

NATIONAL COUNCIL OF INSURANCE LEGISLATORS  
JOINT STATE-FEDERAL RELATIONS & INTERNATIONAL INSURANCE ISSUES COMMITTEE  
NEW ORLEANS, LOUISIANA  
NOVEMBER 19, 2022  
DRAFT MINUTES

The National Council of Insurance Legislators (NCOIL) Joint State-Federal Relations & International Insurance Issues Committee met at The Sheraton New Orleans Hotel on Saturday, November 19, 2022 at 10:30 a.m.

Senator Paul Utke of Minnesota, Chair of the Committee, presided.

Other members of the Committee present were:

Rep. James Kaufman (AK)	Rep. Matt Lehman (IN)
Rep. Deborah Ferguson, DDS (AR)	Rep. Brenda Carter (MI)
Sen. Jason Rapert (AR)	Sen. Bob Hackett (OH)
Asm. Ken Cooley (CA)	

Other legislators present were:

Rep. Tammy Nuccio (CT)	Sen. George Lang (OH)
Rep. Rod Furniss (ID)	Rep. Carl Anderson (SC)
Rep. Edmond Jordan (LA)	Sen. Mary Felzkowski (WI)
Sen. Robert Mills (LA)	Sen. Mike Azinger (WV)
Asm. Jarett Gandolfo (NY)	Sen. Eric Nelson (WV)
Asw. Pam Hunter (NY)	Del. Steve Westfall (WV)

Also in attendance were:

Commissioner Tom Considine, NCOIL CEO  
Will Melofchik, NCOIL General Counsel  
Pat Gilbert, Manager, Administration & Member Services, NCOIL Support Services, LLC

## QUORUM

Upon a Motion made by Sen. Jason Rapert (AR), 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 Sen. Hackett and seconded by Rep. Brenda Carter (MI), the Committee voted without objection by way of a voice vote to adopt the minutes of the Committee's July 19, 2022 meeting in Jersey City, NJ.

## PRESENTATION ON NATIONAL 988 SUICIDE & CRISIS PREVENTION LIFELINE

The Hon. Charles Curie, Consultant for Elevance Health and former Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA) thanked the Committee for the opportunity to speak and stated that just to give my background real quickly I was a

Deputy Secretary for Mental Health and Substance Abuse Services in Pennsylvania for Governor Ridge from 1995 to 2001 and then I was appointed by President Bush and confirmed by the Senate to be Administer of SAMHSA within HHS from 2001 to 2006. I'm very pleased to be here today presenting on 988 and I'll be giving a little background on that but first I'll let my co-panelist introducer herself. Stephanie Pasternak, Director of State Affairs, Gov't Relations and Policy & Advocacy at the National Alliance on Mental Illness (NAMI) thanked the Committee for the opportunity to speak and stated that NAMI's mission is to build better lives for people affected by mental illness. We represent people living with mental health conditions and their family members. I've been with NAMI for about three years now and our areas of focus are raising public awareness, education, support, and advocacy around mental health and I'm joining you from our national office but I really must give credit to the heart of NAMI which is our grassroots network of 600 local offices in our 49 state organizations who offer programs free of charge in their local communities.

Mr. Curie stated that I also might add that throughout my 43 year career, I've had the opportunity to work with NAMI both at the state level and federal level and they are a tremendous resource for public policy issues for knowing evidence based practices and knowing the latest in behavioral health so you'll have some resources at the end of this presentation. Also, I might mention I currently am with The Curie Group, a group I formed 16 years ago, a consulting group and I'm here today working with Elevance as well. We're going to begin the presentation today talking about what is 988 - the new mental health crisis emergency number. And in considering it, 988 really is a culmination of efforts on the part of suicide prevention advocates over the past two decades. Suicide prevention really came into the forefront of public policy considerations during my tenure at SAMHSA with the publication of President Bush's new freedom commission of mental health. And that commission examined the mental health service delivery system and for the first time identified suicide prevention and suicide as a public health issue that needed to be addressed in some sort of formal way. And out of that, I refer you to look at that report, a model was identified that the Air Force had implemented in how to prevent suicide as their numbers were very high in terms of suicide in the 1990's. And they were able to implement a program around education, around involving people at all levels in the Air Force. Families as well. And it really brought the suicide rate down and many of those principles in that program are in that report and it also informed suicide prevention today. In 2005 we made suicide prevention at SAMHSA one of the specific stated priorities and since those days there's been very active participation on the part of a range of advocacy groups and the taskforce in particular that I know Ms. Pasternak participates in and NAMI's been a part of to really take a look at what's needed in order to address suicide prevention.

When we look at 988, the forerunner of 988 was a national suicide prevention lifeline. You may be familiar with the number 1-800-273-TALK. That was the number that's been highlighted through the years that if someone is suicidal or someone is considering or in the midst of a mental health or substance use crisis to call that number. What's interesting as I flew into New Orleans today is I'm reminded that we implemented that hotline in 2005 and the first test of that hotline was Hurricane Katrina in New Orleans and again, I made many visits to New Orleans during that period of time and kind of had flashbacks this time coming back thinking about we're actually talking about the origins of the hotline and how Katrina was really the first test of that and today we see 988. But after two decades of work one of the major pillars that the suicide prevention advocates and public policy officials felt would set the stage to address suicide prevention in a real way is to implement 988, a three digit universal dialing code knowing that it would be much easier to dial 988 than to memorize the number. And it offers the promise of the new response at the local level in every state. But it's really an entry point. There's really much more to do. It's an opportunity to re-imagine the crisis services system and that's going to be a

focus of our conversation today, is what needs to be in that system. What does our current crisis response look like? Well, because of the lack of available mental health resources and the increased demand around mental health right now and substance use, communities are facing more and more challenges. And again, 988 was not created to address necessarily the COVID challenges we're seeing now but it's actually very timely. As we take a look currently, two million times each year people with mental illness are booked into the nation's jails. Again, can that be avoided if we have another crisis response system? One hundred thousand people die of drug overdoses unfortunately in a 12 month period and each year annually there's between 45,000 to 50,000 suicides each year in our country. I want to contrast that with the time I was at SAMHSA the numbers were 28,000 to 32,000 during that five year period. It averaged right around 30,000 a year back in the early 2000's. Today, it's 45,000 to 50,000. What contributes to that? Part of that is the returning Veterans have contributed significantly to that rate. Also, I do believe we are reporting more accurately because we've made that part of the public policy approach to ensure that local jurisdictions are reporting it accurately and we're getting an accurate count. But unfortunately, the rate continues to go up. Also, with COVID, lately the data's been telling us one out of three Americans are experiencing a mental health issue. Contrast that with, during my time at SAMHSA and for decades it's been one out of five Americans have mental health issues. But again, we've seen that increase over the last year or two and COVID has contributed to that.

Ms. Pasternak stated that I'm going to jump in here because fortunately over the last few years there's sort of been a national consensus on what a mental health crisis system should look like and a couple years ago SAMHSA put out behavioral health crisis guidelines and it really boils down to three core services: 24/7 crisis call centers giving you someone to talk to; mobile crisis teams so someone to respond; and crisis stabilization options, somewhere to go. Breaking these three pillars down a little bit further, the crisis call centers are really contact centers because they are also available by text and chat, are staffed by trained crisis counselors and for 988 compared to the National Suicide Prevention Lifeline they're receiving more training on a wider variety of behavioral health related crises and they provide local referrals to follow up services and are able to dispatch mobile crisis teams if they're available in that area. Some people need more support than can be offered over the phone when they're in crisis and ideally, a mobile crisis team, which is usually a pair of behavioral health professionals, can come out and deescalate the situation. If they happen to need even more support they can transport them to either a local ER or a crisis stabilization option if that's available. Breaking down what crisis stabilization is, these are only available in a few communities across the country but generally, they're 23 hour facilities that are meant to be an alternative to an emergency room as emergency rooms tend to not have psychiatric professionals available to treat people in crises. They're also very loud, very bright, and not a very therapeutic setting for someone in crisis. So, these facilities have behavioral health professionals and generally at the end of the 23 hours folks are discharged back into the community but if someone needs an in-patient level of care than they can be transferred to an in-patient facility. And I want to stop on this last point. So, if you work with your local police departments, many of them have the priority of diverting people away from arrest in our local jail system but you might hear them say, "well they're in our jails because there's simply nowhere else to go; there's nowhere I can divert people to." And this third pillar is so important because it really answers that question and Mr. Curie will address that.

Mr. Curie stated that in Maricopa County in Arizona when I was consulting there at the time, they have one of the first programs and a model program in which they set up a 23 hour crisis stabilization in a store front and they did it with not only the local healthcare and behavioral health system but with law enforcement and law enforcement actually helped establish it and shape it. And it did give police officers and first responders a place that if someone needed more of a response that they could handle a call out at a home but needed some care that would be a

first opportunity. And what we might want to mention with the continuum of care is 80% of the calls can be handled by phone with trained professionals. So, that's another reason it's important 988 having the appropriate expertise in place locally. It does take that burden right off of 911 immediately and obviously 911 has its own response but 80% can be handled typically and we've seen that consistently through the years by phone. On the crisis mobile, again you can resolve 70% there as you can see from this figure and then then I'll Ms. Pasternak describe the rest of the continuum. Ms. Pasternak stated that just so you know what you're looking at here, this is what it looks like when a local community actually implements the full continuum of care. This is a graphic representation of what's available in Tucson, Arizona. Arizona's doing a lot of amazing things in crisis care. I won't break down everything here but as you can see when people call in 80% of those calls are resolved over the phone. For the percent of calls that do need a mobile crisis team option, 70% of those are resolved in the field without going to any further facility. And then for most people that end up at a crisis stabilization facility the vast majority can be discharged back into the community avoiding any in-patient care stays and that saves hospital funds. It also saves money to our justice system and you see 911 and law enforcement up at the top there. These systems have to have close partnerships to work well and in Tucson the police officers can actually drop someone off at a local crisis stabilization facility and in ten minutes get that person seen by a provider instead of hours waiting in an ER with someone to be admitted.

Mr. Curie stated that the federal action to create 988 was from the National Suicide Hotline Designation Act which was passed and signed into law September of 2020 and it did create the three digit number for mental crises and suicide to be that universal telephone number available everywhere in the country. Again, similar to 911 in terms of the concept and the goal also was to re-imagine as we've been talking about that continuum of care. What does a crisis system look like? What does the continuum look like that a community needs? And base that on the data and the experience we have thus far in terms of what would be anticipated in that structure. Ms. Pasternak stated that I will just add that there was a funding option made available in the National Suicide Hotline Designation Act really looking at how 911 is funded today which if you don't know, you pay a small monthly fee on your phone bill. Usually, the national average is about \$1 a month and this Act made clear that if states wanted to fund 988 in a similar way, that they have the ability to do that and that can cover costs associated with the three pillars of crisis care. Mr. Curie stated that I also might mention money has been made available from the Federal Government to states in order to implement 988. The Omnibus Act of 2020 with the American Rescue, there was a total of about \$282 million available to states and then there was \$35 million in the SAMHSA block grant that was made available to states and there have been waivers with the Centers for Medicare and Medicaid Services (CMS) to be able to pay for crisis intervention. So, I encourage you to consider how is your state using those resources? Are they maximizing them? And are they being used to help build that continuum of care. Ms. Pasternak stated that I'll go through this really quickly just to explain how does 988 actually work practically. So, if someone calls or texts 988 what happens is they hear an automated message that says if they are a Veteran they can press one and be connected to the Veterans Crisis Line and that's actually administered separately by the Veterans Administration. Or they can press two if they are a Spanish speaker if they'd like to be connected to a Spanish sub-network. If they press neither of those automated options they are routed based on their area code to their nearest local call center and if a certain amount of time passes and that local center does not pick up there are a series of national backup centers run by Vibrant Emotional Health that will pick up those calls generally after two minutes if no one has picked up locally and the system is designed that way so that if a local call center is overwhelmed at a certain moment and simply can't pick up a call, there is a way to get them a response no matter what.

Mr. Curie stated that the reason that's so important is in 2020 before the implementation of 988, on the suicide hotline that was in place it was documented by the New York Times that 17% of calls were abandoned and this is something that with 988 we want to make sure is addressed in states because the last thing you want are individuals calling in because they're in a suicidal crisis or a mental health crisis and they're put on hold. You don't want that to happen and so the backup system's been very important. I also might mention that Beacon Health, working with Vibrant Emotional Health and Beacon's division of Elevance is backing up the text function of that as well. Ms. Pasternak stated that other things are expected to change with 988. It's an easier to remember number. Vibrant is estimating that in year one, for reference the 988 officially launched in July, that they will have a doubling of contacts and they have started to release actual monthly data and the data for August of this year compared to August of last year when only the ten digit number was available they noticed a 45% increase in contacts. Mr. Curie stated that they did anticipate that if you build it they will come and it's being borne out here. The other thing that we want to examine is how much diversion from 911 is happening in 988? I think that's another important metric to examine. Ms. Pasternak stated that when 988 launched this July you might have seen a local headline something like the new 911 for mental health is here and it's 988. There are some similarities but I want it to be clear that there's really major differences between these two emergency lines. With 911 the goal is really for the operator to collect enough information to figure out which service they need to dispatch to your location: fire, police, EMS, or a mixture of all those. 988's a little different. The call itself is an intervention. The call's picked up by a trained crisis counselor and their goal is to use the least invasive response possible. So, as we said, somewhere between 80-90% of crises can be actually resolved over the phone and it's fairly rare that they actually need to dispatch a service but we know that people are still going to call 911 when they're in emergency. That's the number they know. So, there's going to need to be standard operating procedures about transferring calls back and forth between 911 and 988. Mr. Curie stated that and when you think about it for a moment, 911 is called and what usually happens - they send out an ambulance and they send out perhaps fireman or police. They send all those resources out. Again, if 80% can be resolved over the phone without having that, we're hopeful that 988 will certainly streamline things and also ultimately not only save lives most importantly but also be cost effective overall.

So, what happened on July 16th? That was part of the law that would be implemented on July 16th when they flipped the switch so to speak. Effective July 16th and this in place right now, everyone can text or call or chat on 988 no matter where they live. Their call will be directed to the 988 suicide and crisis lifeline network which again came out of 1-800-273-TALK. And the lifeline again is focused on not just suicide. It's a range of mental health and substance use crises such as the opioid crisis and the Fentanyl crisis. This is a resource that's available and helping people really in any type of emotional distress. And again, we at least have the three digit number in place and we have the beginnings of it but again, there are some policy making challenges here that need to be considered and Ms. Pasternak will speak to those. Ms. Pasternak stated that at NAMI we've been calling July 16th a starting line for 988 but we are far from finished. If there's not further action at the federal and state levels there's some challenges we're going to have. Call centers are going to continue to operate with very limited public funding while experiencing an increase in call volumes. Mobile crisis teams are not going to be available in every community and where they're not available that burden is going to continue falling on law enforcement to be that first responder. Crisis stabilization options are only available in a few communities. If we don't build those out further we're going to continue to see the cycling that we know happens in the ER's and jails with no other options to turn to. And also 988 it'll be a national number but there's going to be a wide variation in the quality of that response community to community. Mr. Curie stated that as Ms. Pasternak was saying we really have a patchwork quilt right now across the country when it comes to crisis and the continuum in

each local area. First of all, historically it's been underfunded and that's a concern continued today. Again, I mentioned earlier some of the funding streams that are available. Again, I think it would be important to ascertain in your state how those are being used. There's mobile crisis teams only in certain areas of the country and very limited availability. In fact, I think you're probably all familiar right now with the emergency room boarding crisis that's occurring and where literally you have people who have a mental health crisis going through emergency rooms in certain parts of the country. There seems to be a real spike among teenagers and young women but they're sometimes boarded in the emergency room for days. I've even heard as long as a week at a time and again, with no place to go. So again, the need is great there.

Ms. Pasternak stated that what NAMI and our partners in the mental health and really a cross section of advocacy organizations have been pushing for is for states to pass legislation that implements an infrastructure to support the new 988 line and those related crisis services. The key points that state legislation should hit on is identifying dedicated funding mechanisms that are sustainable and the monthly fees can certainly be a piece of the puzzle here. Define the requirements for 988 crisis services. What kind of training are people going to be required to receive to work in this system? Look at additional resources such as state general revenue funds and insurance coverage. And then importantly create oversight coordination and public reporting on 988 to ensure smooth implementation. I won't go through this but I'll just make folks aware that NAMI's live tracking 988 legislation and I'm sorry that link doesn't show up very well but it's [reimaginecrisis.org/map](https://reimaginecrisis.org/map). You want to see where your state is at with passing the model bill and other measures as well. Just giving you a sense of what's happened so far in state legislation - seven states have created a permanent 988 advisory body. Five states have enacted those telecommunications fees that we've just mentioned. California was the most recent to do so with AB988 and you'll notice throughout the five states that have them those fees are pretty low especially in comparison to 911 fees. In California it's going to start at eight cents for a couple years and then we'll be capped at thirty cents moving forward. Thirty states have passed appropriations for at least one of the core crisis services. Another interim measure states are looking at is to do sort of a study of what's the state of play in crisis care in their state now. Where are there gaps? Let's put a taskforce together to make financing recommendations. And three states have passed 988 legislation that strengthens commercial insurance coverage of crisis care. Additionally, things that our states are grappling with outside of legislation I think I've mentioned most of this but I will say they're also trying to develop a culturally competent diverse workforce so that the call takers can respond to people from a variety of backgrounds and that they're also reflective of the communities that they are serving.

Mr. Curie stated that I think it would also be appropriate if you would like to request a briefing of your state officials. These are the mental health authority or CMS, whoever's managing the public health, and ask them about their sustainability plans. You know, what are their thoughts, what are they looking at? How to use the funding? Also, what are the overall plans they have in place for 988 implementation and the crisis continuum of care. Ms. Pasternak stated that the bottom line here is that states are really going to need to bring different funding sources together to make 988 fully work and that's going to of course include insurance coverage. At NAMI we've been also assessing the public opinion of mental health crisis care and it probably doesn't surprise you to learn that the American public is not very happy with the state of behavioral health crisis care and we partnered with a polling firm in June 2022 and found that four out of five people believe that people should receive a mental health professional to respond to them when they're in a mental health crisis rather than a law enforcement officer. The poll showed a lot of support for the call centers and the related response services and nearly three in four people are willing to pay a monthly fee on their phone bill to support this system. And so these are the top areas of concern for 988 moving forward. One is the overall availability in terms of capacity and

determining those long term funding streams and how insurance coverage is going to play into this and workforce issues. Because you can fund the programs as much as you want but if you don't have the people to implement then you're going to have a challenge and we certainly have a workforce shortage. Second is elevating policy maker awareness of 988 and third is elevating the public awareness. We did a poll also right before 988 launched and found that only 4% of the general public had any awareness of 988's existence. In our more recent poll in October we found that that is up to 44% but everyone can benefit from this so, we certainly want a wider public awareness. And just finally to wrap up some tips on how to get involved - find out who's in charge of 988 planning in your state. Is there one of those task force or advisory bodies that's been set up already? Is it your state mental health agency that's taking the lead or your state public health agency? Or a few agencies co-leading? And importantly, within that is there a financing or insurance work group that you could send representatives to? Is there a separate advocacy coalition in place? A lot of times those are run by state NAMI organizations. And just in general, is your state agency that's responsible for Medicaid coverage and commercial insurance regulation at those 988 planning and implementation tables? And you can visit our 988 hub at [reimaginecrisis.org](http://reimaginecrisis.org) for more information. And you can see our state map and we also have a short explainer video and again, the link isn't showing up great but I have also linked to where you can find your state's 988 data.

Asw. Pam Hunter (NY) stated that I absolutely agree that we are in crisis for many reasons but these are some of my thoughts and I've been thinking about this a lot lately. So, 988 I'm thinking it's like the treatment to the problem but how are we really taking care of the underlying issues that are really affecting our people across the country? And not wanting to take anything away from something acute like I need to call 911 now to take care of the problem or I need to call 988 now to take care of the problem. But people are in crisis to the point that we spend lots of money on this and it just doesn't seem like we're really tackling the problem of the underlying issues to get to the point of not needing this. And it's getting worse. It's not getting better. So, that's my thought and I don't expect you to really have the whole answer but if we don't ever take time to really get to the underlying issues of why people are in crisis we're going to be in my state house and others across the country asking the feds and not for profits are still going to keep asking us to fund the programs that are so desperate in the community without really taking care of the underlying issues. I'm trying to understand the providers that provide these services. It's important for people to have consistent care and we talked about making 988 a sustainable but consistent care. If there are a lack of providers and say I'm talking to a mental health counselor and we're having a great relationship and sometimes they're the ones you find online but you might not get the same person again. How is that helping someone if they're not having a consistent relationship with someone and being able to have consistent conversations? That's my one question. Another is, how does this translate to young people? Because I have a 22 year old and I can tell you he has never heard of 988 and wouldn't know anything about this. They live online even though you could do this on the phone. And that demographic it seems to me is a huge group of people who have these issues so how are we targeting our younger people? And also just generally with demographics, is there some information that you have you can send to us saying you're compiling all this information and we see the age of people who are calling and non-veterans. I'm a Veteran myself and I get that whole separate thing but do you have the age of people who are calling and the demographics of people that are calling. Is it in the Midwest? Is it in the northeast? Where are the people calling from and what are the issues? That could help legislators tackle these issues easier.

Mr. Curie stated that I'll talk a little bit about the underlying problems. I think it's important to take a look at both mental health and healthcare in general. It would be important to begin integrating at the service level behavioral health into primary care and into pediatric care. There are

screenings. We see that if you screen and identify early you can prevent exacerbation of mental health issues and this many times can be picked up again in those other medical settings where you don't necessarily have behavioral health capacity. That would be I think one consideration is where can you begin to integrate behavioral health capacity not only in terms of assessment but then a clear pathway to needed initial treatment. Asw. Hunter stated that I hear what you're saying and I definitely do not want to be argumentative about this at all but if you look at trauma in communities and you're looking at where people are, if someone is homeless or indigent your primary care provider is not taking enough time to figure out if you are stable to live or if you have enough food. I know how my son acts when he's hungry and that exacerbates and I just think it's broken and our young people are just dying. Mr. Curie stated that I think you're exactly right. Again, I think it's only a piece of the issue to begin to reach out in those integrated settings in all of our systems in health and human services. And today we have a great deal of knowledge on trauma informed care and I think we need to be thinking in terms of people are in trauma. And again, there's a lot of guidance on how you begin to ensure all the systems that are touching people are trauma informed and I think that's also a beginning point to look at.

Ms. Pasternak stated that I'll just add that we were here to focus just on the crisis care of the broader continuum but we certainly hope that if people do come into contact with the crisis system that that's their first and last time doing so and that's going to take a more build out of outpatient services. I know crisis stabilization facilities where they are do try to take care of some of those basic needs in addition to mental health care. If someone's hungry they get food. If they need a shower, they get a shower there and if they need housing, they get connected to those right services that do address some of those underlying issues. Regarding your question about are we tracking demographics of who's calling, SAMHSA is. That's publicly available on their website but also states can go even further in what they track and New York's law actually in my opinion went further than any state's 988 law thus far regarding reporting metrics about who's coming into contact with mobile crisis teams - their race, ethnicity, if they identify as LGBTQ plus. And then what were the outcomes of those calls - are they being transferred to law enforcement? We certainly want to know that. Are they going to the hospital? Are they going to some other crisis care option? And that's supposed to be reported publicly monthly and I'm failing to remember the start date of that but that's in state law. Mr. Curie stated that I also might mention when we look at resources to address the types of issues you've described, one thing we did not mention is over the course of this year and next year, I think there's been close to half a billion dollars allocated to certify community based behavioral health centers, and that's available to the states. Again, we're going to have workforce challenges regardless of how much money is coming into the system but states need to examine how are those dollars being used to establish capacity for behavioral health in communities, especially communities that do not have the capacity right now and that was one of the purposes of community based health centers (CBHCs). Ms. Pasternak stated that sorry to keep belaboring the point but to jump on that regarding CBHCs, what I think what you're describing of people is they see one doctor and then the next week they see someone else and how are they supposed to have quality care if that's their experience. CBHC's are meant to help address some of these issues that are in the public mental health system. They receive a much more sustainable payment rate than traditional community mental health centers have received and early results show that they've been able to hire more people and offer more services and retain that staff to offer a higher quality of care.

Sen. Utke thanked Mr. Curie and Ms. Pasternak and stated that in previous meetings related to these topics we're talking a lot about the treatment or catching them in crisis but it's important to go back on the prevention side and actually drill down to the root cause and try to get them the help they need.



## PRESENTATION ON IMPLEMENTATION OF THE FEDERAL CLINICAL TREATMENT ACT

Megan Lydon, MPH Policy Fellow at Bristol Myers Squibb thanked the Committee for the opportunity to speak and stated that today I'm going to be talking about improving access to clinical trials and the role of state Medicaid departments in accomplishing this. So, to start off and frame this issue, clinical trial diversity is an issue for individual patient access, health equity, and regulatory decision making. Right now, U.S. clinical trials are not very representative of U.S. demographics as a whole or patient populations and this is especially a problem among racially and ethnically diverse communities as well as patients with disabilities who are severely underrepresented in clinical trials. And this has long term ramifications on the safety and efficacy information of the products that are being tested in clinical trials. When we test a product we want to make sure that the patients who are being tested in those trials are representative of those who are eventually going to be using the drug or therapy after it's approved and prescribed by their physician. And this is an issue that has also caught the attention of the U.S. Food and Drug Administration (FDA) and other global regulatory agencies for the reason of proper safety and efficacy information that is applicable to the U.S. population as a whole and the FDA in particular has issued a number of guidance on promoting diversity in clinical trials and has even highlighted it as a major factor in some regulatory decisions recently. This issue has also gained a lot of traction among stakeholders throughout the research system. Patients, survivors of diseases, physicians, research groups, as well as advocacy organizations like the American Cancer Society and the National Minority Quality Forum have all really advocated for the removal of some of these barriers to better increase access for patients, especially over the past decade as a lot of those disparities have become more pronounced.

So, in response to a lot of this, Congress passed the bipartisan Clinical Treatment Act (CTA) in 2020. The CTA directs state Medicaid programs to cover routine costs associated with clinical trials regarding cancer or other life threatening conditions and this routine cost piece is really important because these costs are not related to data collection or monitoring of the specific therapy or anything like that. They're related to the clinical management of the beneficiary so it covers drugs to treat the side effects of a specific trial therapy or follow up appointments with a doctor if they're having some sort of symptoms following their participation in a clinical trial. And because these are all related to the clinical management of the beneficiary in the Medicaid program this will have little to no impact on Medicaid budgets going forward and this legislation was really important because prior to its effective date of January 1, 2022 Medicaid was the only major payer that did not cover these costs. Medicare has covered them since 2000 and the Affordable Care Act (ACA) guaranteed coverage for commercial patients since 2010 and this is a huge issue because Medicaid insures approximately one third of the entire U.S. population, a little bit under that. And even though some states did have mandates prior to the CTA's passage many of these mandates of covering routine costs had more restrictions. Some of them only covered cancer trials or would only cover trials located in the state and even with that, that still meant millions of Medicaid patients had no access to this benefit. It is especially important because many patients, especially low income patients, cite financial barriers as one of the greatest obstacles to participate in a clinical trial and accessing really innovative life saving therapies when they've exhausted their standard of care options. So though this was passed by Congress it is up to state Medicaid departments to implement the CTA and this is done through state plan amendments or spa's. These spa's allow Medicaid departments to make changes to their programs while still complying with federal requirements and claiming matching funds and CMS has created a number of different templates, three specific ones for the CTA to implement these in individual states. And each of these templates identify specific population groups or pathways within a state's Medicaid department.

The first is categorically needy or those that qualify for cash assistance, medically needy or those who normally do not qualify for cash assistance because their income or assets are too high but their medical needs or their bills put them under that threshold, and then alternative benefit plan groups which relate to a specific delivery system or area of the state. And one important thing to note is that not all states will have all three of these pathways. Some states do not have the medically needy pathway, and alternative benefit plans mostly just apply to ACA expansion states so not all states will have implemented spa's for all three of these categories it will just vary depending on the state and its Medicaid department. As of yesterday this is the patchwork of spa implementation across the country. As you can see, states have made a really important first step forward in implementing these spa's and getting them on the books for the Medicaid patients in each of the states and it's especially interesting to note that it's quite a patchwork across the country. There is a regional distinction or specificities in specific areas of the country but as you can see the majority of states have gotten spa's on the books for their patients and this is especially impactful for patients who are seeking trials located out of state or patients in rural areas who might not be able to access the academic medical center in their state. They might be closer to one in a different state so this has really helped to increase access for patients across the country and states have been a great partner in this so far. One thing to note though is despite the implementation of spa's and what a positive step forward it was, many barriers still remain to accessing and participating in clinical trials. Clinical trials can be very disruptive to daily life and there are a number of practical obstacles that patients may face, especially lower income patients or rural patients might face particularly in accessing clinical trials. One being research is often conducted at large academic medical centers which may be far away from where someone lives so they have to cover the cost of potentially getting themselves there or lodging there especially if there are multiple site visits required throughout the duration of a trial. That can be an additional barrier especially for rural patients. Other costs of missing work or covering childcare or other caring responsibilities can be another financial obstacle for patients that is not covered in that routine cost piece of the CTA.

Next, moving on to medical and research institutions, these can be very complex to navigate especially for those who do not have much familiarity with the system and this could be a barrier that prevent patients from getting in the door for a trial. There could also be low trust in PhRMA or medical research or different levels of health literacy that impact how a patient understands clinical trials, the results, and the benefits that they can potentially get from participating in a trial. And finally, one thing to note is clinical trial sites are just getting back up and running fully after the COVID-19 pandemic and with this new benefit generated by the CTA some staff may not be familiar with processing Medicaid claims yet and this could lead to some potential delays for patients. And then finally, a really important piece going forward is public and provider awareness, in particular providers or physicians are really important in letting their patient know that a clinical trial is occurring and assuring that there is a clinical benefit to their participation. And they're often the ones that are referring their patients to these trials so physician awareness is a huge important variable in implementing the CTA and pulling through for patients. One survey done about a year ago found that just one in five physicians were aware of the CTA so this was before its full effective date and then another similar survey hasn't been conducted since but it's something to note when we are thinking about how these patients can fully access the benefits afforded by this legislation. And finally, public awareness of the CTA is really important because especially for patients with cancer or other life-threatening conditions, if they've exhausted their standard of care options it's really important they can benefit from innovative therapies as quickly as possible so knowing about these trials and knowing that they have the coverage of routine cost is really important and is a really great opportunity for state legislators and other people throughout the medical system to be partners in raising awareness through

social media newsletters and Town Halls just to make sure that patients and their loved ones are aware of this benefit for whenever they do need it.

Next, a couple of things could change Medicaid eligibility and thus impact trial access and diversity. First, as many of us know the unwinding of the COVID-19 public health emergency (PHE) will likely be coming in the next couple of months. During the PHE, Medicaid enrollment increased by about twenty million enrollees to about ninety million total enrolled around the country and once the PHE expires and the redetermination requirements are reenacted if someone hasn't aged into Medicare or found some other type of health coverage they could not only lose their health care but they could potentially lose their access to clinical trials as well. There has been some discussion recently of moving these patients to State exchanges. I think that is still in the experimental phase to better understand what that would look like state-to-state but this is something to consider as the aims of the CTA could be impacted by these changes in redetermination requirements and underrepresented populations may continue to face some barriers in this area. And then one proposed rule is expected to have somewhat of the opposite effect. So this is a proposed rule from CMS that would better streamline enrollment and verification requirements for Medicaid and children's health insurance program (CHIP) patients and this could have a really positive impact on clinical trials especially considering how long trials often last. They can be weeks, months, or years and if a patient is turning off and on Medicaid and they are unsure if they're going to have access to a benefit and if they're going to have the routine costs covered, by streamlining eligibility and enrollment they can be more certain that financial uncertainty and surprises won't occur throughout the duration that they are involved in the trial. So finally I just want to leave you all with an anecdote about the importance of the CTA. This is a headline from one state. This one patient had stage four cancer and tried all the standard of care options and had exhausted a lot of options and her provider deemed them a perfect candidate for a specific trial for her condition. But she reached out to her State health plan, this state also had implemented an spa covering categorically needy beneficiaries, and was denied coverage of routine cost three different times. One was for the trial being out-of-network. One was for a paperwork issue and one was for the plan did not cover experimental treatments. And in particular that first and third reasons are explicitly outlined as a benefit of the CTA that the State had on the books. There was just a lack of awareness at all levels that just really highlights the importance of this for patients and making sure that the patient themselves are aware of it and that providers are aware of it and that the health plans are aware of this to make sure these patients can access trials as quickly as possible for long-term health benefits.

Rep. Deborah Ferguson, DDS (AR), NCOIL Secretary, asked if these are placebo controlled trials? Because one of the big discussions in the medical community is whether placebo controlled trials are ethical and particularly if you're asking Medicaid to pay for it. Can you address that? Ms. Lydon stated that the CTA will cover all trials related to cancer or life threatening conditions. It will cover the routine costs associated with that for the patient. Obviously, it will not determine what arm of the trial a patient is going to be entering or what trial specifically they are going to be entering. So, the CTA is really just aiming at covering that financial barrier that patients face as an obstacle to get into the door at clinical trials so it will cover all kinds of trials but once they're in the door the cost will still be covered but it doesn't have any sway on what trial a patient is involved in.

## UNDERSTANDING THE HEALTHCARE PROVISIONS IN THE FEDERAL INFLATION REDUCTION ACT

Alexander Dworkowitz, Partner at Manatt, Phelps & Phillips, LLP, thanked the Committee for the opportunity to speak and stated that I'm going to provide an overview of the Inflation Reduction

Act's (IRA) healthcare provisions. I'll start with an overview then quickly go through the three main pillars of the law and then end with a perspective of what does this actually mean for states. So, there are three main pillars of the law when you think about the drug pricing provisions. Number one is for the first time, the federal government under Medicare can negotiate the prices for drugs that are paid for under both Medicare Part B and Medicare Part D. Second, also for the first time, manufacturers are required to pay rebates to the federal government if they increase the price of their drugs at a rate faster than the rate of inflation. And third, the Medicare Part B benefit has been changed substantially. The biggest change being there's now a \$2,000 out of pocket cap on what beneficiaries can pay for their Part D drug spending. We don't have to go through all the details here but this is just to note that this is not the first time that the federal government has intervened in impacting the price of drugs under Medicare or Medicaid. Also I wanted to note that some of the points on the right hand side here we have from 2019 and President Trump proposing using international reference prices to impact the price of drugs and then we have the U.S. House of Representatives passing in 2019 HR3 which also took into account international prices for drugs. That's not exactly how the IRA works but certainly was an influence on this law. So, I'll start with the first pillar, the drug price negotiation program. So, what HHS can do, or will do, is establish a maximum fair price (MFP) for selected drugs and each selected drug will have a ceiling price under the law. The law actually has a very detailed formula about the most the federal government can pay under Medicare for these drugs but importantly the federal government has leeway to go below that maximum price. So, the law says this is the most Medicare can pay for a drug but CMS has discretion to go even lower. An important point is that this doesn't apply to all drugs. There are really three main restrictions here. Number one, we're talking about drugs that cost Medicare a fair amount of money. These are drugs that cost the Medicare program at least \$200 million dollars per year. Second, these are drugs that have been on the market for a while. So, if you have a new drug that's approved next year, it won't be eligible for negotiated price for at least nine years. And it depends on whether it's an oral drug or a biologic. Biologic's can go up to thirteen years. And third, these are about drugs that do not have competition. These are drugs that do not have an available generic or available biosimilar. And finally, two other points on this slide. The MFP will kick in on the Part D side in 2026 for a few numbers of drugs and on the Part B side in 2028. And also note even though we talk about this as Medicare negotiation it actually is a Medicaid negotiation too because the law was drafted saying the negotiated price impacts the Medicaid best price. So, for any of you who are familiar about how Medicaid drug payments work that essentially means that Medicaid has to get the lowest available price on the market subject to certain exceptions. So, the federal government negotiates a lower price for a drug under Medicare and Medicaid programs get the benefit of that low price and it works the same way with the 340B program.

There's a lot here so we don't have to go through all these slides but just note there's a detailed process in the law that talks about how the government has to go about picking which drugs are subject to negotiation. There's a long timeline. Though it's probably a little hard to see here I think one key date is September 2023. So, less than one year from now that's when the Federal Government will come up with its list of drugs that are subject to negotiated price for the first time. Those drug prices won't take effect until 2026 but within a year from now we're all going to know these are the first ten drugs that the government's going to negotiate and step in and set a price for. This point I essentially already covered but the key here is that if there's a marketed generic or marketed biosimilar that competes with a brand drug in question that brand drug is not going to be subject to a negotiated price. So, that creates sort of different dynamics and it's not what we're used to because there's actually a bit of incentive now if you're a brand manufacturer that you want a generic to compete with you because if you have a generic competing with you, you're free from this program so it's going to be interesting to see how this all plays out.

Inflation rebates is the next pillar I mentioned. There's a lot of details here but just fundamentally it's a simple concept. The idea is that if you as a manufacturer increase the price of your drug at the rate faster than inflation you have to pay back to the federal government the difference of that increase. So, say your drug is \$100 and inflation is 5%. You're allowed to increase it up to \$105 without any penalty but if you go up to \$110, you're now overcharging by \$5 and you have to pay the government back that extra \$5. So, you're not making any money off that additional increase. This is based on the Medicaid drug rebate program which has been around since 1990. So, there are a lot of similarities between how the Medicaid rebates work and the new Medicare Part B and Part D rebates will work but a couple important differences I want to point out are that in that first line generally Part B and Part D will not impose rebates for generics and biosimilars. Under Medicaid there is no such escape hatch. And also that line about whether rebates are owed if there is no price increase. Yes, there's no rebates owed right if the manufacturer does not increase the price of a drug at all there will be no rebates under Medicare at all but under Medicaid there will be rebates. For most brands at least the minimum rebate is 23.1% of what's called the average manufacturer price.

Part D redesign is the third major pillar. I think this chart, to the extent you can see it, really gets at the key differences here. To the left is the current benefit of how things look under Part D and the right is what it's going to look like in 2025. The deductible's the same, about \$500 will be increased for inflation, and then there's not too much of difference under that next coverage phase. The beneficiary has to pay 25% and that's going to remain the same. There's a bit of difference in the manufacturers have to kick in 10% for coverage of the drugs in that coverage phase but that's going to look pretty similar. It's the top that looks really different. So, we're getting rid of the coverage gap phase entirely and then you look at the top the way it works currently is that the federal government is paying most of the costs above the out of pocket threshold. That that orange bar is now shrinking a lot so the Federal Government above the catastrophic cap isn't paying much anymore. Instead that's being shifted to the plans and to some extent the manufacturers. And the other key difference is that, again on the left side, you see that little slim dark blue on the left. That's the enrollee costs - they owe 5% above the catastrophic cap under the current rules and then in 2025 that will go down to zero. The difference between 5% and zero is not a big deal, right? Well it actually can be a very big deal because if you think of a drug that's priced over \$100,000 or \$200,000, 5% of that is a big difference versus zero. The catastrophic cap is going to be \$2,000 per year indexed for inflation but that's coming down. So, clearly there's going to be a real impact on Medicare beneficiaries that have really high drug costs under Part D.

A few other changes to note. There's now cap co-pays of no more than \$35 a month for insulin and \$0 for vaccines. As I mentioned before that because the plans are going to really absorb the costs above the catastrophic cap that money's going to have to come from somewhere. So, the incentive really is that you increase premiums. The law prevents increased, well I shouldn't say prevents premium increases, but caps them at 6% until basically 2030. So, what that means is that the Federal Government is going to have to come up with the additional money but after 2030 we're going to see the ability to increase premiums at a higher rate. Finally, I just want to note the marketplace changes. These are not drug price provisions but the law is keeping it effective, the additional marketplace subsidies under the American Rescue Plan Act. You can see sort of in the middle there, that's what happened prior to 2021 in terms of subsidies for buying plans for the exchanges and to the right side from 2021 now through 2025, those percentages are lower. So, what does this mean for states? It's not the easiest question to answer because a lot of this involves prediction and I can't promise what's going to happen but there's speculation as to what might happen and it's worth taking that into account. One of the

big questions is what does this mean for the commercial health insurance market. This is a law that's designed to reduce costs under Medicare. It's not a law that's designed to reduce costs under the commercial health insurance market and there's a concern that there might be a bit of a cost shifting going on. Drug manufacturers are going to have lower revenues from the Medicare program and where are those additional revenues going to come from? They may make efforts to seek higher revenues from the commercial health insurance market. This may happen through higher launch prices for drugs. Also, when you know think about the way these new Medicare rebates work, the manufacturer's only paying rebates to the government for Medicare units so if you imagine you have a drug say 80% of it is sold in the commercial market and 20% is sold to Medicare enrollees or say Medicare and Medicaid, it's a drug that generally is used in the commercial health insurance market not Medicare and Medicaid. Think about what that means for a manufacturer. You may say, well we can still increase the price of our drug, we won't get any additional revenues on the Medicare and Medicaid side but we will get additional revenues on the commercial side and that's 80% of the business for this drug, so that's fine. So, that's the potential for what may happen. I don't know if that's actually what's going to happen but it's something that some have speculated could occur.

The second point here is how this might impact state legislation. So, to the extent there's efforts to control drug prices at the state level you could see this law being a model in some ways. An easy point is the \$35 insulin copay cap. Many states already have this or something similar. It's possible that other states might be encouraged to do something similar for their commercial health insurance market. Another point I think is the state of drug price affordability boards. Most states don't have them but some do. I know boards are intended to reduce the price of drugs generally in the commercial market and one of the challenges for those boards is understanding if they're going to come out with a price that commercial health plans should not pay more than that price. Where is that number going to come from? They don't want to make it up out of thin air. Well, now we have a federal law that's going to give them that price. These are going to be published federal prices where the federal government's going to say that we are not going to pay more than X for this drug and so you can say as a state, we're going to follow that. We're not going to pay more than X for that drug either and then also think about the inflationary rebates. As I mentioned they do not apply to commercial drug units. Initially they did but this was struck by the U.S. Senate Parliamentarian due to Congressional rules. So is there going to be an effort by states to try to address that by perhaps requiring inflationary rebates on the commercial side as well? And finally, the fact that the Medicaid PHE is going to come to an end soon and we have these higher subsidies and the exchanges through 2025 perhaps that's going to lead to more of a shift to marketplace enrollment in the next few years.

Sen. Utke stated that as you went through all of that what I thought in the back of my mind is when it comes to healthcare and the costs that you're talking about and some of it's being shifted, it's kind of like the balloon when you squeeze it on one section which we're going to reduce, who's picking up the balance? And so with that at this point what do you envision the success of this will be or what will be the result or what do you think we'll see down the road? Mr. Dworkowitz stated that it's a very good question and it's hard to know exactly. I think one big question is, is this going to actually impact drug development? Are there going to be fewer drugs brought to market due to the lack of anticipated returns from the manufacturers? I don't know. I've heard good arguments on both sides. It may be not so much overall drug development is impacted but maybe certain niches are impacted because of certain incentives under the law. In terms of the cost shifting it's certainly plausible there could be some cost shifting to the commercial market. But we'll see. It may be that there's a version where this does result in lower costs in Medicare and there's not a profound impact on the remainder of the market but it's just hard to know that.

Asw. Hunter stated that we had a conversation I think last year relative to 340B and the savings and you're at Manatt in New York so you understand where we are with the 340B program and the savings. So I get the fact that the reduction needed to happen, it's too expensive. But several years ago we had a panel with actuarial folks, doctors, and the insurance plans and still we could never get to how is the pricing for drugs priced. You have the people at the table, and no one can say and I get the role of shareholders but the savings that Medicare recipients are getting is important. You're talking about seniors, people with fixed incomes. people who are disabled. The 340B program which gives savings especially to federally qualified health centers (FQHCs), you see in New York what's happening. The state wants the savings back. Is the federal government then in turn going to supplant dollars to these places and it's not just urban centers, but rural areas where healthcare is not accessible in order for programming? We have hospitals who are getting these 340B savings and they don't need it. The last panel probably wouldn't agree with what I just said but FQHCs need these savings. If they're not getting that and the federal government doesn't supplant it they cannot deliver the services to the people who desperately need it. I don't want that to go and it's very confusing. People don't understand 340B but this is happening right now and it will affect every single state who has FQHC's who are not watching this. This is very concerning to me and also, the middle can't absorb the increased costs because they're defraying costs from Medicare. That's important. Seniors shouldn't have to, but the middle shouldn't have to take care of that either and I think that needs to be watched in a way that the working poor cannot afford to have these increased costs and these high deductible plans.

Mr. Dworkowitz stated that 340B is a complicated program. There's some weird dynamics going on with this law and 340B because in theory you can say if you're a 340B covered entity and if you are a FQHC, I like this because the negotiated prices that Medicare gets pass on to me for those drugs so you say oh that's great. The complication is that the savings are not supposed to go to the covered entities. Everything is supposed to go to the Medicare program. So, even though I might be buying the drugs as an FQHC for a lower price, Medicare's going to come in and pay a lot less because the law's designed to capture those savings so I may be getting actually less in terms of revenue for those particular drugs. Again, those are only negotiated drugs but that dynamic is definitely at play here.

## DISCUSSION AND CONSIDERATION OF RE-ADOPTION OF MODEL LAWS

Sen. Utke stated that per NCOIL bylaws all Model laws must be readopted every five years or else they will sunset. The models scheduled for re-adoption today are on the app, the website and they start off in the binders on page 350. The models are the Exhaustion of Administrative Remedies Model Act, and the Producer Compensation Disclosure Model Amendment to the Producer Licensing Model Act. Hearing no questions or comments, upon a Motion made by Rep. Carter and seconded by Sen. Hackett, the Committee voted without objection by way of a voice vote to re-adopt the Models.

## ADJOURNMENT

Hearing no further business, upon a motion made by Sen. Hackett and seconded by Rep. Matt Lehman (IN), NCOIL Immediate Past President, the Committee adjourned at 12:00 p.m.