

NATIONAL COUNCIL OF INSURANCE LEGISLATORS
HEALTH INSURANCE & LONG TERM CARE ISSUES COMMITTEE
NEW ORLEANS, LOUISIANA
NOVEMBER 17, 2022
DRAFT MINUTES

The National Council of Insurance Legislators (NCOIL) Health Insurance & Long Term Care Issues Committee met at The Sheraton New Orleans Hotel on Thursday, November 17, 2022 at 10:00 a.m.

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

Other members of the Committee present were:

Rep. Deborah Ferguson, DDS (AR)	Sen. Paul Wieland (MO)
Asm. Ken Cooley (CA)	Sen. Michael McLendon (MS)
Rep. Tammy Nuccio (CT)	Rep. Jim Perry (NC)
Rep. Rod Furniss (ID)	Sen. Vickie Sawyer (NC)
Rep. Thaddeus Jones (IL)	Sen. Jerry Klein (ND)
Rep. Matt Lehman (IN)	Sen. Shawn Vedaa (ND)
Rep. Joe Fischer (KY)	Asm. Kevin Cahill (NY)
Rep. Rachel Roberts (KY)	Sen. Bob Hackett (OH)
Rep. Cherlynn Stevenson (KY)	Rep. Carl Anderson (SC)
Rep. Mary DuBuisson (LA)	Rep. Kevin Hardee (SC)
Rep. Edmond Jordan (LA)	Rep. Jim Dunnigan (UT)
Sen. Robert Mills (LA)	Sen. Mary Felzkowski (WI)
Sen. Lana Theis (MI)	Sen. Eric Nelson (WV)
Sen. Paul Utke (MN)	

Other legislators present were:

Rep. Reginald Murdock (AR)	Sen. Kevin Blackwell (MS)
Rep. James Kaufman (AK)	Sen. Scott DeLano (MS)
Rep. Kerry Wood (CT)	Sen. Walter Michel (MS)
Rep. Matthew Gambill (GA)	Sen. Joe Thomas (MS)
Rep. Carolyn Hugley (GA)	Sen. Paul Lowe (NC)
Rep. Brian Lohse (IA)	Sen. Bill Gannon (NH)
Rep. Rita Mayfield (IL)	Sen. Jay Hottinger (OH)
Sen. Julie Raque Adams (KY)	Rep. Brian Lampton (OH)
Rep. Michael Sarge Pollock (KY)	Sen. George Lang (OH)
Rep. John Illg (LA)	Rep. Forrest Bennett (OK)
Sen. Kirk Talbot (LA)	Sen. Roger Picard (RI)
Rep. Kevin Coleman (MI)	Sen. Mike Azinger (WV)
Rep. Lori Stone (MI)	

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. Bob Hackett (OH) and seconded by Sen. Paul Utke (MN), the Committee voted without objection by way of a voice vote to waive the quorum requirement.

MINUTES

Upon a Motion made by Sen. Jerry Klein (ND) and seconded by Asm. Kevin Cahill (NY), NCOIL Vice President, the Committee voted without objection by way of a voice vote to adopt the minutes of the Committee's July 14, 2022 meeting in Jersey City, NJ.

INTRODUCTION AND DISCUSSION ON NCOIL BIOMARKER TESTING INSURANCE COVERAGE MODEL ACT

Asw. Hunter stated that today we are introducing and discussing the NCOIL Biomarker Testing Insurance Coverage Model Act (Model). I am the proud sponsor of this Model and I have also introduced this in the State of New York. A copy of the Model appears in your binders on page 33 and it's on the website and the app as well. For those of you who were at the Summer Meeting in Jersey City this past July you may remember we had a General Session dedicated to this topic. That session was a great opportunity to learn more about the issue before developing a Model. I'm looking forward to discussing the Model today and hearing everyone's thoughts about how it may be improved. Similar legislation has been either introduced or signed into law in states such as Arizona and California and Illinois and again I've introduced this in New York. One last thing before we get started, this Model will not be voted on today. We're still in the development and information-gathering phase. Depending on how things go today we may be voting on this Model during our next meeting in March.

Dr. Marc Matrana, Director of Precision Cancer Therapies (Phase 1) Research Program, Endowed Professor of Experimental Therapeutics and Associate Director of Clinical Cancer Research at the Ochsner Cancer Institute, thanked the Committee for the opportunity to speak and stated that he is a practicing medical oncologist and sees cancer patients every day and he also directs Precision Medicine at Ochsner Health. I've been instrumental in passing legislation here in Louisiana around comprehensive biomarker testing and precision medicine in general. We've actually passed about half a dozen laws to really protect the interests of cancer patients, make cancer care safer, cheaper, and better for our patients all around. But really the question is what is biomarker testing? What do we mean by biomarkers? Well at the most broadest level, a biomarker is anything we can measure in the body to help us make a better decision for a patient but when we were specifically talking about cancer the biomarkers that we often use are things like genes. So, we can sequence a gene and it can tell us if a cancer patient will respond better to drug A or drug B. This is not some new experimental thing. This is actually a standard of care. If I don't do this testing and if I don't prescribe the right drug for the patient my patient is going to have a far worse outcome. In fact, they're going to have a shorter life expectancy. I'll probably get sued for malpractice or I certainly should. But the problem is that not every insurance company is paying for guideline based proven comprehensive biomarker panels and this is unfortunate because patients really need this. In the state of Louisiana through the cancer advocacy group of Louisiana, we were able to successfully pass a number of bills that guarantee that our patients will have access to this type of testing.

To give you a few examples - with lung cancer you're going hear about this from one of our patient's here today but there are 14 different genes that we know of today that drive lung cancer. Most of those are associated with a therapy and if you get on the right therapy for the

gene that's driving your lung cancer you're going to have a far better outcome. You're going to be able to go to work and be a productive member of society rather than having to take chemotherapy. You're going to live far longer. Maybe a decade longer than counterparts who don't have those same mutations that never got tested for them or are not on the right therapy. And so the legislation that we are proposing here is not to approve anything that's experimental, it's not to approve anything that's not proven. It's to simply approve guideline base testing that's going to save lives and at the same time save a lot of money. In 2003 it cost \$2.7 billion dollars to sequence the first human genome. Want to guess what it cost today - \$200. It took 13 years to sequence the first human genome. I can do it in a couple of days with a machine that's about the size of a small fax machine or a small printer. We've made dramatic improvements in the cost of testing and by getting the testing for patients we're then able to put them on better, more effective therapies. They are able to go to work every day, pay taxes every day and be productive members of society. We no longer have them sitting in hospitals dying of their cancer. It saves vast amounts of money when we get the correct testing and we get the patient on the right therapy.

I told the CEO of our hospital just a couple of weeks ago that we're not going to call precision medicine precision medicine in a few years - we're just going to call it medicine. Because that's what it is. Every one of us are our genes and once we really uncover this in a big way this will be the basis of all medicine. As you mentioned Asw. Hunter, Arizona, Illinois, Louisiana, and Rhode Island already passed these bills and they're being considered in other states as well. We can make decisions based on genetic information that can tell us if our patient needs a standard dose of drug, a half dose, a double dose, or a completely different drug. Before we were shooting in the dark - take two aspirin and call me in the morning and I hope it works. Maybe it won't and then we'll try something else. Now I can take a tube of blood and within days have an answer of exactly what will work for each patient. What won't this legislation do? It won't require unnecessary unproven tests. It's going to tie coverage to U.S. Food and Drug Administration (FDA) approved and cleared tests, things that are clearly labeled and indicated for these tests. It's going to tie this to Centers for Medicare & Medicaid Services (CMS) coverage determinations and nationally recognized scientifically sound practice guidelines that are written by the best physicians America has. And again, it won't increase costs, it simply won't. It will save a lot of money across the board.

Tammy Middletown, Volunteer at the GO2 Foundation for Lung Cancer thanked the Committee for the opportunity to tell her story and advocate for other patients. Ms. Middletown stated that she is a lung cancer survivor from Alexandria, Louisiana and a volunteer with the Go2 Foundation. In December of 2018 a CT scan showed a large tumor in my left lung during an Emergency Room visit. It was suspected to be lung cancer. At that time, I chose to go to Anderson Hospital in Houston, TX for additional treatment and diagnosis. In the beginning I had two tissue biopsies that failed to identify my type of cancer. One for my right adrenal gland and one for my left lung. My oncologist decided to pursue next generation sequencing biomarker testing on a liquid biopsy of my blood. This confirmed a diagnosis of stage four ALK positive non-small cell lung cancer. Based on this diagnosis, I was immediately started on a course of radiation and the targeted therapy developed specifically to treat ALK positive lung cancer. Treatment started a month after the initial tumor was found. Soon after starting targeted therapy my health began to improve. I was stable until April of 2021 when a new spot appeared on the right adrenal gland. Again I had another tissue biopsy that did not yield any actionable information. My oncologist pushed to do another set of next generation sequencing biomarker testing on another liquid biopsy. This revealed that there had been no additional mutation burdens and we could locally treat the new spot with radiation. That meant I could stay on the targeted therapy that I had been on for two years at that point. After that round of radiation I've

continued to be stable for a total of three years and nine months. This is all on the same initial treatment that I started with in January of 2019.

Next generations NGS biomarker testing allowed my cancer to be diagnosed quickly so that I can start treatment with a protocol that is effective for ALK positive lung cancer. In April of 2021 NGS biomarker testing guided treatment decisions that has allowed me to continue on my original therapy rather than hopping from one treatment to another. This buys me time for research to happen and cures to be found and it gives me hope. It also keeps other treatment options on the table for me in the future. Access to the information from comprehensive biomarker testing allows me and my oncologist to always make the best decisions for my treatment. As an example, because of the specific genetics of my cancer we knew that immunotherapy which is a powerful treatment for lung cancer would have zero effect on my cancer. On this journey I've discovered that access to good cancer care is a roll of the dice. I have been fortunate to access care at the center with the resources to fight for me, to get the right testing and the treatment that I need. That is not the case for every patient. Cancer care should not be a roll of the dice. All patients should have access to the testing needed to best direct their care. On their behalf I advocate for other patients to have access to the same testing I've had and they need.

James Gelfand, President of the ERISA Industry Committee (ERIC), thanked the Committee for the opportunity to speak and stated that ERIC is a national trade association that represents employers on benefits issues. Our large employer member companies sponsor health insurance benefits for tens of millions of Americans all across the country. Our members primarily offer self-insured plans where ultimately the employer is on the hook for the cost of healthcare for our employees, their families, and retirees as well. Some of our members also offer fully insured options to some or all of their beneficiaries. In all of these cases the benefits are designed to maximize value for beneficiaries. We are fiduciaries to these plans and we have a duty to design and implement health insurance benefits that provide high quality care, that meet the needs of our beneficiaries and that do so in a way that is value driven and responsibly spends plan funds. Overall, ERIC members pay about 85% of healthcare costs on behalf of our beneficiaries. And it's widely acknowledged that employer sponsored benefits are the most comprehensive and have generous coverage generally available. Health insurance is a voluntary benefit that employers offer to attract, retain, and support employees. Between 160 and 180 million Americans get their health insurance through a job and 110 million of those get their health insurance through a self-insured plan. For large employers they could instead choose to pay a fee under the Affordable Care Act (ACA). The fee is \$2,500 per person which is much less than what the average cost is to actually insure our employees.

For small employers with fewer than fifty employees there's no penalty for dropping insurance and as costs continue to rise small businesses are dropping coverage and their employees and their families end up either on taxpayer-subsidized ACA plans, on Medicaid, or uninsured. But employers do want to offer coverage and most small and medium-sized employers would prefer to buy fully insured state-regulated plans because it's the most simple arrangement, they pay the insurance company and their employees are taken care of. However many of these companies opt for self-insured Employee Retirement Income Security Act of 1974 (ERISA) plans mostly to escape the extremely high cost of State mandated coverage rules. I used to work for a U.S. Senator from Maine and at the time Maine was one of the states with the most health benefit mandates in the country. As a result we had chased away all but one insurance company. The cost of insurance were ludicrously high. The individual and small-group markets were basically dead in our state. After the ACA passed, Maine reduced some of these burdens to bring the market back and indeed many states are now cognizant of the need to allow flexibility in

coverage but many state legislators are frustrated at their inability to regulate self-insured plans. At the same time they propose and pass laws that push more people into self-insured coverage. I know that there are State advocacy groups that have a grand vision of eliminating the risk of preemption for some or all health plans but this would be strongly opposed by many stakeholders in D.C. So until that happens legislators and regulators who want to keep control over health benefits in the state might consider how increasing mandates and therefore increasing costs could lead to fewer covered lives within the States purview.

Let's talk for a minute about those costs and the cost of health insurance which stems directly from the higher cost of healthcare that is delivered. Those costs continue to grow. They've devoured the wages of working families putting more pressure on both workers and employers. I remember over a decade ago when we were all shocked that General Motors was spending more money per vehicle sold on health care than they were on steel. Then I remember being shocked again several years later when the Kaiser Family Foundation confirmed that health insurance now cost the average family in a given year more than the cost of a motor vehicle. And no doubt this year or next new statistics will come out that shocks us further. Most of these unsustainable costs increases are attributable to hospital cost, some to drug cost, some to paying providers, some of the middleman administrative entities. But the thing to keep in mind is as healthcare costs expand to take up a greater and greater share of the economy the healthcare industry is making more and more money while families are forced to face those consequences. Eventually if we continue down the path of ever-increasing healthcare costs without finding a way to reign them in, we will end up with something akin to Medicare-for-all because employers will not be able to continue to sponsor plans. On the specific subject of mandating coverage for biomarker testing, ERIC believes that this mandate would likely increase costs, would drive waste in the healthcare system, and would further enrich the medical industrial complex without really benefiting patients.

We appreciate that there are members of NCOIL who see the great promise in biomarker testing and we see that promise too but mandating coverage will actually move us in the wrong direction. And don't take it from me, take it from the California health benefits review program at UC Berkeley. They wrote "under existing law, plans and policies are required to cover medically necessary diagnostic lab services and ongoing disease management services. Additionally, biomarker testing is broadly covered by California's Essential Health Benefits (EHB) Benchmark plan. They further wrote that broadly speaking all enrollees with health insurance subject to a proposed bill in California have coverage for biomarker testing that is supported by medical and scientific evidence and is determined medically necessary. In other words, when biomarker tests are useful, and that is, when they provide accurate and actionable information for patients and providers, those tests are already covered. They may be covered due to existing law such as the ACA's EHB requirements or they may be covered under ERISA plans because they're medically necessary, they provide clinically useful information, and that information leads to better and more efficient care. Both employers and health insurers want better and more efficient care. They can save money by providing effective treatment sooner by avoiding treatments that would harm patients or would be a waste of time and money. And by ensuring optimal care they can often stave off more serious and expensive interventions later. They can learn in advance what problems are likely to arise and address them in the plan of care prior to those problems metastasizing. Employers and insurers make these kinds of investments all the time and they do so voluntarily because it's the best way to drive value in the health plan or insurance coverage. But the Model proposed would broadly require insurance to cover biomarker testing when the testing is supported by medical and scientific evidence which is defined to mean that the test is FDA-approved, developed to inform pursuit into an FDA-

approved drug, is covered by Medicare or supported by a national provider group or multi-stakeholder group.

Basically, this means that the test works. It doesn't mean that the test is actually useful. For a test to be useful the patient's provider would need to learn actionable information. If you got a certain result from this test what would you change in the course of treatment or the care plan? And if the answer is that something would in fact be changed then the test is likely already covered under current law and best practices. That sounds like a test that's medically necessary. It's needed for a provider and a patient to make a consequential choice about care. So under current law and policy when might a biomarker test not be covered today? Well, going back to the California analysis, they projected that if the mandate was enacted the primary change would be the test will be conducted more often when they weren't really called for. They described this as test use for screening purposes rather than tests that would be due to indications and lead the clinical responses. They projected that the use of biomarker testing would increase at about a \$1,000 a pop but that it wouldn't likely improve health. Reading between the lines they anticipated that providers would start ordering more of these tests in order to obtain information that wasn't actually useful or actionable. But of course the providers would now be reimbursed for ordering those tests. So, they would make more money but the patients and the employers would pay that money and health would not necessarily be improved. I don't need to tell you that a lot of tests on the market today are deeply problematic. Worse than just not being useful, many tests provide information that is unreliable. These tests are causing patients to make drastic and incorrect choices about their healthcare. They're scaring patients. They're charging thousands of dollars in order to tell patients something that may be wrong or misleading.

In my previous role working for a patient advocacy group we were extremely concerned about certain genetic tests that were being pushed by for-profit companies. Those tests were providing questionable results to patients. Patients were then acting on those test results and making decisions that would have long term and drastic effects particularly on their fertility, their biomes and their overall health. At the time we advocated that test results from these genetic tests should always be put into context and should always come with counseling from an expert and should fully disclose in a way that was comprehensible to those with low health literacy their potential to be inaccurate. And I can't imagine mandating that insurance pay for those tests which would result in many more of those tests being delivered especially knowing how it might affect patients. Employers don't support mandates for this kind of reason. If a treatment service or product is going to improve health and especially if it's going to bring value by improving health and lowering cost of course we want to cover it but broad mandates often don't distinguish and recommendations from a provider group or a consensus group don't necessarily meet these objectives nor does attest mean FDA-approved. Mandates could lead to waste in the healthcare system and when we waste money on one treatment that money is no longer available to spend on useful and needed treatment for this particular patient or for others. In conclusion, I would just mention perhaps the most important takeaway from the California analysis of the proposed legislation was that there were many patients who should have gotten biomarker tests and they didn't get them but the reason was not because insurance companies refused to pay for those tests. It was because the doctors didn't prescribe them. What that demonstrates is a lack of awareness of these tests and a lack of education and that's something that can and should be addressed but that a mandate for insurance coverage will not address.

Asw. Hunter stated that my first question is Dr. Matrana - we're talking about costs and sometimes associating costs with someone's life is hard to swallow. Asking how much your life is worth is difficult. But you talked about how much a test cost and now it costs \$200. Can you

briefly elaborate how you got to that so that we know when we go down this path it's not trying to figure out that the doctor isn't doing what they're supposed to be doing because they're not prescribing the test, compared to these are new initiatives in trying to help treatment in furthering someone's quality of life. Dr. Matrana stated that the cost of this type of testing has dramatically gone down in the last few years and comprehensive biomarker testing for oncology, what we call in NGS for example, is just a few hundred dollars now. Believe it or not sequencing every gene in the whole genome sequencing is even cheaper and can be about \$200. But the cost savings is not so much in the testing, it's in getting the right patient on the right therapy at the right time and because of the way cancer tests and the drugs work we now have many drugs that are approved not based on the type of cancer a patient has but based on the mutation that's driving that cancer. So, for example just a few weeks ago a drug was approved for any cancer patient who has a RET mutation. We don't know if they have a RET mutation unless we do comprehensive biomarker testing. And that's not a singular example. There are half-a-dozen drugs and next year there will probably be a dozen and the next year there will probably be two dozen that specifically prove not based on the type of cancer but on the mutation the patient has. So if we're not testing every cancer patient for these mutations we are missing these mutations and missing the opportunity to get them on the right therapy that will dramatically improve their outcomes and allow us to avoid much more costly and toxic therapy for these patients. The idea that these tests are already covered is an interesting one and I would just add to that prior to this legislation being passed here in Louisiana a great deal of my time was spent arguing with insurance companies on coverage for patients to get guideline based testing that a patient absolutely needed for me to make treatment decision for how to treat their cancer. After the legislation went into effect I spend far less time doing that and I spend far more time treating patients.

Asw. Hunter asked Dr. Matrana if in his experience he has seen widespread providers just not asking for these tests? Dr. Matrana stated no that's not the case at all. I think providers understand the importance of these tests. Are there singular examples of providers out there who might not be ordering based on the guidelines, of course. But what we've done in our health system for example is we've actually taken the decision to order these tests or not out of the doctor's hands so they don't even have to worry about this. At the time cancers are diagnosed by the pathologist we have an automatic system, an algorithm, that identifies which patients need the testing and which patient would not benefit from it so they're automatically tested based on an algorithm that is guideline and scientifically-based so that we don't even have to worry about whether the doctors are doing the right thing or are they ordering something they're not supposed to.

Rep. Deborah Ferguson, DDS (AR), NCOIL Secretary, asked Dr. Matrana if he could respond to what Mr. Gelfand stated regarding FDA approved versus the guideline based testing - are you using a different guideline as an oncologist? Dr. Matrana stated that the absolute gold standard of cancer care the world over is the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology and a lot of coverage is based on the NCCN guidelines. The NCCN is a group of the largest cancer centers in the world and they all send their top experts to write the guidelines which outside of Europe which has their own guidelines, the whole world uses to treat cancer and we based our practice off of those guidelines they don't get any better than that. Rep. Ferguson asked if those have gone through the FDA process. Dr. Matrana stated that most of them have but not necessarily everything in the guidelines are FDA-approved as a lot of times the approval may lag a little bit from what's based on the guidelines. The guidelines are based on pure scientific evidence and FDA approval may come later down the pike.

Sen. Paul Lowe (NC) stated that if it's cheaper, then what is the challenge for states not using it or having this legislation? Dr. Matrana stated that what I have been told is, and I'm not an expert in this, often insurers are not looking at cost savings over five to ten year periods for cancer patients. They're looking at it over a much shorter period because they don't expect that the cancer patient will remain employed with the same employer and therefore they would be changing plans. And so they want something that might save them money in six months rather than a cancer patient living for five years and they're going to save money over the five-year period. Sen. Lowe stated that so they're not looking for them to live, that's what you are saying? Dr. Matrana replied yes, that's correct.

Rep. Tammy Nuccio (CT) asked if there is a compromise here between having for lack of better words a free-for-all to be able to order a test whenever you want or to establish guidelines that put in medical necessity and accuracy of the test? Dr. Matrana replied absolutely and I think the Model looks at guideline based FDA-approved and tied to CMS coverage determinations. So yes we would not support legislation that would just allow any doctor to order anything at any time. We would want the appropriate test to be ordered as my colleague said that would obviously have a benefit towards patients and change the outcome of what we do for patients which is what biomarkers do.

Rep. Nuccio asked Mr. Gelfand if he agreed with that and also noted that this is the first time she has seen anybody here from ERIC so thank you for being here because ERISA plans are the majority of insurers and anything we do at a state-level absolutely does not impact the majority of people. I can't tell you how grateful I am that you're even at that table. Mr. Gelfand stated that I think from the ERISA plan perspective we'll be much more interested in things that are medically necessary. I think also other things to take into account would be perhaps getting other organizations and perspectives involved such as the Patient Centered Outcomes Research Institute (PCORI) and discussing using these tests versus not using these tests. Rep. Nuccio stated that I agree with you about getting other perspectives involved, particularly federal perspectives. But I'd be interested in understanding how we could develop medically necessary and accurate enough testing to be able to put it through because there is a cost-savings benefit to being able to identify these treatments earlier and not going through the Step Therapy of ten different things before we get to something effective. And there is also a quality-of-life issue beyond just the financial aspect of it. So I know we're not voting on this today but I think the work that we should be doing is finding that compromise between medically necessary and accurate and from there figuring out how we can make it work for both.

Hilary Gee Goeckner, Director of State & Local Campaigns, Access to Care, at the American Cancer Society Cancer Action Network (ACS CAN) stated that as the legislation is written there are clear guardrails for the circumstances under which testing is appropriate and this does not include screening but this is diagnosis, treatment decisions, and ongoing monitoring. These are all to impact treatment decisions. And then the clear medical and scientific evidence must be met in order for a test to be covered.

Sen. George Lang (OH) stated to Mr. Gelfand, if the testimony we heard from Dr. Matrana is accurate, is it not possible that the markets will force these changes themselves without having a government mandates? In fact it's going to save money and as you mentioned, it only really affects the small mom and pop shops because the large self-funded groups are subject to ERISA and they would not fall under these mandates. So, if these claims are right is this something the market would naturally do without the government interfering? Mr. Gelfand stated that if the kind of savings projected in some of the literature I've seen is accurate, there's no question that insurance companies and risk plans would on their own demand these tests be covered. I think

what's happening right now is that they're indeed seeing that some tests are indeed providing savings and are improving care and those are being covered and then there are some that may not be proven yet and as a result they may not be covered yet. And so over time that'll change if more evidence comes out but yes we do think the markets will resolve this issue.

Asw. Hunter thanked everyone for their comments and stated that in advance of the Committee's next meeting, please send any thoughts or comments on the Model to me or NCOIL Staff.

DISCUSSION ON POLICIES THAT ENABLE VALUE-BASED PAYMENT ARRANGEMENTS FOR GENE THERAPIES

JP Wieske of The Campaign for Transformative Therapies (Campaign) thanked the Committee for the opportunity to speak and stated that the Campaign is a piece of the Council for Affordable Health Coverage and it is a big coalition with all sides represented. The intent in this discussion is trying to find some ways to pay for these really significant gene therapies that are coming across the pipeline. In talking a little bit about gene therapy what we are talking about is some transformative treatments that fundamentally change the interaction with a patient in their diseased state and have a durable sort of cure for really serious medical conditions. The expectation is that these are going to be quite expensive as we move through. One of the gene therapies we talked about that is out already is Zolgensma and it deals with spinal muscular atrophy. It's expensive but it is changing the lives of children. We're also talking about the next couple that are definitely coming out that are related to hemophilia. Those are also likely to be very expensive but again, sort of change the way people interact. If we look at what's coming this is a message from the future that everybody needs to pay attention to. There's a ton of gene therapies that are going to be coming out in the next three years and financing these is going to be a major issue both for private health insurers and through Medicaid as a matter of course. Sixty-three are expected to be approved by 2030 and that means that there are going to be some significant costs that are going to attach.

So when we look at hemophilia specifically, the question is if gene therapy is going to cost \$3 million dollars for a patient to get, is there actually a value delivered? That question actually has been answered to some degree. There is a report on this which found that this \$3 million dollar gene therapy will not only deliver a much better result for patients, but in the long run may be less expensive. Obviously the issue here is that it's a \$3 million dollar gene therapy and being able to afford it. So, one of the things that we do need to talk about is around Medicaid and financing. There are arrangements that are in play and we were just talking about the issues in private insurance around access how both private and public use access to sort of limit the use of expensive drugs in some cases. The costs are significant as we attach. And then inside Medicaid there is a requirement to cover all medications. So how do we sort of look at this in a different way and move forward? Again we're looking at something that's going to transform the way medicine interacts with patients. We're going to be taking people likely off of Medicaid and public assistance into new jobs in some cases. And this explosion is coming. So you need to find some solutions that are balancing access and costs and what we're talking about from our standpoint when we looked at this is something of value based payment arrangements. There are a number of names that have been used such as outcome-based arrangements or value-based purchasing arrangements. The idea is that you have a shared risk model and it holds manufacturers accountable from the standpoint of a requirement that they have to deliver on the outcomes that they're promising and the drug has to do what it's supposed to do.

But that also means that you broaden the patient access. So these contracts both privately and publicly are done on a one-on-one basis. If you have seen one contract you have see one

contract and that's part of the issue that this is going to be a costly endeavor for states to get into and this is something that they need to start planning for now as we see the coming approach. The contracts deal with who gets access to the drugs and what the drug actually costs and what the risk structure is and who the eligible patients are and how the rebates are tracked. All these issues are going to be important. There are a variety of these arrangements. There's a pure outcome space determination, a warranty model, some ability for a payment over time installment plans. All these are in addition to having issues surrounding the technicalities we'll also have such as accounting issues. I would also note one of the things that you may want to look at and understand as you're looking at the pricing is what you're doing from a reinsurance standpoint. If you have one plan covering a \$3 million-dollar gene therapy whether it's a care management organization or it's in the ACA or something else, that means there's potentially some adverse selection. One of our co-workers worked at a plan that had 24 of the 26 hemophilia patients in the state of Nebraska enrolled in this plan. Needless to say that plan was not in fact profitable and there's some adverse selection that was sort of applied as a result. So those issues are going to be increasingly important. We believe that using the value-based payment arrangements ensures both broad access and controls costs and as a result aligns incentives between the manufacturers and the payers and the patients.

I want to note some challenges that are sort of in play as you look at this issue and as you talk to your Medicaid folks and other folks. The administration of these again is a one in one administration of the specific drug that attaches. You need to negotiate the specific terms. We just had a call with the Center for Medicare and Medicaid Innovation (CMMI) this week to talk with them about what we can do to promote these outcomes and these contracting arrangements from a state by state basis. So hopefully the federal government will make it a little bit easy. How do you actually measure these outcomes and what outcomes do you want? When we talked to individual state Medicaid folks we had some interesting results and I will tell you that Medicaid offices are not necessarily thinking about it in the same way. Some want clear clinical data, others only want to use claims data. Regarding third party evaluation, how do you pay for this third-party evaluation piece of it? Where does the trust start attaching as a matter of course? And again, operationally how do you deal with managed care organizations, medical providers and others? And then you get to ambiguity over best price. But there are opportunities. And again we're looking at an opportunity as we get into these that medicine is changing, it's changing for the better. There's going to be value delivered to patients and there's going to be value delivered to Medicaid overtime. But there is an upfront cost that attaches and we have an opportunity to align these incentives appropriately. Broaden the access, risk share, manage those costs and manage those costs on the basis of outcome and data analytics so you actually know that you're getting what you're paying for. I would note that it's a number of states from a Medicaid standpoint have already been here. They've already done some of this work so those are certainly folks that you can take a look at and they're up there on the screen. What we're asking for here is for you to be aware of this issue from our standpoint and to take a look at your Medicaid and your insurers to have this discussion up front and to start looking at policies that make sure that this is a path forward from that standpoint.

Bert Bruce, U.S. President of Rare Disease at Pfizer thanked the Committee for the opportunity to speak and stated that he is here with his colleague Jesse Lemberger, a Senior Director in Pfizer's Strategic Pricing group. While JP and I have never met before it's going to look like we've known each other for a while because we're going to primarily be here to educate a little bit and talk about some of the exact challenges that we're going to look to be able to face together and be able to bring these transformative therapies forward. If we think about where medicine has gone, we think about gene therapies in what we're calling this third wave of potentially transformational innovation. If you go back years ago to symptomatic treatment with things like

aspirin, then there was the biologics that were modifying the disease. But as JP talked about what we're looking at now are fundamental diseases and changing the outcome. Some might use the word cure. Some are not actually designed to cure but they're designed to be a fundamental change to a disease. And that's a very significant breakthrough in those areas. Now I'll take a little bit of time just to talk a little bit about gene therapy and what it is and what it isn't because the first column here talks about the area we're going to spend some time talking about today, it's called gene therapy. Sometimes it's called gene transfer and what it's doing is taking effectively a gene that is not working properly and replacing that gene with one that is working properly. So it's not changing the underlying biology of who a person is, but it's correcting something that's incorrect, then allowing that function to work the way that it was supposed to design to.

That's different than the middle column. There's exciting science, it's earlier in this space which is actually going in and editing a gene and changing the way that a gene is designed. And then there's a third category called gene regulation. Some of those are a little bit earlier and they are more designed to change an individual's foregoing biology. But that's not what we're going to be talking about today, it's going to be about the first category I called gene therapy. We're effectively thinking about it that's taking something that is not functioning properly and replacing it with something that is. And this simple schematic shows a little bit about how that works. There is something that's called a capsid and that sounds like capsule, you can think about it that way. It's an empty container and you put a properly functioning gene which is called a transgene inside of that. The two of those together are called the vector and then you're able to infuse or deliver that to target organs in the body, most commonly the liver but there can be other places. And when it arrives then the capsule dissolves and the correct gene is taken up by the body and replaces. And that's effectively the function of how gene therapy works. There are 7,000 rare diseases and one of the reasons that there's a lot of promise and most of the examples JP was referring to are in rare diseases of which 95% do not have any approved therapy. And for the vast majority of them there's nothing behavioral, they are genetic and they mostly affect children which means they affect parents which means they affect working parents which is why we're here today. And so if we think about that frame with so many diseases that don't have a cure, if 60 come by 2030 that means that they'll still be well over 6,000 that still have no cure and that's one of the promises in the potential is for very small populations and very targeted ways that a very big difference can be made in areas where there's significant unmet need. But rather than show you another slide because I can't envision how many you're going to see over the next couple of days, I'd like to share a short video and this is about a child and his mom and the child has a disease called Duchenne muscular dystrophy (DMD) and we'll see a little bit about how this affects their day.

After the video, Mr. Bruce stated that DMD is diagnosed usually in boys between three and four years of age and they start off like most boys. This is a disease by the by the way that's specifically only for boys. So I'm not just using the word boys. But then they're not able to keep up with certain milestones, not able to walk as fast or they may be a little bit more clumsy in gaining their balance and it's effectively a genetic disorder that eventually removes the body's ability to continue to develop muscle. Now if you think about what the child in the video was not able to do and you think about what he was still able to do, you'll see that there was a lot in that video. As boys progress through they lose the ability eventually to be able to walk by themselves, but the child still had it. He was in what they call the ambulatory phase where they're still able to move around but as the disease progresses they would lose that ability to ambulate. They call that non-ambulatory. So that exercise that he was getting with his mom or with the physical therapist is very important for him to be able to delay the progression of the disease for as long as possible. And there are different costs obviously that are going to be

associated with that age. And so the earlier that a boy like the child in the video would be able to have a treatment that could arrest the disease from progressing any further or change the course of that disease is perhaps a significant breakthrough for himself. Now if you look at DMD, every state has boys that are affected but every state doesn't need to have nor do they have a treatment center for the disease.

There are 33 Duchenne centers that are certified in 21 states. And so what does that mean? Just like most children's hospitals 90% of which treat children that come from out-of-state, the same is true for Duchenne. So, whether you're a state that has a certified center and these centers provide phenomenal care, or your state does not, that simply means that boys in your state and their parents would travel to one of these centers. But therein lies some of the challenges and the opportunities we have to talk about and should and if a product comes to market here then there has to be an opportunity for the states to work together and for us to work with the states to be able to ensure that access is available. If access is not available then that can mean delays in time for the boys to have access to the medicine and you can imagine in a disease like this every day is very valuable. And so that's part of the reason why we're here is to be able to start the conversation around what are pathways we'd be able to pursue together to ensure that when medicines are available for this disease that patients and their parents have access to those medicines as quickly as they possibly can. Right now there are about 28 states that have the capacity to treat these patients. And what we're doing is states have to sometimes apply to get permission to enter these innovative agreements and so that's a very important permission that we want to talk about because it allows us to be able to think about what type of value-based agreement, what type of model is appropriate? Is it the same for a hemophilia patient as it would be for a Duchenne patient as it would be for a different type of patient? And we see here that CMS has already approved these types of special protocol agreements, the ability to sit down and have these conversations with over 13 states. And there are some including Louisiana where that is pending and those asks have been made to allow us to be able to come to the table. Oklahoma is another example. And so sometimes it overlaps where we're looking to get care and sometimes it does not but what all of these are going to require is the ability for us to partner together to be able to understand how we can create new pathways and to find what those pathways are for individual diseases as we look to bring forward these breakthrough medicines to the patients who need them.

Sen. Mary Felzkowski (WI) stated that we talked about these are coming in the future - do we have any of these gene therapies that are being utilized now and what treatments? Mr. Wieske replied yes - Zolgensma is one that's fairly common and I think the hemophilia is expected to get approval both for hemophilia A and hemophilia B I believe this coming year maybe as soon as in the next few months. And so those will be out and that means once those are priced that's going to be a significant cost driver and so getting ready is the key. Sen. Felzkowski stated that for the states that put this in, was there legislation passed or did their health departments just work with CMS on their own to do it? Mr. Lemberger stated that to clarify, the products are covered and Zolgensma has three publicly available innovative agreements in the market. CMS had to approve the waivers before the negotiation could take place. So all the other states actually cover Zolgensma without an innovative agreement. Sen. Felzkowski stated that so with the agreements were they just negotiated with CMS on their own or did the legislature get involved? Mr. Wieske replied yes and I say yes because it varies state-to-state as some states require their Medicaid required to go to the legislature to get formal approval. In other states they're allowed to negotiate the agreement on behalf of the state and can negotiate directly to do the state plan amendment. There are also other drugs outside of the gene therapies that are in the protocol as well on things that are more population based in some cases. So some of those agreements exist and they continue to be worked on but there are options. In our white paper which you can

download we discuss the states that have used it. We have some samples to plan amendments available as well in the states that we believe need legislation and in the states where you can negotiate directly.

Rep. Ferguson stated that if a person has a gene therapy for something that is curable are they then still able to pass that gene on it when they have children or does it correct it completely for when they have children? Would they also still be subject to the same disease even though that person's cured? Mr. Bruce stated that with the examples we're talking about today it wouldn't affect one way or the other what happens between generations. So you're not changing that ability to pass it on for the good or for the detriment. It's only affecting that individual for their lifetime. Now the other side of that is because you were introducing a one-time therapy that is going into the muscle or going into in this case target the muscle but going for a specific disease it's not like if one doesn't work you can flip over to a different one. And so oftentimes the patients and their parents are making decisions even in participating in these clinical trials are making a one-time decision for your life. And so that means that the selection process is going to be important. Some products are intended to be for every individual who has a disease. Others are not. Others are intended for a subset because of the severity of the disease and what the potential benefit could be.

Rep. Ferguson stated that I'm trying to understand this quality payment so say they have gene therapy and then the patient's not cured then the company would pay 80% back if the patient continues to need treatment and really wasn't cured - is that how it works? Mr. Wieske replied yes - they would negotiate those agreements based on specific metrics to specific drugs and what they're promising. So those are going to vary by agreement. If you're looking at something that obviously costs \$3 million dollars you're expecting that is on a patient by patient basis. In other cases for therapies that are a little bit lower cost not necessarily gene therapies but those that are in a population basis - for example there's a heart attack drug and they measure the number of people who have a second heart attack over time and there are others looking at whether or not individuals are on ventilators. There are some that are looking quite frankly whether the patient survives after the first year and then there are different measures after the second year. So there are some variations but state plan amendment allows the negotiation broadly and then individually drugs are negotiated between either the insurer or the Medicaid Agency for what they're measuring and who's measuring it and how they're tracking it.

Rep. Jim Dunnigan (UT) stated that as far as the treatment, how quickly is it effective, and how long does it last? I expect it depends by person but just generally. Let's say there's a treatment for this young guy in the video - what would that do for him? Mr. Lemberger stated that we don't have clinical data. Rep. Dunnigan asked what do you realistically think it will do for him? Mr. Lemberger stated that realistically it would slow the progression. The clinical trial is looking at slowing the progression. So we would hope that it would hold his current status steady for the foreseeable future. Obviously that's a reason to try to treat as young as possible. So now there are patients out there who are eight through eleven but eventually we'd be hoping to treat patients right as they're diagnosed or soon after they are diagnosed. Rep. Dunnigan asked if it would reverse the condition. Mr. Lemberger stated that this type of therapy will not reverse the disease entirely but we're hoping it will slow the progression for many years. Rep. Dunnigan asked if the treatment is an injection and how often does it occur. Mr. Lemberger replied that it is a one time injection. Mr. Wieske stated that to use a hemophilia example as I understand it they are going to be measuring how much factor you have to use and reduction comes relatively quickly and the hope is within a certain period of time that it may not be eliminated but the risk levels drop precipitously for the hemophiliac as time moves on.

Rep. Nuccio stated that if I'm hearing this correctly then these treatments are not going to reverse the disease so somebody will still incur healthcare costs going forward just hopefully at a minimal a level. And then from the cost-share perspective of this are you assuming whether it's Medicaid or private insurance there's going to be a limitation of stop loss or reinsurance or carve out because of a three-plus million-dollar claim on any one individual policy is going to increase rates for every other member significantly and that's also going to max out their lifetime out-of-pocket max which is then going to also incur more costs going forward for the rest of the members of that policy. Mr. Wieske stated that one of the issues you're going to have when any one of these gene therapies come on is depending on the size of the population that's impacted you may have a large number up front. And the hope is that you have lower costs as time goes on and that normalizes the access to that treatment. And so there is an upfront issue but to your point I think that's one of the things that I think may need to be discussed from an access standpoint – how do you pay for a significant gene therapy? And again to pick on Medicaid, if some care management organizations are covering and others are not you're going to have adverse selection and you're going to have issues potentially with individuals who are employed and maybe to get access to it will go through Medicaid in order to get access to the treatment because it's that important. So that's I think a concern. On the flipside I think most of these diseases that we're talking about are rare diseases that are significantly debilitating and so as a result they're probably already on Medicaid and there are real possibilities depending on what it is that they go off Medicaid so that the costs drop not only for their treatment but as well as for other social welfare programs and they will have better lives and in some cases able to work in ways that they couldn't before.

Rep. Nuccio stated that you just said something that always makes me uncomfortable when we start talking about insurance legislation in benefits like this - "we hope." So how long before you think your industry would have something more definitive than hope for a three plus million-dollar product? Mr. Wieske stated that I think it's a therapy by therapy issue that you look at. So I think if you look at the example I cited for the two genes therapies, they clearly found value and they clearly found it was durable. Once those are approved those are going to be changing lives and cutting costs I think overtime significantly with obviously a significant upfront cost. So I think that's one and I think there's going to be varying success and varying issues like what you talked about with delaying the progression of certain diseases so they're not as debilitating over time and others will be closer to curative. So it's going to vary depending on the gene therapy and I think it has to be looked at on a one off basis from a coverage standpoint.

Mr. Bruce stated that I agree completely with Mr. Wieske and I think we'll all agree that hope can be a dangerous word and it can be a powerful word and you're 100% correct in both. Patients and parents are hoping that these medicines will bring the benefit. We will know five and ten years later much more than we will know when we bring the products out to what extent they're able to deliver on that benefit and the alternatives are part of the equation as Mr. Wieske is talking about. Just to use the two that we've talked about if we're talking about hemophilia, hemophilia patients have access to many different types of medicines. They may not be curative but they're expected to live a normal life span. They incur costs over that life span but they live a normal life span. The child in the video is not going to live to 30 under probably any circumstance and the costs are going to become more significant over that period of time and there are no other alternatives. So what we would be looking at is to be able to have those discussions of what would be appropriate to be able to think about how to provide access to a boy like the one in the video. And what about a boy that's five years older than him? It's going to be a difficult discussion to have to understand what is that value for different people at different times given different alternatives but that's why the encouragement that we want to have is to be able to come to the table to be able to have those specific conversations whether you're going to

be the states that would be receiving those boys or the state who will be getting a phone call from other states because you're treating them. So I appreciate your question and they are difficult challenges and that's why we're here to start the conversation.

Sen. Mike McLendon (MS) asked when the price is negotiated, is it negotiated with the manufacturer or is it through a pharmacy benefit manager (PBM)? Mr. Wieske stated that it's the manufacturer typically and in the agreements that are available they're negotiated down on a one-on-one basis and they're looking specifically at what the outcomes are. So again, while you're saying hope the idea is that if the outcomes are not matching what the cost is that there's a rebate attaching. They're obviously expecting that it's going to hit that but they're negotiated with the manufacturer. Mr. Lemberger stated that PBM's are on the pharmacy benefit and these are on the medical benefit. These are delivered through outpatient hospitals so we typically do not go through a PBM for these types of products. Sen. McLendon asked if you look for it to stay that way? Mr. Lemberger replied yes and stated that we would prefer to negotiate directly with the health insurers. Sen. McLendon asked if pricing is on an individual case basis or is it per disease pricing? With the example you gave, is that pricing that family pays the same as another family that has the same symptoms? Mr. Lemberger stated the product is dosed by weight so there are some technical limitations to delivering the exact same price to every patient. We hope to overcome those limitations and provide the same price per patient but some of those things are out of our control. Sen. McLendon asked if where the patient lives plays a part in it? Mr. Lemberger stated that where they live will only matter whether they have to travel out of state to get therapy. It would not play a role in the price.

DISCUSSION ON GOLD CARD LAWS AND PRIOR AUTHORIZATION REFORM EFFORTS

Asw. Hunter stated that in the healthcare context a gold card is something that is issued to health care providers upon meeting certain condition, typically quality metrics, that allows them to bypass turned prior authorization requirements. We did have a general session on gold cards at our annual meeting in Scottsdale last November which focused on the Texas Gold Card law that has recently been signed into law. A gold card bill was introduced here in Louisiana this year, but it was ultimately changed to be a piece of broader prior authorization reform legislation. Both those pieces of legislation can be found in your binder starting on page 36 and they are also on the website and the conference app. Today's session is meant to serve as a follow up to the Scottsdale session so we can learn a little bit more about gold carding and the thought process that led to the Louisiana bill change.

Jeff Drozda, CEO of the Louisiana Association of Health Plans (LAHP) thanked the Committee for the opportunity to speak and stated that I'm sure if you have not seen prior authorization or gold card legislation in your state yet, you will. And I just want to mention a couple things about prior authorization and there are significant benefits to it. However, from the provider side it definitely needs some significant improvement in terms of fraud, waste, and abuse and in terms of inappropriate use of high-cost care. Employers ask us to do what we can to keep the cost of premiums down and prior authorization is one way that we do this. Even CMS uses prior authorization for outpatient services and other sorts of services. So to talk about the Texas legislation, I know that you've heard a little bit about this beforehand but on October 1st they finally came out with their rules a year after passage in 2021 and there are over 100 pages of comments talking about the complexities and the confusion from both the plans and the providers. So, this brings us to what we saw in Louisiana with regard to gold carding prior authorization and it was sponsored by LA Sen. Robert Mills. I do want to thank him publicly because it's his leadership that turned a bill that was a one-size-fit-all bill, into a bill where both parties came to the table to work together and really force the health plans to come up with a

program that we can implement in the next year. Sen. Mills took that Texas bill and got it down to a two-page bill and if you're looking for gold card legislation in your state and if you're looking for model legislation I strongly encourage you to look at Sen. Mills' bill because I think it avoided the pitfalls that happened in Texas and some of the other places around the country. In a nutshell, the bill directs the health plans to come up with a program excluding pharmacy services and says you need to file that plan with the Department of Insurance (DOI) in a form that will be developed by the DOI and then after a certain date the program will be implemented. So it's very simple but it does force both parties to come to the table and ask what can we do that's best for the patient? And that's the number one goal for all parties involved.

Maria Bowen, VP of Government Affairs at the Louisiana State Medical Society, thanked the Committee for the opportunity to speak and stated that I think all of you have a similar society or a medical association in your state so you're probably familiar with who we are and what we do on behalf of physicians. A lot of times I tell people physicians are not good physician advocates. They are very good patient advocates but they do not do a very good job of advocating on behalf of themselves or on behalf of the practice of medicine. That is because they are very frequently in clinic and in hospitals with 24/7 jobs. It's hard for them to rearrange their schedules. So, I'm going to try to do them justice, but I invite you if you are a physician to feel free to chime in. So I think many of you have likely seen a lot of these graphs and charts that are provided by the American Medical Association (AMA). What I would like to reiterate to you is that from a physician perspective it's the patients who are receiving or attempting to receive the medical benefit but they're also the ones who were the victims of delayed care and if you look at every one of these graphs that I've provided for you they clearly show that from a physician outlook patient care is delayed - 93% of those would report some delay. And you can see by the graphs that they are significant in certain circumstances - 34% of physicians reported that delayed care has serious adverse effects on medical care.

So, the impact on the physician office and their practice is equally challenging. If you look at what we're talking about on this slide, two days in a physician's life is spent on prior authorization. Some of the facts that are available or available at the top of the slide are from the Physicians Foundation and that's a great survey that just came out this past week that you may want to look at and I can send all of this to NCOIL staff if anybody would like to receive them. Keep in mind that physicians do work seven days a week. Patients do need medical care seven days a week. Getting prior authorization does not always happen seven days a week. Again, this is a challenge in the physician community that we look to overcome. So back in 2018 a group of national organizations convened and developed a consensus statement to improve prior authorization. Those are the groups that were involved and these are the five reform categories that were addressed. Yet here we are in 2021 and while we've made the consensus statement and seemingly agreed to a number of different things most of my physician providers would tell you that it's not much better. Regarding the Louisiana legislation, just to give you an idea of why Sen. Mills helped us with this, this is from a physician in his district. The physician was requesting a prior approval to insert a spinal cord stimulator into a patient with spinal cord damage. The request was for imaging of the lower back so that the physician could appropriately place the wire to stimulate the spinal cord. The request for imaging was denied. This is the denial - "your records show that your doctor needs imaging to assess your spinal cord. Your entire spinal cord should be visible on neck and upper back studies. Lumbar spine or your lower back pictures would only be needed if your doctor knows or suspects that your spinal cord extends into your lumbar spine."

Even me with a non-medical background can tell you that's a bit ridiculous but this is what they get every day. These are the types of reports that I hear from physicians. It's ludicrous at best

and when they go to overcome some of these denials keep in mind that they are inserting themselves into a contract that they are not a party to. The contract that is being discussed is between the patient and the health insurer. So they're already in a predicament but they will also tell you that it's very easy for someone to deny them where it may be more difficult for someone to look in the face of the patient and say no. And yet on the other side of it, does a patient always understand what is needed or why they are asking for those services? So there are a lot of challenges when we start talking in medical terminology. As Mr. Drozda said, this is what we started with the original bill and some of the outlines are there. The amended bill is really I think kind of clever. It gives the opportunity for the health insurers to be very creative in what they come forward with to help us try to alleviate some of the challenges that we face with prior authorization. We are looking forward to seeing what those look like. And I will say just in conclusion everybody asks me what we're going to do next? I don't know. I work for a board of directors. I have a council that I have to answer to and we have to vote on those things. So, right now we are watching the Texas rulemaking, we're watching what's happening both with Federal legislation and rulemaking. We're waiting to see what happens in July 2023 with plans that are filed with the DOI. And our follow-up discussion on any legislation next year will not occur until January. So, those are kind of our talking points and I've given you the link to the AMA website fixpriorauth.org. It is a great resource if you've not looked at it. It has the opportunity for patients, physicians, consumers and employers to provide stories on prior authorization if they have those to share. And I would just encourage you as legislators to please reach out to your physician community. Obviously, Sen. Mills did discuss what was happening in his community with a number of physicians. Reach out to them and talk to your employers. There are also statistics that show a great deal of employer impact when an employee is awaiting healthcare services and a lot of that is related to denials for prior authorization.

Miranda Motter, Senior VP of State Affairs & Policy at America's health Insurance Plans (AHIP) thanked the Committee for the opportunity to speak and stated that I was here back in November of last year where I did have the opportunity to sit alongside the Texas Hospital Association and the Texas Medical Association to talk about the Texas bill at that time and to talk about the concerns in the challenges that we saw with that law and I also spent a lot of time talking about options and talking about alternatives to things like a one-size-fits-all sort of blank check for providers. But we spent time talking about electronic prior authorization and how that really can be significant for providers to do just what Ms. Bowen stated earlier in terms of reducing administrative burden for them. Our recent statistics even tell us that doctors today continue to manually submit at a 60% rate prior authorization submission and even in the pharmacy space which is largely electronic they're still doing so at around 38%. So when you think about electronic submission those are the types of things that can really give providers faster time to decision, faster time for patient care, and it can significantly reduce administrative burden and it actually provides them a lot more information we found through that survey in those results that I shared back in November of 2021.

In March of this year I had another opportunity to present before NCOIL to talk about again another kind of opportunity that really sits in front of providers as they think about trying to reduce administrative burden. And the time I spent here was focused on how providers can do so by taking on a financial risk for the medical decisions that they make for coverage issues by entering into value-based relationships. And we heard the prior panel talk about that certainly in the context of drugs and gene therapy but that is a significant way that providers can look to either waive or reduce significantly prior authorization. So here today I have the privilege and opportunity to share really briefly some survey results from a gold carding program survey that we asked our plans to share. And we did so really in further of this consensus statement that

Ms. Bowen mentioned earlier that health plans entered into with hospitals, with physicians, and with pharmacists back in 2018. And as you can see in one of the documents I shared it really lists with quite a description the work that health plans have been doing in furtherance of that consensus document by further targeting the types of services that are subjected to prior authorization and by providing the availability of automation for providers and their offices to take advantage of electronic platforms so that they don't have to 60% of the time submit these prior authorizations manually. Regular reviews of our prior authorization, both the systems and the services that we require prior authorization, are important as is using input directly from providers to make sure that those are still consistent with evidence based clinical guidelines that will ensure quality care and then will protect patients. And then lastly, continuing to wave in certain instances those prior authorizations when needed.

So, I wanted to just make sure that the results that I share with you today is in furtherance of that 2018 commitment. We've been really striving to work with providers on the ground to get this work done so that we can again continue to improve the process and improve potentially the administrative burden that we know providers feel but do so in a way that doesn't jeopardize or risk quality of care for patient safety and at the same time make sure that we also are not jeopardizing affordability. I would also just reiterate before I move on the issue that Mr. Drozda did raise. Purchasers of healthcare whether it's employers fully insured, whether it's the self-insured employers, whether it's the federal government through Medicare and certainly through Medicaid, all of the purchasers are looking to and demanding ways to ensure affordability of care and to reduce fraud, waste, and abuse and to ultimately make sure that patient safety and quality of care is preserved and all of these purchasers are using prior authorization and demanding that. So let me get into the survey results. There are six highlights. Gold carding programs have increased since 2020. Gold carding programs are most effective when they are used selectively, so not one-size-fits-all. And they should be continually evaluated so there is regular review of the provider, regular review of the decision that they made and making sure that they are connected to and align with evidence based quality standards. As I said earlier gold carding programs today are being used more frequently. In 2019 around 32% of plans were using those and today around 58% of plans are using those. Another finding in the survey is that gold carding programs work better for some services than they do for others – 73% of plans reported that gold carding programs work better where there is a clear and a consistent clinical standard for that service. So for example things like high-tech imaging, cardio services, elective inpatient medical services, orthopedic services. Those are all places where there are clear and consistent clinical standards where gold carding programs can be effective. Another finding in the survey is that gold carding programs include those providers where there is a sufficient prior authorization volume so in other words you can actually look and test a measure and that they also have a low denial rate and a high approval rate that's really important.

Asw. Hunter stated that due to time constraints, the Committee's meeting must conclude and before that Sen. Mills is going to make some comments. Asw. Hunter thanked Ms. Motter for her remarks and noted that the documents she referenced can be found on the website and on the app. Sen. Mills thanked Asw. Hunter and thanked everyone for speaking today and stated that it's a work in process in Louisiana but for the other legislators in the room I was surprised at how much pent-up frustration there was with the medical doctors and the physicians and the providers when we did speak with them. And as hard as they work they're not necessarily that good at getting it out in the public and letting you know what their problems are. So Ms. Bowen has a full-time job trying to represent them and get that voice out. They're generally under-represented and we need ten Ms. Bowen's out there to probably properly represent them because Mr. Drozda and others are so good at what they do. But we started five miles apart and we got maybe a mile apart towards the end. We're making some progress and I do appreciate

the work on this. It's important for prior authorization. We don't have a good handle on it yet but we're making progress and we've got to keep working.

ADJOURNMENT

Hearing no further business, upon a motion made by Sen. Hackett and seconded by Sen. Klein, the Committee adjourned at 11:30 a.m.