 2016 and 2026 in Arkansas, the total number of retail pharmacies has dropped from 802 to 735, while at the same time nonprofit, so entities not really being taxed, 340B entity owned pharmacies have increased from about 6 to over 50. My question is, at some point, while 340B has some good, it also brings the question of how's it being administered? Why can the nonprofit entities seem to make it where the ones

who are out there paying taxes are struggling to survive? Ultimately what's this going to do for patient choice and innovation?

Ms. Smith stated that I think there are a number of providers in our healthcare system where we are at a real crisis point. So, primary care is another example, behavioral health care is another example. And one of the things that I think that we have heard over the last couple of years is a lot of concern about integration between, for example, hospital systems and these other providers. But when you ask a lot of these providers, why did those pharmacies have to shut their doors? Why did the primary care practice merge with a hospital or health system? Consistently, you're hearing that the business model just no longer worked for them, and that is either because their expenses, their input costs, have risen beyond what they're able to bill for and part of that is also the administrative overhead. So, thinking about reporting requirements, cybersecurity requirements, a whole bunch of stuff that they have to deal with when they're trying to give drugs to patients or deliver care. So, in many instances they don't want to have to go into a relationship with a hospital or a health system or any other entity, because as I think many people know today, the largest employer of physicians is actually UnitedHealth Group, but they are sort of forced to. I think when we think about these policies, we need to think about them holistically like, what are we doing that is frankly, just not supporting independent pharmacies, not supporting independent physician practices so that they end up in these situations. I just want to be clear that I think we're very sympathetic to this desire and I think we want as many providers who want to remain independent as possible can do so, but it's just the business model is not working.

Dr. Nikpay stated I think that's exactly the rationale for why you need transparency because fees that go to pharmacies are accruing and that has an impact on the covered entity. But the other thing that I have learned from my own research is that, in the contract pharmacy space, about two-thirds, maybe a little bit north of that, of contract pharmacy relationships are between covered entities and some of the biggest pharmacy giants you could imagine. Your CVSs, your Walgreens, that are in kind of a vertical chain where they are part of a PBM. As an economist, we don't really like vertical integration because there's a lot of shenanigans that can happen across that vertically. And collecting data on what is actually happening, what these fees are, is very important. And I think some of the states that I've been talking to who are contemplating this are starting to talk now about actually asking for the contracts. They want to see what the fee structure looks like, which also can tell them something about what's happening to independent pharmacies potentially and how they are or are not benefiting from 340B.

Rep. Oliverson stated just a couple things I want to point out. One is that NCOIL already has a comprehensive Model on pharmaceutical price transparency and so you might recommend some improvements to that in the future when it comes up for re-adoption. We can obviously look at that, but I don't want to get into a game of pass the buck here, especially on a situation where we already have a pharmaceutical transparency Model. As the sponsor of that particular Model, I will say the same thing that I said when we passed that Model several years ago, which is that there really is nothing to fear. We're not talking about changing the Program structurally or disenfranchising people or really doing anything other than just wanting to understand where the money goes. The only people that have to fear from transparency for a program like this are people that are misappropriating those funds. I would say to Rep. Meskers that there is some language on page 35 (Section 4(a) and (b)) that I think gets at some of what you were talking about. But I am very happy to work with you if you have some more specific pieces of information that you would like to see included in the report that would help establish what portion of this $1 billion and climbing profit margin is actually going to help people who cannot afford care and hospitals and FQHCs and other clinics who are desperately trying to provide that care at a loss and truly depend upon this program for survival and not as a revenue source.

That is where we're at. At the end of the day, we could sit here and probably talk for several hours about who's doing what or whether this is good or bad but the reality is that we don't really know and that's what this is about. This is about gaining knowledge. I will tell you how I would use this information. As a lawmaker in Texas, I sit on the Appropriations Committee and I sit on the Article Two Subcommittee, which is health and human services. So, one of the things that I want to know is to what extent my public hospitals that provide the vast infinite majority of indigent health care in my very urban county of Harris County, to what percentage are they benefiting from, being disadvantaged by, or struggling to keep up with the indigent care that they are providing in lieu of the fact that they are surrounded by tax-exempt 340B entities that may or may not be diverting that benefit away from them? So, that would be helpful to me. As somebody who sits on Appropriations, who makes decisions about where state funds go, to make sure that those entities that are out there are truly doing charity are able to keep up. And that's what this program was designed to do. It's morphed into a whole lot of other things, and that's the conversation we've had. The last thing I'm going to say about this is that NCOIL has a history because insurance has typically been the business of states. NCOIL has done great work with transparency legislation in terms of shining a light and encouraging the federal government to take action. And so, if we're not going to take leadership by providing data and providing an impetus for action to be taken on a program that is exclusively under federal control, then what are we doing?

Asm. Dilan thanked Rep. Oliverson and everyone for their comments. If anyone has any further follow-up questions or comments they can reach out to me, Rep. Oliverson or NCOIL staff.

PRESENTATION ON DEVELOPMENTS IN THE FLOOD INSURANCE MARKETPLACE

Asm. Dilan stated that we just heard about one federal program that is experiencing issues. Well, another such program is the National Flood Insurance Program (NFIP), which similar to the 340B program, serves a great purpose but has experienced difficulties. With further reforms to the NFIP being contemplated and also with the continued growth of the private flood insurance market, it's a great opportunity to have a dialogue about flood insurance in general and the road ahead.

Jake Clark, Managing Director, U.S. Public Sector at Guy Carpenter thanked the committee for the opportunity to speak and stated we are the reinsurance arm of Marsh. Together with the broader Marsh, we bring some unique insights to the flood insurance landscape here in the U.S. Torrent, a subsidiary of Marsh, acts as a TPA for a number of write your own (WYO) companies that support the NFIP. In addition to that they've recently stood up Managing General Agent (MGA) that's looking to offer low limit flood solutions to homeowners in a handful of states with the concept that over time, that would be expanded. Marsh, meanwhile, services both residential and their commercial clients by sourcing flood solutions across a number of insurance carriers in the U.S., and we at Guy Carpenter support clients and entities that are holding portfolios of flood business through both reinsurance, which includes capital market solutions. Our work also includes engagements on behalf of the NFIP. We've been supporting the Federal Emergency Management Agency FEMA since it began exploring private market support in 2013. All of the work around flood typically entails supporting analytics and advisory services. We do this utilizing commercial modeling vendors, but around that we have also built flood models and brought on actuarial support to supplement the manner in which these tools evaluate the peril. So, over the course of the next 20 minutes or so, I'll provide some colors to the trends and challenges our firm is seeing, and some of the opportunities that we see in this space.

First, the natural inclination people have when the topic of flood insurance comes up is to focus on FEMA, but it's important to recognize a few aspects around this peril. Currently only about 4% of U.S. homeowners purchase flood insurance, an frequently cited statistic and

one that has held steady for quite a number of years. At the same time, 99% of counties across the U.S. have experienced significant flooding events in recent times. While we see positive signs of change and enhanced capabilities that enable the insurance sector to play a larger role addressing the financial impacts of flooding, the challenges associated with the protection gap that exists around this peril are challenging. We point to some high level observations regarding flood exposure in the U.S. We often think of flood risk in terms of FEMA's maps and the special flood hazard areas. The Specialized Flood Hazard Areas (SFHA) is FEMA's designation for the 1 in 100 year floodplain. These maps, however, are often either outdated or do not fully represent the flood risk from all sources of flooding. Private companies have recently been stepping in to create more comprehensive flood risk maps. While studies have shown that approximately 25 million people live in these SFHAs, that number significantly underestimates those that are exposed to 1 in 100-year flooding. When capturing all sources of flooding, including fluvial or riverine flooding, pluvial which is precipitation and rainfall, or coastal so think of storm risk, that figure is closer to 40. On the right side of the slide, we compare the SFHA figures to this more granular cut of data. And we show some figures at the bottom right that showcase some of the larger NFIP states. The other point to draw out on this slide is the fact that 30% of losses emanating from flooding often happen and come from outside the SFHA, and those are statistics often cited by FEMA data. The peril of flood is not abating, and we believe strongly that to truly address the protection gap that is associated with flooding, the private public sectors need to be working more in concert to affect that.

On this next slide, overall flood insurance policy counts have remained relatively stable from our perspective since 2021. The NFIP, their in-force counts have been trending lower each year over the past decade, while private flood has been growing. Currently, we see over 60 entities offering private flood insurance in the U.S., although we believe it's sort of the top 10 that are really dominating. Since 2021, in force residential policies with private carriers have increased by over 100%. But as you can see on this slide, they still only represent about 10% of the market at large. The private market remains slightly more skewed also toward commercial risk. Commercial risk, and we respect this is in part driven both by sort of their business distribution of the carriers involved, but also in part by strategies, these carriers are using to manage their portfolios against broader natural catastrophe exposures and concerns as well as distribution channels that they utilize to manage their business.

This next slide further drills down in color regarding the market and the distribution of flood policies and related premiums. The states in yellow represent the 10 largest NFIP states, California being the only one that doesn't present a significant hurricane exposure. In addition to residential, we illustrate commercial in force policies and premiums on the right. Of 5.2 million policies in place in total, over 35% are located in Florida, and then the next largest state Texas comes in at about 12.5%. From our perspective, we see muted private market interest in Louisiana and Texas. A handful of states bring other challenges that extend beyond the perils of flood but likely are influencing broader flood take up. Additional color around Louisiana, the largest MGA focusing on flood that's actually made some pretty impressive inroads in this area is avoiding the state given both the frequency and potential severity of the peril that exists there. And so, for reasons like that, but others as well, it suggests to us that FEMA and the NFIP are not going anywhere soon. But more robust action could be taken to help bring greater private market solutions online faster. On this slide, in respect to product offering, we've seen an evolution over the past decade of product offerings that are varied and illustrate that there is market appetite across the insurance sector to take on this peril. There are currently 48 markets working with the NFIP through the WYO platform. Not that long ago, there were well over 70. We're aware of a few carriers that have left the WYO space in recent years, and we think this is both due to their perceptions of potential reputational risk of being involved, as well as the expense versus the offered compensation for handling the business. Certainly, the challenges associated with federal shutdowns, lack of long-term reauthorization of the NFIP, and some bureaucracy that's

associated with a federal program have not helped. On the private side of the equation, we're seeing a variety of approaches develop. We're seeing lower limit and lower risk offerings. Typically, these are insurance offerings providing $5,000 to 50,000 of limit being offered both via endorsement or standalone offerings. We've seen admitted and excess and surplus line solutions, managing general agencies and underwriters facilitating placements in this space as well as white label offerings, and the use of parametric solutions. Typically, all flood offerings made by primary carriers are relying on reinsurance support behind them and we've also noted that some states recently have enabled markets to utilize surplus lines offerings a little easier, trying to entice and facilitate a growing market.

We can't leave the topic without some comments regarding FEMA and the Review Council. For a long time, and we believe beyond politics, if you will, many have pointed to the unsustainable state of affairs surrounding not just the framework of the NFIP, but the broader framework of disaster risk management across the country. And from our perspective, what we see is an overreliance on debt financing at both the state and the federal level to address recovery efforts after events have happened. Specifically, the Council suggested 10 guiding principles, of which one focused on the NFIP, generally calling for greater private sector involvement. We agree, and what we're seeing suggests the primary carriers are developing offers and want to see this happen. Frankly, we don't believe the issue is a supply issue on the part of the insurance sector. The challenge is trying to figure out ways to grow demand and cover the number of people that should have insurance, but don't. As already mentioned, we believe there will always be a role for the NFIP. Issues like severe, repetitive loss properties in states like Louisiana that see both frequency and severity of flooding events, and the current rate structure of some of the federal offerings are issues that are going to be with us for some time. The progress that has been made since 2017 when FEMA started engaging with reinsurers, we believe needs to continue. And we'd like to see certainly some actions expanded and see some of these processes move faster.

As a summary slide, I'll just finish with a few observations. FEMA's engagement with reinsurance we would argue has sparked some of the transformation we have seen over the past decade in this area. The analytic tools available in the market would not have evolved as quickly or to the extent that they have without it. While some of the analytics involved can be complicated given the nature of the peril, our industry is in a good position, we think, to understand and manage the risk in their portfolios. More importantly than that, they've got a greater ability to communicate risk to residents and businesses. And those skills have improved markedly. FEMA's engagement also primed the market by bringing reinsurers and capital markets to the table. The primary market has the ability to write and better manage their catastrophe exposures by spreading risk across the financial system and insurance linked securities (ILS) help facilitate greater consistency with both product offering and pricing to the original customer. Finally, across Marsh, we're trying to find solutions to move and help close this protection gap. We believe greater and enhanced private-public partnerships can help facilitate this. We are currently working with a number of stakeholders to promote the Community Resilience Act, which is designed to help pair risk transfer solutions with mitigation efforts that are rolling out. And we believe these can be effective tools to help support low to moderate income elements of our communities, as well as small business components of communities that often lack flood insurance, but yet play a vital role in the economic vitality that our communities are trying to build.

Rep. Meskers stated it seems to me that at some level, the prime focus you have is on demand for flood insurance policies and the ability to place flood insurance policies, is that the right assessment? Mr. Clark responded maybe in part. I think the amount of residential flood insurance that exists in the market, I think you can make a pretty solid argument it's been pretty stable for a long period of time despite some of the developments we're seeing. So, where NFIP policies are going down a little bit, maybe some of those policies

predominantly are moving to the insurance community. But there's not enough going on to protect the many people that get impacted by this peril that have no insurance at all. Rep. Meskers stated, as legislators, our biggest issue, we hear it from every point in the political spectrum is affordability. And yet we have an uncovered liability, which is flood insurance, in the proper way. The underwriting of all of our mortgages is Sallie Mae, Fannie Mac, etc. It sounds to me like we don't have a way of, or we haven't used our tools at the federal government, to further require the right levels of flood insurance in those policies. And the problem at the local and at the national level is that's going to raise a premium cost in your mortgage rates. So, part of it may be that as a solution. I know the federal government is running around in circles deciding whether or not to privatize the entities they had to intervene in the last financial crisis. Perhaps the sale of those entities and the revenue generated should go to subsidize premiums to create a sustainable flood insurance market. But what I'm just wondering is how you create the demand. And it sounds like if it becomes part of the mortgage process, it's almost one of the simplest solutions.

Mr. Clark stated I would agree that that could be part of it. I think another step that we think could be made right, ever since the mandatory purchase provisions came in, everybody's been focusing in on that 1 in 100-year threshold, and you're either on one side of the line or the other. FEMA already in their rate making approaches is trying to mute that distinction a little bit so that more people become aware. So we see things whether it's make offer provisions mandatory or maybe looking beyond the 1 in a 100. So, we're forcing that dialogue with more people. That could help. We've seen a few other efforts out there with private carriers, putting out a quote on every offer that they put out. And again, some of these efforts that we've seen are only currently happening in a few states right now, but they seem to be having success in in growing flood sales.

Rep. Bob Foley (ME) stated just two points I'd like to make. Has there ever been any discussion with the private insurance companies to require them to cover flood insurance as a normal coverage on all property & casualty policies? Spreading the risk has always been what insurance has been about and it seems that we're trying to cover a large risk with a small pool of people. And if we spread that risk over all property & casualty, we could certainly make sure the coverage is there and that the pricing becomes a lot more affordable. My other point would be, after September 11th, we created the terrorism risk insurance act (TRIA), which was a mandatory coverage that had to go on all commercial policies. And it created an enormous amount of revenue that sits there waiting for the next terrorism event to happen. Has there been any discussion about perhaps looking at that sort of a model? A concern that I have, and I write a lot of flood insurance back in Maine, is you have a duplicate system going. You've got the federal government and their expense, and you got the private sector and their expense. And now you have two companies that are taking expense out of the system rather than paying it towards benefits and costs. So just curious if those have been discussions.

Mr. Clark stated I believe at certain times those have been discussions and they seem to always get constantly hung up with how can you force people to buy the product. At the same token, I think there needs to be more of a debate in terms of how much basically taxpayer funded debt is going to pick up the problems after they happen. So, I do think there's a place for that debate. My own personal feeling is there's a solid portion of the NFIP portfolio that certainly could move to the private sector. There's a component of that portfolio, if you think about severe repetitive loss properties or some of the grandfathered policies that exist within that portfolio, that are completely underfunded where some sort of public role still needs to happen, but we do think there could be other solutions to cover some of the adverse exposure that flows from that through private, public partnerships.

DISCUSSION ON RECENT FEDERAL EXECUTIVE ORDERS ON “ACCELERATED MEDICAL TREATMENTS FOR SERIOUS MENTAL ILLNESS” AND “INCREASING MEDICAL MARIJUANA AND CANNABIDIOL RESEARCH”

Asm. Dilan stated the next item on our agenda is a discussion of the recent federal Executive Orders (EO) on “Accelerated Medical Treatments for Serious Mental Illness” and “Increasing Medical Marijuana and Cannabidiol Research.” You can review both of these Executive Orders starting on page 37 in your binders and on the website and the NCOIL app. These orders will certainly have significant policy implications for states and the marketplaces they touch so it’s important that legislators know how these developments will affect our constituents.

Daniela Sharfstein, Regional Director of State Government Affairs for Jazz Pharmaceuticals stated Jazz is a global biopharmaceutical company dedicated to developing life-changing medicines for people with rare diseases. We are also the company with the only Food & Drug Administration (FDA) approved cannabis derived drug in the U.S. Jazz has over 25 years of cannabinoid research and we’ve invested over $1 billion in this and our drug Epidiolex was approved by the FDA in 2018 to treat rare forms of epilepsy. And like other prescription drugs, like statins or antibiotics, we are available nationwide, we’re prescribed by doctors and dispensed at pharmacies. So, I always like to set that standing. What I am supposed to talk about is some of the changing landscapes in cannabis and hemp, which is evolving quickly. At the outset, what I want to focus on is that we are not dealing with a single market. We are dealing with three distinct categories. First is FDA approved medicines. Second are state authorized medical and recreational cannabis, and then third are hemp derived products. And the thing that I want to really emphasize is the need to keep these three categories different. All of these categories operate under different laws, different safety standards, and different implications for insurance and of course patient safety.

So first, the FDA lane. In the U.S., the FDA determines what is safe and effective medicine. FDA medicines undergo rigorous clinical trials, FDA reviews, strict manufacturing standards. State cannabis and hemp products do not meet these standards, and this creates real risk for patients. So, what does the EO do? It essentially creates two categories and for the purposes of the Controlled Substance Act (CSA), it recognizes accepted medical use for FDA approved products and then it reduces the federal state conflict for state medical programs. And then third, it expands research opportunities. So, what it does not do is also important, and it does not make state run medical cannabis an FDA approved drug, nor does it legalize marijuana federally. And it does not apply to recreational cannabis. So those are the things that it does and what it doesn’t do, and we want to keep the lanes separate there. In a similar manner and equally important is the hemp policy space, which is legally distinct from marijuana. And Congress is cracking down on intoxicating hemp products by revising the federal hemp framework, and these new rules and regulations go into place November 2026 which is effectively the federal government asking states to reconcile their intoxicating hemp and marijuana policies. We’re seeing a lot of activity at the state level in this area. There were 45 bills across 30 states and we’re seeing four Models emerging for this area. Of course, the first is aligning with new hemp federal definitions. The second is putting hemp into existing cannabis regulatory systems. The third is banning intoxicating hemp products completely. And the fourth is creating new adult use hemp frameworks.

So, to sort of sum up the purpose of my area, it’s as you’re evaluating these options and you’re reconciling with what your state is going to do for both marijuana and hemp, I want to emphasize that there are meaningful differences between these three categories in testing, labeling, clinical evidence and that the lanes are not interchangeable. Blurring the lines between FDA approved medicines, state cannabis, and hemp creates risks for everyone. Policy changes in one lane can have unintended consequences in another lane. And we saw this directly at the federal level when they were revising the hemp definition, Epidiolex

was pulled into that definition, and that would have limited access to our patients and their use of Epidiolex. And so just making sure that those lanes are separate is really important. And getting these distinctions right is important for innovation and for patient safety.

Gretchen Shaub, Senior Director of Government Affairs at Definium Therapeutics stated we are a pre-commercial biopharmaceutical company focused on brain health and psychiatry innovations, primarily at this point, using schedule one psychedelic compounds going through the FDA approval pathway. I think to level set on kind of where the industry is right now, there are several companies that are in late stage clinical trials with different types of psychedelic drugs that are currently in development but standing in schedule one under the CSA. And so, really needing to work in these very large four areas to understand potential patient access should any receive approval by the FDA in the near future.

So, we are focused not only at Definium, but as an industry, on the interagency coordination between Department of Justice, particularly the Drug Enforcement Administration (DEA) on the rescheduling of these products, and FDA approval and that really gets into infrastructure and systems readiness, adoption by insurance, upscaling and updating the state controlled substances acts is another bucket that we are trying to work in parallel to really prepare for potential approval of these products. And then the fourth is ensuring providers have clarity on prescribing, and patients have timely access. And all of that really gets to the timing and the need for a sense of urgency in updating existing statutes and policy frameworks for controlled substances. So, this is kind of the four levels within this pathway. Most of the work is in the top category, so we are seeing a number of clinical trials moving further along. Several companies have been designated breakthrough therapy designation by the FDA for their psychedelic compound, given the mental health indications that we are also looking at, including generalized anxiety disorder, severe depression, Post Traumatic Stress Disorder (PTSD), among others. Once these applications are put in front of the FDA, which feels fairly imminent for at least a couple companies, the FDA will review and move through the approval process. Once something is approved the DEA at the federal level then it has 90 days to determine where on the controlled substances list that product will be placed and then all 50 states have their own process for moving through aligning with the DEA to ensure rescheduling updates are made for those approved products. Recently in April, the Administration released an EO on Accelerating Medical Treatments for Serious Mental Illness. Part of that EO comes from years of work that has been conducted in the clinical trial space. We're also seeing a lot of accelerated enthusiasm both across administrations and Congress to really start to think about the next steps for operationalizing these treatment options should they gain FDA approval and become available. Excitingly, just this past week, as in a direct result of both the EO and a lot of work that has been happening on the industry side and both academic research as well, the FDA issued finalized clinical trial guidelines. There were draft guidelines that were put out in 2023. Now, we were at a place where there are over 25 companies that are all in late stage clinical trials, and so to have finalized guidance for how those trials should be conducted is very promising and shows how in lockstep the agency has been with research and taking this seriously and seeing the promise across the entire category.

The FDA also put notice for a public hearing on September 14th that will be focused on provider training and credentialing, patient safety, and overall best practices for data collection for these new innovations. And it's important to note that and HRSA also issued an RFI with similar themes, really seeking broad feedback and helping to further prepare the landscape to operationalize these things and making sure that at the federal level, there is a floor or a foundation being set for these new innovations that states can look to as individually we proceed in hopefully being able to have access to these treatments for patients. And then, in tandem on the congressional level, Congressman Morgan Luttrell from Texas introduced a bill early this week to codify the EO, and I think one of the bigger things to note within that EO is that it really doesn't change the work that has already been

underway in terms of the clinical trials and development and following the existing regulatory pathway for approval of a medication. It's really asking that the FDA and the DEA and other federal agencies of jurisdiction are working together sooner rather than later to make sure that there is a cohesive and coordinated strategy for working within the myriad issue areas that are captured with these new treatment options. And there is also the Path Caucus, which is the Psychedelics Advancing Therapies Caucus which holds quarterly briefings and really shifting the narrative now thanks to the EO around systems readiness rather than clinical research and design.

A lot of this work was happening prior to the EO but tying a line and taking an opportunity based on a lot of the work that was done for Epidiolex over a decade ago to modernize patient access and a part of that at the state level is updating the CSA for FDA approved medications that are subsequently DEA rescheduled. It matters greatly because most of these statutes were written and adopted in the early 1970s with a focus really on illicit drug use and drug diversion and they largely remain unchanged today. We are seeing great advancements in science and technology that have really been accelerated with the use of controlled substances so there's an opportunity to have a larger conversation about creating efficiencies there. Timely action at the state level, particularly for rescheduling, is critical for supply chain and ultimately treatment administration. We can't have conversations about getting on formulary or prescribing if we're not able to manufacture and distribute the product once it's approved legally across the states. And to that end, any delays in rescheduling at the individual state level due to regulatory alignments really do create unintentional access barriers for both physicians, health systems, and ultimately patients. Definium successfully ran legislation in Arizona, Colorado, Georgia, Illinois, Tennessee, and Utah this past session. Very technical bills and at the top here, there's some language that we have been using as model legislation to improve the timing and clarity around rescheduling of FDA approved products that are DEA rescheduled. So just all that to say, the EO does not impact the work that's already being done by companies that are seeking FDA approval and now with the announcements that have come out early this week at the federal level they are all intended to help with these key considerations for patient access across all of the different innovations within psychedelic medications for mental disorders.

ANY OTHER BUSINESS

Asm. Dilan stated you can take a look at the NCOIL website and app for an update on the state of catastrophe savings accounts legislation from the American Bankers Association (ABA). If you are interested, please reach out to Kevin McKechnie of the ABA with any questions. And we'd like to thank Mr. McKechnie and the ABA for working with NCOIL on this.

ADJOURNMENT

Hearing no further business, upon a motion made by Sen. Boyd and seconded by Rep. Meskers, the Committee adjourned at 1:00 p.m.