NEW YORK STATE DEPARTMENT OF HEALTH
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
FULL COUNCIL MEETING
FEBRUARY 19, 2026, 10:15 AM
ESP, CONCOURSE LEVEL, MEETING ROOM 6 ALBANY
TRANSCRIPT

Mr. Kraut: Thank you. Dr. Yang. Thank you. Members of the committee, Jeff Kraut and I have the privilege to call to order the February 19 meeting of the Public Health and Health Planning Council. I want to welcome our members, our staff participants, and observers.

Dr. Yang already spoke about the importance of filing the Record of Appearance form, which we require everyone attending the meeting to fill out. You can do that online or fill out one of the pieces of paper on the table outside.

She also provided you the guidance on the fact that we're webcasting some rules and suggestions to make this meeting successful. So I won't repeat those. I just want to remind members, staff, and particularly the public, the best thing to do is to join the department Certificate of Need LISTSERV, the PHHPC Unit that regularly sends out important council information and notices such as our agenda, our meeting dates, and our policy matters. And there are printed instructions on the table how to join the LISTSERV, or you may contact Colleen Leonard for assistance in joining.

Today, we're going to have our annual meeting. I just want to make a note of this. It's going to be held at May 7, the next meeting of the full council.

Today we're going to hear reports from Dr. McDonald who provide us a report on the Department of Health activities followed by Dr. Whalen on a report of the Office of Public Health. Then Dr. Torres will provide us a report from the Public Health Committee, followed by Dr. Rugge and Ann Monroe will give us an update on the activities of the Health Planning Committee. Dr. Yang will present a regulations for the Council's review in action, and that'll be followed by Dr. Kalkut who will give the project review recommendations and establishment actions that were reviewed at the previous establishment and Project Review Committee.

We're also going to do something that we've not done before. We are going to consider Elixir, a licensed home care agency that we had previously approved. We're going to consider revoking the certificate of that entity.

And before we begin, I just want to remind councils members who attend our meetings that we've organized the agenda, particularly the Establishment and Review Committee agenda by topics or categories, which captures the roles and responsibilities of the council. And we are batching Certificate of Need applications. And I'll ask the members to please take a moment to review those applications that are being batched. And if thought about, if you'd like one project to be moved out of a batch to be considered in a different category or to be considered separately. When you do so, just please let us know. Let Colleen know, and then we'll inform Dr. Kalkut as well.

My first action is I'm asking for a motion to adopt the December 4, 2025 PHHPC meetings.

Dr. Berliner: So moved.

Mr. Kraut: I have a motion by Dr. Berliner, a second by Mr. Thomas. All those in favor? Aye.

Council: Aye.

Mr. Kraut: Opposed? Motion carries.

Dr. McDonald is on his way down and I'm going to suggest maybe Dr. Whalen. Well, I was going to thought it was Dr. McDonald. Maybe. Dr. Whalen if you'd like to start giving the report of the activities of public health. Thank you so much.

Dr. Whalen: Good morning and thank you. Happy to address everyone this morning, and I'm going to be reporting out for the Office of Public Health. I'll start with the Center for Community Health. I'm sure many of you are aware that the United States childhood immunization schedule recommendation was on January 5th. Health and Human Services new immunization guidance came out that changed the United States childhood immunization schedule.

The federal government did not remove any vaccines from schedule. However, some vaccines that had previously been recommended for all children are now reclassified as risk-based or shared clinical decision-making. Primary changes include COVID,

rotavirus, and influenza immunizations would be based on shared clinical decision-making, which is the decision to vaccinate made by each patient individually based on a discussion between provider and patient. Hepatitis A, B, RSV, and meningococcal immunizations are recommended for certain high-risk groups. And human papillomavirus recommendations has been changed to a one-dose only administered at age 11 to 12 years.

There has been a response from the New York State Department, from the department, as well as the New York City Department of Health to remain consistent with guidance that has been issued by the American Academy of Pediatrics. We continue to urge New York State providers to continue the prior immunization practices, which are relying on evidence-based resources.

At this point, we know the ACIP has been scheduled to meet February 25 or 27, but there is ongoing litigation. We received word yesterday that American Academy of Pediatrics v. Kennedy put forth strong arguments in federal district court in support of our preliminary injunction to block Secretary Kennedy's January 5 changes and to prevent ACIP from proceeding for its February 25 to 27 meeting. So we will remain apprised of things as they occur and continue to recommend evidence-based resources and practice on immunization for children across the state of New York.

And I see Dr. McDonald has joined us.

Mr. Kraut: If you want to finish, Dr. Whalen.

Dr. Whalen: Sure. So continuing with Center for Community Health, I wanted to mention the Dietary guidance for America. The Department of Health and Human Services and United States Department of Agriculture released the dietary guidelines for America on January 7, 2026. This represents a notable shift in federal nutrition messaging and has generated a lot of media attention.

Key changes in this guidance include a stronger emphasis on real or minimally processed foods with explicit discouragement of ultra-processed foods and refined carbohydrates. Strong framing on added sugars with no safe amount of sugars. More prominent protein forward messaging inclusive of both animals and plant sources. Shift in fat and dairy framing to emphasize importance of whole milk.

Change in guidance of alcohol. So previously, there was a definition of moderate intake as to one drink per day for women and

two drinks for men. The updated guidance now talks about less or limiting alcohol consumption without providing quantitative definition or sex specific thresholds. They do not make reference to the health consequence of higher alcohol consumption consistent with what we know and has been reported out previously by the Surgeon General's advisory on alcohol and cancer risk.

And they do recommend breastfeeding baby for the first six months exclusively. And if breast milk is not available, feeding baby iron-fortified infant formula. And recommending continued breastfeeding as long as mutually desired by mother and child for two years and beyond.

So in brief, these guidelines have some positive, and some not evidence-based and some negative. We feel that the emphasis on real unprocessed foods, fruits and vegetables is important. There is really not a lot of evidence based on the recommendations around increasing protein. There are some concerns around emphasis of red meat and dairy. They did maintain the importance of less than 10% of diet and saturated fat, but the guidance seems a little bit contradictory of this when red meat and dairy are so prominent in the food pyramid.

So next update is on fact sheet of New York State mental health pregnancy associated deaths. The Division of Family Health recently published a fact sheet on mental health and pregnancy associated deaths on the maternal mortality website. This is part of the Maternal Mortality Review Initiative, which launched in 2010 to provide a comprehensive review of maternal deaths in New York State. We know we continue to experience significant disparity around maternal morbidity and mortality and are really working at addressing that across multiple sectors.

We know that mental health conditions from 2018 to '21 were a leading cause of both pregnancy associated and pregnancy related deaths. And there is a tremendous amount of work that is being done at the department and in collaboration with partners, including the Office of Mental Health in New York City that is being done and continues to be done across the state to influence these rates.

From the division of public health infrastructure, we have begun receiving community health assessments and community health improvement plans and community service plans from the hospitals and local health departments for the 2025 to 2030 state health improvement plan. We are currently reviewing and analyzing the submitted materials, and this will help identify key priorities and

services, which will support the overall prevention agenda strategies, and help identify further collaboration and activities.

We are looking through the public health infrastructure grant at providing some funding to community-based organizations via a competitive grant to engage in activities of the prevention agenda. As you know, the prevention agenda is something that occurs across the state through our local health departments, hospital partners, community-based organizations. We really want to ensure that all partners are coming together and able to support this work so that we can make meaningful change in these objectives and particularly addressing the social determinants of health across the state.

From the Office of Science and Technology, I'm happy to say that the release of the new 2025 to 2030 prevention agenda dashboard has been updated to the website. This has got most complete and recent data and indicators for the 2025-2030 plan. And it's an interactive visual presentation of this data so that we can track progress of the state health improvement plan across the state and at county and sub-county levels. It is a key source for monitoring progress that communities across the state will make regarding meeting the prevention agenda objectives.

Also, the Office of Science has launched and developed a science hub website. This website will provide information about the Office of Science and their mission, and it will contain links to the dashboards and other reports, and it houses recent scientific reports. So we feel this is incredibly important given the preponderance of misinformation that we are seeing in media to have an evidence-based resource for the public. It also takes time to really explain some public health science and epidemiologic concepts, which is so important in reviewing information from a public health perspective.

And that is report out for Office of Public Health at this time.

Mr. Kraut: Thank you Dr. Whalen. Are there any questions for Dr. Whalen?

I have one. I'm not sure if you mentioned it or I read it. Did we join WHO for the alerts? I'm not sure if you ... Oh, you're going to talk about? Okay, fine. I'm going to steal that thunder.

Dr. Berliner: Who calls it WHO?

Mr. Kraut: Yeah, what?

Dr. Berliner: Important?

Mr. Kraut: Who?

Dr. Berliner: Who calls it WHO?

Mr. Kraut: Who? All right. Dr. Seuss. Sorry, Dr. Berliner, I'll be back to you in a minute. All right, thank you very much. Dr. Whalen. Thank you. And did they start construction on the lab?

Dr. Whalen: Yes.

Mr. Kraut: Okay. Great.

Dr. Whalen: Yes.

Mr. Kraut: All right. I'm going to leave him alone. That's it. I'm not asking any more questions. It is my pleasure now to hear from Dr. McDonald who's going to update the council about the department's activities since our last meeting.

Dr. McDonald: Thank you.

Thank you, Jeff. And it's good to see everybody again. I'll just open with this, I suppose every day is historic, but every day is not memorable. Let me just take you back though, to Tuesday, February 19, 1901. It was on Tuesday, February 19, 1901 that then-Governor Benjamin Odell signed legislation that created the New York State Department of Health.

So today we are celebrating our 125th birthday. We look pretty good for 125 to say that, and you're a big part of that as well. But I'd like to take you, if you don't mind, just a little bit of what it was like to live in New York State in 1901. Keep in mind, in New York state then there was 7.4 million people. But think about things that were common then that aren't common now, right? Like indoor plumbing wasn't common at all. Either were telephones, let alone in your house, let alone in your pocket. Just, phones weren't really a thing. Automobiles weren't a thing either.

But I think you could imagine that with sanitation being a big concern, public health was a very different experience back then. And you may find it surprising that my predecessors as commissioners, I'm the 18th commissioner, which I think is stunning. We've only had 18 commissioners in 125 years. So there's some longevity to the position, which makes me optimistic.

But the first several commissioners really, if you think about what were the priorities of the first three decades of the New York State Department health? It was combating diphtheria, polio, and tuberculosis. Those really were what people were focusing on. And it may surprise that in 1901, the New York State Department of Health was the largest producer of diptheria antitoxin which is impressive, right? And I think that's really quite a big deal.

And it's interesting, other little tidbit of knowledge. In 1912, the department produced rabies vaccine. Other little things that might surprise you about the department is really just in 1955, there was a big initiative from the New York State Department of Health to distribute over half a million polio vaccines. The Salk vaccine. And I just want to put that in the room for just a minute. Could you imagine what it was like to live in New York State in 1955 and why was it different for New Yorkers than anyone else? Because New Yorkers had known a governor who was paralyzed by polio. They probably knew people with polio. I just can't imagine what it was like to wait with anticipation to get the polio vaccine.

And it may surprise you too, that in 1948, the New York State Department health operated seven TB hospitals. We operate none today because TB is controlled. And another little thing about 1901 that is interesting is the hospital that we call Helen Hayes Hospital was actually started in 1901, but it was called the Reconstruction Hospital for Children. And the main patient of the Reconstruction Hospital for Children was children with complications of polio.

I'm giving you a lot of that background to say that public health accomplishes an awful lot. And it is rightfully taken for granted. People don't go into public health for fame or fortune. They find neither. But quite frankly, people have busy lives and a lot to do and they don't have to worry about what is their health department doing to keep them healthy. They just get to enjoy the comfort of knowing the health department is keeping them healthy.

If you're looking for a tangible example of how does the health department help you? If you took a breath of air today, had a sip of water, maybe went to a restaurant, had a healthcare experience or any number of things. You're welcome. We were there. That's what we do, right?

And I give you that background to talk about. Now we have Governor Hochul and there's 20 million people. I don't know what the budget was in 1901 for the New York State Department of Health, but our budget right now is $111.9 billion as proposed to the

legislature. $99.9 billion is Medicaid. $3.8 billion is the essential plan. If that number sounds low to you, it's because it's a little over $10 billion less than the last because of the consequences of HR1. It gives me a little over $8 billion to do the public health mission of the New York State Department of Health.

Now, just to give you some context about where we're going in 2026, I just want to put the word nutrition in the room. New York State's going to be spending over $1 billion in providing food to New Yorkers. Now $623 million of that is through WIC. Around $380 million is through the Child and Adult Care Food Program. I have $72.5 million for the Hunger Prevention Nutrition Assistance Program. $55 million for Nourish New York. So there's a real strong commitment to nutrition, which I think is really important as a public health and social determinant of health care.

When you look at some of the impact from HR1, I think it's the insurance impacts that most concern us. We still have not heard back from Center for Medicare Services about whether or not our 1332 Waiver will be able to be wrote back to 1331. We expect that to be the case. But when the state financial plan was constructed this year, it was done with a worst case scenario in mind. I think you would agree, with the federal government being as unpredictable as it is, this was the wise approach. We're preparing for the work requirements for Medicaid. We need the official guidance to come out, which we're told will come by June 30 in 2026. We have to implement this guidance as of December 31, 2026.

There are exemptions to who's going to be required to work. And the dollar amount of people have to earn because minimum wage is still $7.25 an hour federally. Thankfully, that's not what the minimum wage is in New York State. You only have to come up with around $600 a month of income.

But there's several exemptions. One is education, at least part-time. Community service. And there's other exemptions as well like being medically frail, American Indian, being inmate, a parent guardian of a caretaker of disabled individual or a child less than 13. Any individual under 18, any individual or 65, any veteran with total disability. Individuals enrolled in the supplemental at nutritional assistance program and temporary as needed families. Anyone who's entitled or receiving Medicare or people who are pregnant. And anyone who's participating in drug and alcohol treat. But there's still a lot of work the department's doing to get ready for this change that's occurring.

But just don't make no mistake about it, what the federal government is trying to do is get less people on Medicaid. That means less people have health insurance. That means there's going to be uncompensated healthcare in New York state and something that we have to address.

Other initiatives in this year's budget is a cardiac emergency readiness. With that is really teaching as many people as possible how to do CPR and putting automatic external defibrillators in a lot of places throughout New York State. What we're hoping to do is actually help improve the recovery time and getting more people to actually survive a cardiac event. So I think that's a nice positive event.

There's a nice investment in artificial intelligence. All of us use artificial intelligence every day, whether you know it or not. We have people at the New York State Department of Health who understand artificial intelligence to the extent that anyone can understand it. But we're hiring more people, but really more so getting an idea of what's going on in healthcare. The strategy here is not to regulate artificial intelligence, but just to really get an understanding of what is going on and how will impact healthcare for the future. And so I think that's exciting.

The Rural Health Transformation Program, keep in mind this is not a grant. It's a cooperative agreement. We have our budget of $212 million that was recently approved by Center for Medicare Services. One of the things that Governor Hochul put in the budget that we need is procurement flexibility. Just to make sure that's really clear, why do I need procurement flexibility? If you file a state financing law and it takes at least 13 to 18 months to do a contract, that's wonderful. The problem I'm running into is I have to have all the money allocated by October 30, 2026. So in other words, I don't have enough time.

Why that's really critically important with this program is if you do not have the money allocated by October 30, 2026, then you do not get other money for the next year. So in other words, it's possible we will spend very little of this money unless we get the procurement flexibility. I made that really clear at the legislature when I had my budget hearing nine days ago. So hopefully, the legislature will work with us in that regard.

Something we've implemented since the last time we got together was the Lead Rental Registry. I'm very excited about this. This was in the 2324 budget. It took two years to create this really

complicated program, but I'm really thankful to the team for doing that. Hard work of doing that. They did a great job with this. But really what it means is the top 25 counties in New York state where lead poisoning in people's homes is a challenge. In order for someone to rent that property to someone who has a child, the property has to be certified to be lead-free. I think we'd all agree that's a much better approach than just waiting for the child to pop positive with a lead level over five.

Now, we've made progress in New York state, right? If you go back to 2010, over 17,000 children had a blood lead level over five. If you look at last year's data, it's 5,000. So that's less. But we're looking for zero, right? In other words, there's every reason to believe we can accomplish this. So I think that's a nice proposal that we have implemented this year, and I'm very glad to see that with workforce.

We do a lot with workforce. We actually have 24 programs that we oversee at the New York State Department of Health to increase the healthcare workforce. This year we have $415 million committed to that. Some of those are previous initiatives that ... It's interesting. When you talk about initiative, I think what people forget is we have to contract to get people lined up and actually get the work done.

But this year we have 24 different programs. So we might be training someone in high school, we might be introducing healthcare to people in high school. We might be helping people become certified nursing assistants. People work in home care. Helping doctors pay back loans, helping nurses repay loans. Helping people in rural health come into fruition and rural health come into healthcare. So there's a lot going on with the workforce world.

And then just about Wadsworth, another little thing about Wadsworth. Wadsworth was started in 1901 as well. Curious little tidbit about Wadsworth. We started on Yates Street in Albany. Interesting enough though, because we had livestock there, referencing making diphtheria antitoxin. Apparently over the years, we became a nuisance to the neighbors. And that's why we moved out to Guilderland, where we have the Griffin Laboratory to this day.

Now, in case you're curious where Griffin is, it's on State Farm Road and it's named that because of us, the state. We went out there and it was a farm, not named after the insurance company. So I just think that's a nice little circular trivia there.

But it's just interesting to know that Wadsworth is on time for its building being built by 2030, and it's currently under budget. They broke ground about five months ago. There's been a lot going on to get the ground ready. Steel is going in the ground next month, which I'm excited to see. It will start to look like a building. If you get interested and you want to drive by the Harriman campus, you can clearly see where our building is being constructed-

PART 1 OF 4 ENDS [00:35:04]

Dr. McDonald: You can clearly see where our building is being constructed. It's quite a thing to see here. It's a $1.7 billion project and happy about where it's headed here. And then just to end on a note, public health is about a lot of things, but it's really built on partnership and driven by partnership. So why did we join the Global Outbreak Alert and Response Network of the World Health Organization? Well, we already had some type of relationship because APHL, Association of Public Health Laboratories, was one of the already 360 organizations part of that. But we at the New York State Department of Health decided to codify our relationship and formally apply and become a member because it's a mutually beneficial relationship. What we get out of it is I get to know about all the epidemics and problems that are going around the world. What they get out of it is they get access to the expertise of the New York State Department of Health Reference Wadsworth again. There's things that Wadsworth does that quite frankly no one else does.

In case you're curious as an example of what is something Wadsworth does that really other people don't do, some of you followed the botulism outbreak from By Heart infant formula, but it was the Wadsworth lab that was the lab that actually identified the botulism and actually the strain. We didn't have any cases in New York, but this example of Wadsworth does things for the rest of the country and Wadsworth was able to identify that. Why that's important is the methodology we use to identify botulism in Wadsworth isn't done at CDC. They use an arcane model where it takes several weeks to get the results and a mouse dies in the process. We do it through PCR, quite frankly, and other laboratory strategies. So Wadsworth really is the cutting edge of public health science. So with that note, if you see some of the Department of Health, you want to wish them a happy department birthday, feel free to do that, and let me stop and answer questions.

Mr. Kraut: Thank you. That was a great report. I love the history lesson and if anybody is interested, a little footnote, the Public Health Council

was established on October 6th, 1913 when the Department of Health reorganized and the first chair of the public health council was the commissioner, not this commissioner.

Dr. McDonald: No, it wasn't. Would that have been Dr. Biggs. I wonder if it would've been-

Mr. Kraut: I think it might've been Biggs because Biggs was the big public health in standardized what... Anyway. Let's not devolve into a history lesson. Although the history of New York State Department of Health is really the history of public health in the United States, it's a proud history and Wadsworth, as we... I don't know if I'll be on the council, but by the time when the building opens, we definitely should have a meeting at the laboratory when it opens. You have to see that, even the disrepair of the current lab, but it's a pretty impressive place to visit. Anyway. Any questions for the commissioner? Excuse me. Mr. LaRue.

Mr. LaRue: Good morning, Scott LaRue, member of the council. I just want to take the opportunity to thank you and the governor for putting the additional funding, the proposed funding in the budget for hospitals and nursing homes. And my role on this council was frequently focused on the needs of long-term care and we've discussed at great length here the many challenges facing that sector of service to New Yorkers, and I am really hoping that the nursing homes get their fair share of the funding that is allocated to help solve some of those challenges that we've talked about here at great length. But we appreciate the recognition and having it included in the governor's proposal.

Dr. McDonald: Thank you.

Mr. Kraut: That same statement could be made by the federally qualified health centers. Everybody is hoping. There's a lot of money in that.

Dr. McDonald: Really when you look at it, the nursing homes get restoration of the 10% cap cut, but they also get money from the healthcare stability fund, which is the MCO tax revenue, plus there's also other funds too and hospitals make out too. There's a lot of investing going on this year.

Mr. Kraut: And by the way, if you want to see more detail on what the commissioner said, you should see his presentation before the...

Dr. McDonald: Yes, watch all four hours of it.

Mr. Kraut: Four hours of it, yes. Dr. Soffel.

Dr. Soffel: Denise Soffel, member of the council. Good morning, commissioner. I want to sort of poke in a little bit at the immunization things because obviously I share concerns that the federal changes could have early damaging impacts on New York State. Do we have any new information on immunization trends since as COVID has now passed its direct impact on immunization rates? So that's my first question. And then secondly, how are we on measles?

Dr. McDonald: So if you look at vaccine trends in New York State, here's a couple footnotes. COVID vaccines are just down across New York State, but across the whole country too. In other words, we're 25% down this year than last year and last year was down astonishingly low. So we just aren't seeing the national appetite for COVID vaccine. I like it and I got it and my family did, but that's just not where we are. The flu vaccine is up this year. We had a really historic flu season, but we saw increases in flu vaccine this year. It was about a 3% increase. I'll take it. When you look at childhood vaccine rates, if you look at the under two population, we saw a real decline during the pandemic, but now it's picking up again. So we're actually seeing increases again in kids. So I'm optimistic about where we are with kid vaccines and heading in the right direction.

As far as measles go right now, we don't have a whole lot of measles in New York State right now. When we have less than five cases, I usually just say we have less than five cases, but we have much less than five cases. You can take that number for what it's worth. So why is measles something I care about has a lot to do with... If you look at the Pan American Health Organization, they're the ones who decide if your measles is considered eliminated or not eliminated. The metric they use is has there been community transmission for 12 consecutive months or not. Starting in January of '25, that's when the Texas outbreak occurred, there's been measles through committee transmission since then. So I don't speak for the Pan American Health Organization, I don't know what they're going to decide when they meet in April, but I think it's reasonable to believe that since it's been 15 months now of continuous measles transmission in the United States, both notably now in South Carolina...

I was talking to South Carolina state health officer the other night, they're seeing it start to abate a little bit, but it's been a problem in the country. In New York State, we've had problems with this in the past, but things have changed since we had problems in the past.

The laws in New York State don't allow for religious exemption. That's a critical difference. If you look at the states where measles has been out of control, they allow religious exemption, which really is an exemption. It's no longer mandatory at that point for school entry, and that to me is a really critical public health tool. So this is where the New York State Legislature got together with the governor and really did something very, very wise to protect us all. So right now we don't have any big measles threat.

Another little thing about measles, just so you know, is we're one of the few states that actually tracks measles in wastewater, and I mean, just measles vaccine, it's different. We did have a measles positive for wastewater in New York sometime last year. We were able to talk about it and it went away and that was that. But it's something we have a lot of tools to monitor for measles in New York right now, there isn't any measles in the wastewater in New York State, so there you go.

Mr. Kraut: Any other... Dr. Berliner? Yeah, could you just...

Dr. McDonald: We did. The Global Outbreak Alert and Response System I did talk about the end, so I think we're... Just to make sure it's clear, no state can join the World Health Organization. You need to be a sovereign nation to do that. So no state has joined the World Health Organization. California, Illinois, New York State, New York City have joined the Global Outbreak Alert and Response Network. That's what we have joined. They are part of the World Health Organization. So our application went to Geneva, we are approved by Geneva. When Geneva knew we were interested, they say we'd love to have you. I mean, it's been a nice relationship so far. I have several people at the Department of Health who are involved in this relationship. It's not a heavy lift in our point, it's meetings during the week, not many, but some. But we get to learn about outbreaks all over the world and that's useful to me.

And part of why it's useful to me is New York State is the gateway to the United States. Everyone's welcome in New York State. I think you know that. We have a 305 foot, one inch welcome sign on Liberty Island that says everyone's welcome, the one that says, "Give me your tired, your hungry, those who yearn to breathe free." So everyone's welcome to New York, but we have a lot of visitors to New York, so it's really in our best interest to be ready for this.

Mr. Kraut: Okay, thank you. I just want to thank you, Commissioner. One thing, maybe when we return back in May, I know a couple of members had asked to get kind of an update on the 1115 waiver

and the performance of the social care networks. So I think we've just put that on a list to hear about.

Dr. McDonald: That's great. Well, I'd be happy to do that. We'll talk about social care networks, career pathways training and everything because we have till March 31st, 2027.

Mr. Kraut: Right. Well, thank you for joining us. We appreciate it very much and good luck with the budget. We're now going to hear from Dr. Torres who will provide us an update on the activities of the public health committee and the ad Hoc committee to lead the state health improvement plan. Dr. Torres.

Dr. Torres: Good morning, everyone. Is it on now? Good morning, everyone, and happy birthday. You all look great for 125. I'm Dr. Torres. I am the vice chair of the public health committee. Our committee is chaired by Dr. Buford. She sends her regrets and as she's unable to be here today. We had a meeting public health committee and the committee discussed the reorganization of the division of public health infrastructure and office of local services and the support these programs provide to the prevention agenda. The key findings and the publication of the state health department or assessment key document, which informs the state health improvement plan, that the community planning by local health departments and hospitals. Sorry. The status of the local community plans of local health departments and hospitals with other local partners for the community health department strategies.

The transition of the prevention agenda from planning to implementation and how to collaborate with statewide organizations and state agencies to support foundational improvements in social determinants of health and provide assistance to local efforts and community implementation. We discuss the community benefit reporting by hospitals, which will occur this July with Bella Elogoodin Director of Patient Advocacy in the office of Primary Care and Health Systems Management. This focus on input from the committee and what information from the reporting effort may be helpful in supporting and improving overall community health improvement efforts across the state. Dr. Buford wanted to make sure that you all knew that there was a schedule of meetings coming up and I want to thank Dr. Whelan and her team for their assistance and input yesterday. Thank you.

Mr. Kraut: Thank you, Dr. Torres. Any questions for Dr. Torres about the committee's activities? Thank you. And it's kind of double duty doing both, and I know as we heard Dr. Whelan said the community

service plans are coming in so they may have some additional information and data that'll be useful to the committees once they get a chance to analyze it.

Dr. Torres: There was a lot of discussion with the community benefit plan and the staff and the department were really helpful in taking the recommendations and reflecting on what's important to document and for the community to understand the input and the impact that the hospitals have in the community level.

Mr. Kraut: Okay, thanks so much, Dr. Torres. I'm now going to turn to Dr. Rugge and Ms. Monroe who's going to give us an update on the activities of the health planning committee.

Dr. Rugge: Thank you. Can I be heard? This working?

Mr. Kraut: Yes.

Dr. Rugge: As it happens, last March with support and guidance from the leadership of the health department, thank you, Dr. Heslin, we began to work on PCI, percutaneous coronary interventions in ambulatory settings, ambulatory care centers. Now 11 months later, we're happy to have the council review our report, five pages, but in that five pages were lots of preparation, lots of consideration starting with reviewing the literature and reports. Already some 30 states have authorized ambulatory procedures or ambulatory performance of PCIs, and the data indicates the quality and the safety and the ambulatory settings is absolutely equivalent to those inpatient settings sometimes may be a little bit improved and also the cost is lower by about 40%, needing only $4,000 to compensate for the ambulatory procedures. We next met with a whole series of experts, including some state level people, Northwell comes to mind, and members of the health department who bring a lot of experience and understanding. I also included a hearing from the state of Illinois who is very detailed in monitoring their performance.

And finally, we concluded with a series of meetings and long discussions about what to do with all this information and material by way of encouraging or providing guidance for New York State to proceed in this direction, in this format. There was no pressure except we worked together to come to a shared understanding, and with that we did perfectly well. IT was only one little small place where we couldn't come to agreement and that is should the hospitals initially in phase one sponsoring these ambulatory settings be 100% in control or simply majority control. Not a huge difference when it comes to the scope of the activities that we are

planning for as a planning committee. Anne Monroe is partner with all this, may have some summary, do you, of our specific recommendations. There are seven for this next phase and also more general pieces of advice for how we proceed phase after phase after phase. Thank you.

Ms. Monroe: Okay. I don't know how to turn this on.

Mr. Kraut: Just pull it up towards you, yeah.

Ms. Monroe: There is it on? Oh, yeah. Hello, everybody. We are bringing this today for a vote and acceptance by the council. As John said, there's been a lot of work done by our committee and we've really hung in there to get the best questions asked and answered. It's true that several states have done this, that it's in their world proven to be very officious and effective, but New York is more cautious, so we're taking a phased approach in our recommendations, and we are talking in specifics most about phase one. And so we're recommending that it be a phased approach and phase one be focused primarily on measurement of quality, efficiency and safety. We're concerned that to move it past phase one without that fundamental data could put New Yorkers at risk. So we are requesting that the council accept our report and that this report has several specifics for folks who are going to go into this demonstration, that it needs to be limited to hospitals with significant ownership of the ASC, the Ambulatory Surgery Center.

That was the only place where the committee did not have full agreement and the agreement was split between that the hospital had to have 100% ownership or the hospital had to have majority ownership. So we leave that to the Cardiac Advisory Committee and the department to make that decision. We were just split on that. That in phase one, the participants need to be hospitals that have existing cardiac surgery programs, so we want to build in the best safety supports that we can for starting out in this work. We said that the phase one should be limited to non-profit ASCs and that those organizations would have to come forward for a CON from this council, a time-limited CON coming forward from us.

That any demonstration or phase one participant would have to include Medicaid and low-income commercial participants. We're trying to keep this out of the who can get this and we want it to be tested on the wide variety of people in New York. And that there needs to be a relevant consumer or patient education program so that participants understand why they may not be in the hospital for something they would've been in the hospital before or they also

understand what the procedure is all about. So that has to be a big part of this first step. For any phases of this program going forward, there is the Society for the Cardiovascular Angiography and Intervention and they have a set of ethical standards which we think must be incorporated into this effort.

Just a couple more things that you have to have appropriate staffing and credentialing for ASCs. This is a really significant step that's being taken and we want to make sure that all those boxes are checked. Now, lastly, the Cardiac Advisory Committee will monitor this with the department, but we don't want to just let this go. We spent a lot of time and effort on this and we want to have periodic reporting back to FIPPIC of how this project is going. We think we can learn a lot from this phased approach and see where we want to take it.

Lastly, if you move beyond phase one, we want to see these projects tested in various geographic and demographic parts of New York. So we don't want it to just be a New York City-based program. In future phases that needs to be spread across the state and we want to look at different types of sponsors. If you remember, we said hospitals with cardiac surgery are in this first round, but there may be ones that don't have cardiac surgery that are ambulatory surgery center sites now that could take this on, and we want to make sure that that gets looked at in future phases if we meet the safety efficiency and quality standards typical of New York. So lastly, on behalf of John and I, we want to thank the committee. We really hung in there and learned a lot through this process. We want to thank the department staff, Eugene Heslin and Abby Haribovichi who were our staff through this whole effort, and we're really proud as a committee to send this forward to the commission. So we're submitting it for your acceptance and approval.

Mr. Kraut: So let's just... Before we open it up for discussion, we have a motion to adopt the report of the health planning committee to the council regarding the placement of percutaneous coronary interventions in ambulatory surgery centers. The motion is made by Dr. Rugge and Anne Monroe. May I have a second, Dr. Berliner? We'll open it up for discussion and then we will take a vote. The vote is to recommend it to forward the recommendation of this council to the Department of Health.

Ms. Monroe: Well, first we're referring it to you.

Mr. Kraut: No, no, but that's what we're going to vote on now, that the council... I'm just making it clear. Our recommendation goes to the department. So is there any questions? It was a very excellent presentation and the process speaks for itself to some degree. Any questions? Any concerns? You all had an opportunity to read it. Okay, so hearing none, I'm going to call for a vote. All those in favor of approving this say aye.

Committee: Aye.

Mr. Kraut: Opposed? Abstentions? Oh, you did public hearing, right? The motion carries. Okay. And I also want to add my thanks to the two of you, everybody who participated from FIPPIC, the department, Dr. Heslin, the staff. Just this is an amazing process to move an issue forward and I hope we avail of ourselves of using the planning the health planning venue as the other venues of the other committees. This is kind of a gold standard on how to move an issue forward and looking forward to the next one, and congratulations to the two of you.

Ms. Monroe: We're ready.

Mr. Kraut: Okay.

Dr. Rugge: Jeff, talking about... Just a couple brief observations. One is I neglected to also thank members of the council who are not members of the committee that were not frequent but always there to participate and to help us. Thank you. And also, just can't help but remark how different we are from some other states. Texas was one of the first states to authorize this kind of ambulatory surgery and they did it without any oversight. No guidelines, no reports. Just did it. But we are being careful in our tradition and I think this will turn out to be an excellent product. Thank you.

Mr. Kraut: Okay, thank you. You want to say what? Okay, do you want to say something? Go ahead.

Dr. Heslin: Okay. Eugene Heslin, Department of Health. So the next steps, the department will be taking these recommendations for consideration back plus work that was done by the Cardiac Advisory Committee will be building draft regulations, which then the Codes Committee, Dr. Yang, will be getting to be able to start the regulatory process to establish the regulations, to be able to have this process move forward and that'll go through the normal regulatory process.

Mr. Kraut: And the public will have another opportunity, both the industry and the public to comment.

Dr. Heslin: Absolutely.

Mr. Kraut: Okay. Well, thank you again. Great. Really appreciate it. I'm now going to turn to Dr. Yang who will give us a report of the Codes Regulation and Legislation Committee.

Dr. Yang: Yes. Hi. Good morning again. This morning at the meeting of the Committee on Codes Regulations and Legislation, the department presented for information the repeal of part 19, addition of sub-part 58-62 Title 10 NYCRR. It pertains to certificates of qualification for clinical laboratory directors. We're forwarding it for information to the council. There are staff from the department here if there are questions.

Mr. Kraut: And then for adoption?

Dr. Yang: And we were presented for adoption and are moving it to the council, the proposed addition of Appendix 5E to subpart 5-1 of Title 10 NYCRR. This is regarding cybersecurity requirements of public water systems and the department is here for additional questions.

Mr. Kraut: I have a motion to adopt that regulation on the cybersecurity for water systems. I have a second, Dr. Berliner. I don't know if many of you might have been present for the discussion at the Codes Committee, but if there's any questions on this, this would be a time to ask. Okay, hearing none, I'll call for a vote. All those in favor, aye.

Committee: Aye.

Mr. Kraut: Opposed? The motion carries. Thank you very much.

Dr. Yang: Concludes our business.

Mr. Kraut: Thank you, Dr. Yang. I'm now going to turn to Dr. Kalkut. I'll turn the meeting over to give a report on the actions of establishment and project review.

Dr. Kalkut: Thank you. I'm Gary Kalkut and will present the certificate of need applications for approval. And as Jeff said, we are going to batch these projects. First 252112C, Roswell Park Center Institute in Erie County. This is to certify a new hospital extension clinic for multi-

specialty ambulatory surgery at 199 Park Club Lane, Williamsville and perform requisite renovations. The department and the committee vote for approval with conditions and contingencies. 252080C, Manhattan Endoscopy Center, LLC in New York County. This LLC is an existing single-specialty freestanding ambulatory surgery center, is seeking approval to convert from a single specialty FASC specializing in gastroenterology to a dual single-specialty FASC with the addition of vascular surgery. Both the department and committee recommend approval with condition and contingencies.

252091C, Surgical Pain Center of the Adirondacks, LLC in Clinton County. This is to convert an existing single specialty ambulatory surgery center to a multi-specialty ambulatory surgery center with addition of ear, nose and throat and podiatry services and perform renovations. The committee and the department recommend approval with conditions and contingencies. 251079C, Community Health Center of Richmond in Richmond County. This is to relocate the main site from 235 Port Richmond Avenue in Staten Island to a new building to be constructed at 21 Grove Avenue, Staten Island and to certified birthing services, outpatient and dental outpatient in an FQHC safety net. The department and the committee recommend approval with conditions and contingencies, and I so move.

Mr. Kraut: I have a motion. May I have a second, Dr. Berliner? Are there any questions on any one of these applications? Hearing none I'll call a vote. All those in favor, aye.

Committee: Aye.

Mr. Kraut: Opposed? Abstentions? The motion carries.

Dr. Kalkut: Dr. Eisenstein has left the room. He has a conflict and recused. 252145C, Good Samaritan Hospital Medical Center in Suffolk County. This is to certify St. Charles Hospital as a division of Good Samaritan Hospital Medical Center, rename the division Good Samaritan University Hospital St. Charles Campus and rename Good Samaritan Hospital Medical Center to Good Samaritan University Hospital. Upon completion of the merger, Good Samaritan University Hospital and St. Charles Hospital will operate as one hospital with two campuses. The department and the committee recommend approval with a condition, and I so move.

Mr. Kraut: I have a motion. May I have a second, Dr. Berliner? Are there any questions on this application? Hearing none. All those in favor, aye.

Committee: Aye.

Mr. Kraut: Opposed? Abstention? The motion carries. Have Dr. Eisenstein please return.

Dr. Kalkut: Application 252116C, Rochester General Hospital in Monroe County. Mr. Robinson is not at the meeting and had a conflict in recusal. This is to certify a new hospital extension clinic from multi-specialty ambulatory surgery, primary care and other medical specialties at 183 Paris Street in Rochester and to perform requisite renovation. Focus will be on orthopedic surgery, pain management and podiatric surgery. Office visits will be primarily for orthopedics and neurology. The department recommends approval with conditions and contingencies and the committee recommends approval with conditions and contingencies with one committee member opposed, and I so move.

Mr. Kraut: I have a motion. Can I have a second, Dr. Berliner? Are there any questions on this application? Hearing none. I'll call for a vote. All those in favor, aye.

Committee: Aye.

Mr. Kraut: Opposed? Abstentions? The motion carries.

Dr. Kalkut: 252114B, Gold Coast Surgery Center in Nassau County. This is to establish and construct a single-specialty ambulatory surgery center for gastroenterology at 123 Eileen Way in Syosset by converting an existing private office-based surgical practice to Article 28. Both the department and the committee recommended approval with conditions and contingencies with expiration of the operating certificate five year from its date of issuance. 252165E, Progressive Surgery Center, LLC in Suffolk County. This is to transfer 100% membership interest from one member LLC and three individual members to two new member LLCs. The department and the committee recommended approval with condition and contingencies with an expiration of the operating certificate three years from its date of issuance. 252173E, Saratoga Schenectady Endoscopy Center, LLC in Saratoga County. This is to transfer 6.67% ownership interest from 14 current members to one new member. The department and the committee recommend approval with a condition. 252045B, Doctors of New York Health Care Center in Queens County. This is to establish construct a new diagnostic and treatment center at 19411A, Northern Boulevard in Flushing. The department and the committee recommend approval with condition and contingencies. Yeah, and I so move my...

Mr. Kraut: I have a motion. Second, Dr. Berliner? Are there any questions on any one of these applications? Hearing none I'll call for a vote. All those in favor, aye.

Committee: Aye.

Mr. Kraut: Opposed? Abstentions?\ The motion carries.

Dr. Kalkut: 241092E, Foxwoods Home Care, LLC. This is to establish a new licensed home care services agency at 705 Renaissance Drive in Williamsville. The department and committee recommend approval with conditions. 232059E, Greifinger Roca, LLC, doing business as Home At Last Home Care. This is to establish Greifinger Roca, LLC as the new operator of a licensed home care services agency, previously operated by Home At Last Home Care Services, LLC at 5127 Queens Boulevard Suites 2D and E in Woodside. The department and the committee recommend approval with a condition. 242282E, The Home Agency Incorporated to establish the Home Agency Incorporated as a new operator of a licensed home care services agency currently operated by Nannys for Grannys Incorporated at 34 Sunset Lane, Patchogue. The department and the committee recommend approval with the condition. 252046.

PART 2 OF 4 ENDS [01:10:04]

Dr. Kalkut: 252046E, The Eliot at Catskill LLC, doing business as the Eliot at Catskill LHCSA. This is to transfer 100% membership interest to a new member LLC with the same members. The department and committee recommends approval with conditions. 252047E, the Sentinel of Port Jervis LLC, doing business as the Sentinel of Port Jervis LHCSA. This is to transfer 100% membership interest to a new member LLC with the same members. The department and the committee recommend approval with conditions and I so move.

Mr. Kraut: I have a motion to move this batch. I have a second, Dr. Berliner. Are there any questions on any one of these applications? Hearing none, I'll call for a vote. All those in favor? Aye.

Council: Aye.

Mr. Kraut: Opposed? Abstentions? The motion carries.

Dr. Kalkut: 242307E 378 Sywood LLC, doing business as Woodbury Heights Nursing and Rehabilitation Center in Nassau County. Established 378 Sywood LLC is the new operator of Cold Spring Hills Center for

Nursing and Rehab 588 bed residential healthcare facility currently operated by Cold Spring Acquisition LLC at 378 Syosset-Woodbury Road in Woodbury. The department and committee recommend an approval with condition and contingencies and I so move.

Mr. Kraut: I have a motion. I have a second, Dr. Berliner. Any questions on this application? Hearing none. All those in favor? Aye. Opposed? Abstentions? The motion carries. I'll turn the chair over to Dr. Yang. I'm conflicted on the next step.

Dr. Kalkut: Thank you. This is a Certificate of Amendment of the Certificate of Incorporation, Northwell Health Foundation. Mr. Kraut has conflict and has left the room. Northwell Health Foundation requests the public health and Health Planning Council approval of its Certificate of amendment of the Certificate of Incorporation of the Northwell Health Foundation in order to change the name from Northwell Health Foundation to Northwell Foundation. The department and committee recommend approval.

Dr. Yang: Thank you. We have a motion. We have a second, Dr. Berliner. Calling a vote. All in favor? Any opposed? Any abstentions? Passes. Thank you.

Dr. Kalkut: I want to ask Mr. Kraut to return. There's a Certificate of Dissolution AHRC Health Care Incorporated. Mr. Perry has a conflict and-

Dr. Kalkut: He's leaving.

Dr. Kalkut: ... is leaving the room. AHRC Healthcare Incorporated requests the Public Health and Health Planning Council approval of its proposed dissolution in accordance with the requirements of not-for-profit corporation law 1002C and 1003 and 10 NYCRR Part 650. The department and the committee recommend approval and I so move.

Mr. Kraut: I have a motion, may I have a second? Dr. Berliner. Any questions? All those in favor? Aye. Opposed? Abstentions? The motion carries. Please ask Mr. Perry to come back. And that concludes-

Dr. Kalkut: 2

Mr. Kraut: Oh yeah, go ahead. Go ahead. Sorry. You have...

Dr. Kalkut: ... 242277B. Hip plus care in New York County. I have an interest. This is to establish and construct a new diagnostic and treatment center to be constructed at 111 West 24th Street, New York, to

provide primary care, medical and medical specialty services to include saline hydration infusion services for patients who exhibit symptoms of connective tissue disorders. The department recommends approval with condition and contingencies with expiration of the operating certificate at two years and the committee recommended approval with conditions and contingency with expiration of the operating certificate from two years of its issuance and was recommended with three committee members abstaining. And I so move.

Mr. Kraut: I have a motion. I have a second, Dr. Berliner. We had at the establishment committee, there was a robust conversation about this proposal. Could I ask the department just for the benefit of the people who were not present to maybe comment on... Are you comfortable doing that or? Shelly? Just the application and then we could talk about what the issue was. And then we'll open it up for questions.

Ms. Glock: Is it on?

Mr. Kraut: Yes.

Ms. Glock: Hi. This is Shelly Glock from the department. As Dr. Kraut mentioned, there was a very comprehensive, robust conversation, EPRC. This is an application that the department had under consideration for a considerable amount of time, primarily to have discussion and to really look at the types of patients and the medical conditions that this diagnostic and treatment center would serve. The department recommended approval. The primary care and other medical specialties as well as the infusion services that are being offered at this diagnostic and treatment center are not any different.

Those are qualified medical services that you've seen at diagnostic and treatment centers on former applications. The discussion was really around the conditions and the connective tissue disorders and trying to come to an understanding of those diseases that the typical person didn't have. So we had a lot of conversation. Dr. Pelosi spoke at EPRC, and spoke about their clinical evidence-based clinical strategies, some of their diagnostics around these medical conditions. And talked a little bit about the infusion therapy really being a treatment of last resort for a smaller percentage of their patients who would need those to treat symptoms.

The Diagnostic and treatment center department recommended approval, it meets the requirements under the statute for the types

of services. It went through character and competence, a financial feasibility look and architectural. So it meets the requirements of a diagnostic and treatment center. And Dr. Pelosi also spoke and I believe provided information to the counsel in a follow-up letter about, there are medical codes for these procedures with Medicare, Medicaid, and insurance companies providing payment for such. Based on those fact patterns and the fact that this diagnostic and treatment center will increase access to care for these patients, we are recommending approval.

But given the understanding around some of the concerns that were expressed, we placed a condition, or I'm sorry, a condition on this project, which is really unprecedented. We placed not only reporting to the department after a year and two. But we put a limited life on this diagnostic and treatment center two-year limited life with the requirement that they need to come back to the department and to the council with their findings. What are their successes? Some of the quality in clinical data around these populations of patients. And we got comfortable with recommending approval with that condition on a project.

Mr. Kraut: Okay. Is there any questions or any comments from the council members. Over there. Yes Mr. La Rue.

Mr. La Rue: I thought at the last meeting they had said they were going to provide the medical research or reference papers that they-

Mr. Kraut: Yeah, they sent us a document, a pretty thick document, I would say that reference... You would've received it in an email, I think from Colleen.

Ms. Leonard: Yes.

Mr. LaRue: I was going to ask my fellow council member-

Mr. Kraut: Colleen, could you just remind everybody what date that was sent? We were sent a fairly detailed document. I have a copy and not that I want you to read it now, but if anybody wants, you could have my copy.

Mr. LaRue: No, I did receive it. I wanted to ask the fellow council member who asked the question whether he had a different opinion after reading the information. If he doesn't mind sharing.

Mr. Kraut: Dr. Eisenstein?

Dr. Eisenstein: I've never been known for not sharing Dr. Larry Eisenstein, council member and thank you Mr. La Rue. I did review the literature and at the committee meeting I abstained with the purpose of giving myself more time to do an in-depth dive into the literature to revisit the testimony. And I feel rather strongly at this point that this is not a application that I support and here's why. One, I read the literature. I think that the literature presented a lot of anecdotal scenarios. There's nothing in the literature that was presented that established standard of care and evidence-based medicine. The way we practice medicine in this country is clinical trials establish standards of care. The literature mostly focused on a couple of very rare diseases, which I absolutely agree with the applicant need more attention, I absolutely agree with the applicant that people are suffering and I think they absolutely have a business model looking at the financials.

But I categorize this in my opinion as a physician, I'm still board certified in infectious disease and I want to talk about that in a minute, because a lot of this revolves around the response to post-viral scenarios. I characterize a lot of this as what I saw and heard as alternative medicine. And I am fearful, it's my opinion, I'm fearful that we're creating a precedent here of approving a CON for something that the literature does not support as the standard of care with... And I'm specifically talking about the long discussion we had on the infusions. So the doctor presented and talked about, these were not my words. This is all on the record, chronic fatigue syndrome. I'm an infectious disease specialist in my training. It's been a while, but that was something I spent a lot of time working on. And they were right that there are people suffering from this, and they were right that it's awful and they were right that there's maybe not enough being done. But to this day, there is no known treatment for it.

So infusion therapy to use their words, makes the patients feel better. There's no evidence that it has any impact. We don't give Article 28s because it makes people feel better. There's a lot of alternative medical therapies that people like and it makes them feel better. There's a lot of things you can do to make yourself feel better. To me, I wish them well, I think they have a business model. I just don't see this as something requiring an Article 28. And I'm fearful of the precedent of allowing something that I consider to be currently alternative medicine to be licensed like this.

And by this vote are we changing the standard for what we are approving for Article 28? And again, I have nothing against them. They have a thriving business model. I like the idea that

somebody's paying attention to rare diseases and people that are struggling and not finding what they need, but that doesn't make their treatment clinically valid by the literature. And that's my position on this. And so I hope that answers your question, Mr. La Rue.

Mr. Kraut: Any other questions or observations?

Dr. Kalkut: Jeff?

Dr. Soffel: Yeah

Mr. Kraut: Yes, Dr Kalkut... I'm sorry.

Dr. Soffel: Oh, I'm sorry. Go.

Dr. Kalkut: You go [inaudible 01:23:25]

Mr. Kraut: Go ahead Dr. Soffel

Dr. Soffel: I just want to briefly respond to Dr. Eisenstein's comment because I think that there's no question that randomized clinical trial evidence is the gold standard for healthcare treatment. There's no question about that. But most of what physicians do has not been demonstrated in a randomized control trial. That doesn't mean that there's no evidence and it doesn't mean that what we're doing is wrong. But I think that using randomized control trials as the only gold standard for evaluating medical necessity and evidence-based treatment is an inappropriate standard because it's not one that is used across the board.

And I think that for me, particularly the fact that many of the patients who are likely to receive care at the center have been dismissed by a lot of standardized medicine because they don't fit neat patterns and clean definitions and crisp diagnoses. And I feel that we have done a disservice to many people who are suffering real problems that we don't quite have enough clinical hardness to put them neatly into a box. But that doesn't mean that they are not suffering and it doesn't mean that they could not be helped by these kinds of treatments.

Dr. Eisenstein: Can I respond please? So I agree with you on the latter part, and that was the first thing I said. People are suffering and it's terrible. The treatments, the infusions that they're talking about, it's one thing when something is evidence-based, but these have been proven to not work. It's the opposite, where it's been studied, it's not

that this hasn't been studied and doctors do stuff which, and I understand there is a component of anecdotal medicine in all aspects of medicine, but using infusions, take the chronic fatigue syndrome. I remember when they said, use this vitamin and use that supplement. And the fact is it's been studied for 30 years and none of it has ever proven accurate. So I'm not saying it hasn't been studied, therefore we shouldn't do it. I'm saying it has been studied and has not cleared the evidence-based protocols. So that's why I don't support it.

Mr. Kraut: Go ahead doc and then Kalkut and Ms. Monroe.

Dr. Kalkut: It's always good to have an insightful infectious disease doctor speaking. I concur with Dr. Eisenstein's conclusions here. There's uncertainty in medicine across multiple domains. Connected tissue disease is one of them. Whether this is sort of traditional connected tissue disease or a amalgam of multiple diseases or syndromes or states not clear, I don't think to anyone. Chronic fatigue syndrome is a good example of something that doesn't really have treatment. As both of us are infectious disease physicians, chronic Lyme disease just flies in the face of what is known about antibiotics and what they actually do. A lot of these diseases are going to be inflammatory diseases, post viral.

COVID had a spectacular inflammation that caused multiple problems and probably contributed to post-COVID disease also. The measurements of inflammation were off the charts for a lot of people with severe COVID disease. I also feel that the endorsement of this council for this D&TC has the risk of opening up doors to this and saying, we think these treatments, even though we don't have treatments for many of the things here, I think the precedent is a problem, perhaps a danger to go through with this. So I'm also not going to vote for this and I welcome anybody else's opinions.

Mr. Kraut: Ms. Monroe.

Ms. Monroe: Yeah.

Mr. Kraut: Sorry. [inaudible 01:27:49]

Ms. Monroe: Am I next, Jeff?

Mr. Kraut: Yes, you are, ma'am.

Ms. Monroe: Okay, thank you. Just two things. One, I think a lot of what we do in medicine is to help people feel better. Palliative care would not exist if it was not about helping people feel better in a situation where there is really no cure. So I don't think that this falls outside of what is reasonable to think about helping people feel better. And I agree with Dr. Kalkut, that there is a risk here, but I am really pleased that the department has put this extra special condition on this application to make sure that we learn from this, just like we're doing with the ASCs, we're taking a small step to see how it works, does it prove what? Prove out to be what they hope it will be and we hope that it will be.

So I'm never opposed to taking a step in a new direction that might have benefit for patients, but I want it to be in a very structured setting, just like we did with ASCs to keep us from going wild on things that prove not to be the case. So I would support this especially with that extra condition that the department has put on it. And let's see, in a year, was it a year, Shelly? They were to come back or when?

Ms. Glock: Two.

Ms. Monroe: Two years.

Ms. Glock: We asked them to come back with a reporting-

Mr. Kraut: Two years.

Ms. Glock: In one year.

Ms. Monroe: When?

Ms. Glock: Reporting at one and two, and then the limited life is for two years.

Ms. Monroe: Okay. Yeah. So that's a short period of time from which we can all learn. So those are my comments.

Mr. Kraut: Mr. Thomas.

Mr. Thomas: Hugh Thomas, member of the council. Just a sort of a comment, I'm not a physician, I'm not a scientist, but we had the physicians here and through no reason other than timing, a lot more work has been done to look at the science and look at the literature and we're having a detailed conversation about this program and this application in the absence of the applicant, in the presence of a lot more work, in other words, Dr. Eisenstein done a lot of work. Dr.

Kalkut's very familiar with this, but the physician sponsoring this application aren't here. And so from a process perspective, Jeff, I don't know where to go with that, and I don't know what the precedent might be at the council.

Mr. Kraut: Well, here's my thoughts on it. First I just want to clarify some of the statements that were made. And so we don't get like a hundred emails. We're not bashing alternative medicine. This is a very specific issue that we're looking at. And so let's just be clear. And I don't even like the term, I like complementary medicine. Because it has a lot of evidence-based other activities here. The point that's being made is we're concerned about establishing a precedent. And I'll give you an example. If you look in California, you see these infusion centers are on multiple corners in other states. And the threshold, remember what we're doing is that doesn't stop them from billing insurance as a provider. It gives them the opportunity to get a diagnostic, a treatment center rate. It's more expensive to operate within the framework of a D&TC. And that's what they're asking permission to do.

Given some of the statements that were made about the efficacy of it, by putting it in a D&TC, we have an opportunity to monitor, to assess it and for it to come back to us. So I think the precedent issue is valid, and I would not want to consider another one of these types of applications until we get that data and feedback. So we would be concerned about those floodgates opening without having these multiple kind of conditions. I think by putting the conditions with the expiration of the operating certificate, we've never done that on a D&TC other than, correct me if I'm wrong, an AMSRT center.

So this is new area for us. We've put some effective controls. The department has reviewed it and seen there's some merit, I suspect in their conclusion. But by doing what Ms. Monroe mentioned that the department went to great pains to put this into an environment where it is somewhat controlled. We will get data and we could reach a conclusion whether or not we should do it again or not do it again. And not revoke the certificate, we would just not renew the certificate. So for those that have concerns, there's some appropriate rails on those concerns, but there's a threshold issue, should we be doing that at all? And I would respect what people have to say. We can always... I mean, right now we have a motion besides us. We have to vote on that. Okay. Yes. I'm sorry.

Dr. Kalkut: And Doug.

Mr. Kraut: Doug, would you like to speak before? I'm sorry.

Dr. Fish: Yeah, just to say, and this is Dr. Doug Fish, also an ID doc. Understand everything and don't disagree with anything that I've heard today. We had a lot of conversation about this. We brought this applicant back multiple times. It's why it took the review over a year for us to come to a point where we felt comfortable making the recommendation to the council. There were changes that they made to their applications and some concessions that were made. These are for patients and conditions for which there aren't really standard therapies and who in some cases are really not satisfied or even able to get into certain practices for the care. But I think Jeff, what you said at the end was kind of really the key.

The thought that we have is there are hydration centers that exist in New York. There are drip bars. We don't think this is one of them, but it is an opportunity for these types of interventions for challenging conditions to be regulated by the department and to have the oversight and the ability to understand what's happening and the suggestion and the condition will help us to do that. And the suggestion be that we just consider this one at this time until that time has passed, as it might be something that the council could consider.

Mr. Kraut: Mr. Lawrence. Just pull it towards you. Thank you.

Mr. Lawrence: Okay. Am I on? No, no, I'm not.

Mr. Kraut: Now you are. Yes.

Mr. Lawrence: Yeah. Harvey Lawrence, member of the council. This is a really interesting conversation, and especially for me, a non-clinician, but a person who essentially grew up in a part of the country where standard of care did not exist. And I had a grandmother who would go out in the field and if you had a fever, grab some bushes and come back and boil it down and then you would take it and for some reason you felt better. I don't know if it was a placebo effect or whether it was something on those herbs. And I think all of medicine at some level started out that way. And then the gold standard was things that you could duplicate and do it. And even with the medicine, there's always a probability with some population, some things work and some things don't. But again, it's more information.

So I think I tend to lean not for randomness, but for certainty. And the question that I think is most important it's do no harm, will this

harm someone? And I think in the context that Mr. Kraut has indicated, if it's inside the system and we're able to evaluate it and look at it for two years and then go back and say, hey, it's not either as harmful, it is not achieving any outcomes that are meaningful, then we or the department can make a statement that is probably much more scientific because you've had the data and you're able to evaluate it and say, "This is a center that has done X, Y, and Z, and here are the outcomes.

And it again, will lead to Dr. Eisenstein's point that again, we will reinforce that if that's the case. But again, to Ms. Monroe's point, there's a lot of medicine where it's basically about how one feels. And sometimes that works. Whether we should endorse things that make people feel good or whether it is about curing them is, I guess the difference. But my issue, if it's not doing any harm and it's going to be reevaluated, then is something that I think I would feel comfortable proceeding with.

Mr. Kraut: Thank you. And thank you for that story. I just got PTSD from my Scottish aunt who would brew something. It was so foul tasting that you just got scared into getting better. Dr. Lim, Dr. La Rue. It's true story. Oof.

Dr. Lim: [inaudible 01:38:34].

Mr. Kraut: Just pull it a little closer. Yeah, just pull...

Dr. Lim: Can you hear me now? Yeah,

Mr. Kraut: There you go.

Dr. Lim: Okay. Sabina council member. So I think I might be the only physician that's not an ID specialist here. So I'm a psychiatrist, but I think I did have mixed feelings about this and mixed thoughts about it, but the way I got to basically approving it at the committee level was exactly for the reasons that Jeff described, that there are, I think we have to remember there's a whole set of regulations under the Article 28 D&TCs, and it didn't seem to me that it was just a practice solely focused on infusions. They would have to meet both the spirit and the substance of what a D&TC and the medical care they provide and including all the regulations like adverse event reporting, all that stuff. I would say that I think the content of the reports that they provide after year one and year two is important.

And particularly I was struck by the condition number four, where that hydration infusion services should be administered solely when

deemed medically necessary by a licensed healthcare provider. And I think that would be really important. I would like to see how they're going to demonstrate that. And so again, as Mr. Lawrence and as others have said, I think there's a lot of different ways that we can approach medicine. And there's lots of non-Western sort of beliefs that I think are important to take into consideration. And I think to put this under the structure of something very rigorous and that can be very closely monitored, that I think is really important. So just my thoughts.

Dr. Kalkut: Jeff.

Mr. Kraut: Okay. I think Mr. La Rue, and then Dr. Berliner, Dr. Rugge. And then let's kind of call a vote, if you wouldn't mind.

Mr. LaRue: And just for the record, I'm not a physician, although I played one on TV.

Mr. Kraut: Play one on TV. Yeah. Don't we all [inaudible 01:40:24]

Mr. LaRue: The comment I want to make kind of goes along with what was just said, is how are we going to measure success when they come back with a report in a year or two years? And I'm not necessarily looking for an answer right now, because I'm not sure we'd know what the answer is, but how... We're going to come get a report. Let's say they found six people who felt it helped them. They're going to tell us six people helped. I mean, how are we going to make a decision in a year or two years that has any merit without some third party looking at it or some scientific information that supports what they're saying?

Mr. Kraut: I think that's why the Department of Health has this condition. They will have a process to look at that information and they will do an assessment. We will not be looking at raw data. We rely on the Department of Health to reach a conclusion with whatever data they can. And it's a good question. I don't know the answer. I know how I would structure a study to do it, but it would look like a double-blind study. Anyway...

Dr. Eisenstein: Can I just follow that up real quick? Dr. Heslin, we talked about this process evaluating data for the ambulatory PCI issue, and there was a concern about the staffing ability, the capacity of the state to do this work. Does that exist in this scenario? And if we're doing a one or two year look, but it then takes three or five years to evaluate the data, have we really put something in place to tightly control it?

Dr Heslin: Thank you Dr. Eisenstein, I'll defer to Dr. Fish who directly supervises that entire division.

Mr. Kraut: Dr. Fish. Could we come back to that? Let me just get all the questions out, because maybe we can get them all answered at one.

Dr. Watkins: I mean-

Mr. Kraut: Just a little closer.

Dr. Watkins: ... the question is do we need something formal to direct the department not to bring any of these forward until the two-year period?

Mr. Kraut: I think-

Dr. Watkins: And I guess Shelly do have any similar applications pending? No. Good.

Mr. Kraut: I'm telling them not to. I don't know. They can do whatever they want, but we will remind them of this discussion. And we're saying it publicly too. So please, it's going to sit there a long time. Dr. Rugge, did you have a question or a comment then Dr. Fish and then I'd like to call the vote, please.

Dr. Rugge: I am a physician, but not for ID.

Dr. Yang: Yay.

Dr. Rugge: At least I used to be a physician. But any case, my question is are there are specific outcomes that are going to be reported and tracked? Because I think the risk is we could have satisfaction as a placebo effect, but we shouldn't be licensing and paying for that. So what are we doing?

Mr. Kraut: So I think the department has to listen to what says... They have to come back with, they have to have a plan, I don't think they have to come back to us, but when the data is presented, there has to be some rational basis of how they went about did the evaluation. Maybe you hired a third party to do it. I don't know. So I'll leave it to Dr. Fish.

Dr. Fish: Thank you. Mr. Kraut. Doug Fish again. So I think one first thing we do is assess, was there any harm? Is there any evidence that there was harm to any of the patients? We will look, did we receive any

complaints from the facility? Right now, we wouldn't get complaints because they're not a regulated facility. So our Office of Primary Care Health Services Management, our surveillance team can go out investigate if we do get complaints. So I think that's an important factor to consider. Third is when we get the evidence and the report, we'll look and see, we'll do a deep dive. We do have the ability to look at data that comes in. We have a data team. We can ask for specific data. We can also look at reports, look at the literature, review what they've sent with our internal team. It would be unusual that it would rise to the point where we'd need to kind of bring in an external entity to evaluate. We don't have a contract that would do that for FIPIC, but we could figure something out if we had to.

Mr. Kraut: Right. And I'm going to utter a phrase I haven't uttered in two years, but I had uttered every year for the past 10.

PART 3 OF 4 ENDS [01:45:04]

Mr. Kraut: As I haven't uttered in two years, but I had uttered every year for the past 10. All-payer database. Once we had an all-payer database. You just take a look at all the claims in the practice, then you take a look at anything that happened after those practices before and you'd get a treasure trove of information anyway. But I just wanted to say all-payer database this year. Okay. I'm going to... I'm sorry. I'd like to call a vote unless there's something new that you want to bring up.

Mr. Lawrence: No, it's not news. This may be an opportunity to actually do a comprehensive study that involves the users and looking for the clinical outcomes, testing the placebo effect, the whole thing. And you might be able to do it with a medical center or an academic center.

Mr. Kraut: Well, remember these doctors are on the faculty of NYU. If I was them, I would look to publish data in a peer-reviewed and that would be evidence in and of itself in a peer-reviewed journal if they gave something that met that standard, that would be to their benefit to frankly ours. I think everybody understands what we're suggesting. Again, we have an unusual... We have a... To prevent a precedent, we're putting contingencies on this. So there's an expiration of the operating certificate. Two years from now, we get to take a look at it and then we can have a discussion. And we're also telling the department not to consider other applications similar to this. That is the, if you vote a yes, that is the motion we are approving. And if it fails, we'll have a discussion of what other

alternatives can do. So may I have a motion? I had a second. May I have a vote? All those in favor? Yay.

Mr. Kraut: Yes. Yes.

Mr. Kraut: Yes. And okay. All those opposed? I have one, two, thee. Three. Anybody-

Dr. Rugge: Abstain.

Mr. Kraut: And one abstention.

Mr. LaRue: Two.

Mr. LaRue: Yeah, I abstained at the committee. And I'm going to again today because I respect all the physicians on this committee and there's not consensus between them. And I don't have the clinical background to vote for this.

Mr. Kraut: Could you just... I'm sorry, we're going to do a voice one.

Ms. Leonard: Okay. Dr. Berliner.

Dr. Berliner: Yes.

Ms. Leonard: Dr. Eisenstein.

Dr. Eisenstein: Opposed.

Ms. Leonard: Lindsay Farrell?

Ms. Farrell: Yes.

Ms. Leonard: Dr. Kalkut.

Dr. Kalkut: No.

Ms. Leonard: Mr. LaRue?

Mr. LaRue: I'm abstaining.

Ms. Leonard: Mr. Lawrence?

Mr. Lawrence: Yes.

Ms. Leonard: Ms. Monroe?

Ms. Monroe: Yes.

Ms. Leonard: Dr. Ortiz?

Dr. Ortiz: Yes.

Ms. Leonard: Dr. Rugge?

Dr. Rugge: Abstain.

Ms. Leonard: Dr. Soffel?

Dr. Soffel: Yes.

Ms. Leonard: Ms. Soto?

Ms. Soto: Yes.

Ms. Leonard: Mr. Thomas?

Mr. Thomas: Yes.

Ms. Leonard: Dr. Torres?

Dr. Torres: Yes.

Ms. Leonard: Dr. Watkins?

Dr. Watkins: Yes.

Ms. Leonard: Dr. Wilcox?

Dr. Wilcox: Approve.

Ms. Leonard: Dr. Yang?

Dr. Yang: Abstain.

Ms. Leonard: Let's see where we are before the chair.

Mr. Kraut: Could you just give me the vote?

Ms. Leonard: Dr. Lim and Dr. Lim?

Dr. Lim: Yes.

Ms. Leonard: Okay. One, two, three, four, five, six, seven, eight, nine, 10, 11, 12. It's not going to pass. We have... We need 14 affirmative votes. And we have 13.

Dr. Berliner: We needed 14.

Ms. Leonard: We need 14 affirmative votes in order to approve. And you are not on the... Because I missed you. Mr. Perry?

Mr. Perry: Yes.

Ms. Leonard: We have a motion. It passes.

Mr. Kraut: Okay, so the motion passes. So just reminding everybody that it's coming back for permanent life. It doesn't mean you have to approve it when it comes back, but it's going to come back. Okay. So the motion carries. Could we be absolutely clear about the math?

Ms. Leonard: Dr. Watkins?

Mr. Kraut: He voted no.

Ms. Leonard: He voted yes, correct.

Mr. Kraut: No.

Ms. Leonard: Abstained.

Mr. Kraut: He abstained.

Ms. Leonard: I cannot. One, two, three, four, five, six, seven, eight, nine 10, 11, 12, 13. Jeff was a yes?

Mr. Kraut: How many votes without?

Ms. Leonard: 13.

Mr. Kraut: It's 13? I'll be the 14th. The deciding vote. I vote yes. We need to get buzzers like in Congress. So every-

Ms. Leonard: Hold on.

Mr. Kraut: Little light

Ms. Leonard: Two, three, four. [inaudible 01:50:12].

Mr. Kraut: I do too. I got to make sure math works. Just out of fairness to the applicant. I don't want to... 14 with the chair? I hate voting, but okay. Well I think this was... It was quite well. Okay.

Ms. Leonard: It does not pass.

Mr. Kraut: Wait a minute.

Ms. Leonard: It will not pass even because-

Mr. Kraut: You got to speak in so everybody hears what's happening.

Ms. Leonard: Math is not my best subject.

Mr. Kraut: Yeah, I know. We're going to call Price Waterhouse and you're never doing the Oscars. Okay.

Ms. Leonard: It will not pass. Now we have four abstentions. Two nays. That's six.

Mr. Kraut: Could you just list the nays?

Ms. Leonard: Yes. Dr. Eisenstein and Dr. Kalkut.

Mr. Kraut: Are nays?

Ms. Leonard: Are nays.

Mr. Kraut: Who are the abstentions?

Ms. Leonard: The abstentions are Mr. LaRue, Dr. Rugge, Dr. Watkins, and then Dr. Yang.

Ms. Monroe: And who?

Ms. Leonard: Dr. Yang.

Mr. Kraut: Does any of the abstentions want to change their vote? Not forcing you. Asking you. Okay. Dr. Watkins, don't feel compelled. I'm just trying to... No, no. I don't want anybody's arm to be twisted.

Mr. Kraut: Okay. Could I have-

Mr. Kraut: No, I'm not going to force it.

Dr. Kalkut: No, I do understand that.

Mr. Kraut: He was clear about that. Okay. Motion fails. May I have another motion?

Ms. Monroe: The motion passed? Excuse me.

Mr. Kraut: No, no. Motion failed. You have another motion.

Dr. Kalkut: Can we defer this application?

Mr. Kraut: Yes. Okay. So okay, if we're deferring it and bringing it back, what additional information do you require? I'm asking of look, the no's may be no's. The people who abstain. I'm assuming you abstain because you had inadequate information. What other before I do that, let me... I have a motion to defer.

Dr. Kalkut: Yes.

Mr. Kraut: Do I have a second? I have a second. Okay. If we bring it back, what information are we looking for? And I'm specifically asking the individuals who abstain that would permit you to render an either A yes no or continue to abstain. Yes. Mr. LaRue.

Mr. LaRue: If we had more details on how we were going to measure success when it comes back to the committee.

Mr. Kraut: Okay. That may be a question that the department would work with, with the applicant on how we would determine the success. So some structural analytic framework. Does that make sense? Dr. Yang.

Dr. Yang: Okay. Also, if there were a way to designate this as a special research project rather than simply a standard.

Mr. Kraut: I don't know if it rises to research, nor does it rise to demonstration project because D&TC exists and I'm not sure that the department would want... I would leave that up to the department to come back. But I just think a framework to understand how we would measure success that might give comfort based on what we've heard. Is that fair statement? Okay.

Dr. Yang: Yes.

Mr. Kraut: So we have a motion to defer, I'll say for one cycle or as many as it takes with the applicant to respond to the department. If the applicant is unable to do so by May, then it's up to the department to decide when to bring them back. Don't rush this. So that's the

motion. I had a second. All those in favor? Aye. Anyone opposed? Anybody abstaining from a deferral? The motion carries. Thank you. Okay, now? Yes.

Dr. Eisenstein: And if that kind of framework existed, I would even be supportive of.

Mr. Kraut: Okay, fair enough. You'll have an opportunity. And look, the whole point is you have to have the information to make an informed judgment on every application. If you're not comfortable, that's what this is what the process is supposed to do. No problems. Now if you're not comfortable, here we go. We're now going to turn to another matter. Another matter Today the council members are going to be tasked with reviewing a project that we approved for a license in 2016. Rarely, if ever has the council had an opportunity to reconsider an approval for establishment licensure or certification, which remains the exclusive authority for certain provider types, exclusive authority of the PHHPC. However, there are times and circumstances that are such that we have to reverse a course of action that was undertaken with appropriate due diligence but later resulted in the commission of a criminal act before I made a motion.

I'm going to turn it over to counsel for some remarks, but I think we might want to go into, I need a motion to go in.

Ms. Marks: She has to talk.

Mr. Kraut: Okay. Let me just get clear before we go into executive counsel. Okay. So what we're going to do, I'm going to ask before there's any motion, I just want to ask the department to speak. After we speak, I want to go into executive session, not to discuss the matter, but to understand and educate you as to any questions about process. Okay. Only not the matter. And then we'll come out of executive session to consider the motion. Is that correct? Did I get that right?

Mr. Kraut: Okay. So we have on web, unfortunately she was unable to join us. Marthe is going to prepare some remarks and we've all received documents about this matter. Hopefully you've had an opportunity to read it. Martha, if I'll turn it over to you.

Ms. Ngwashi: Thank you. Can you hear me?

Mr. Kraut: Oh, very well.

Ms. Ngwashi: Oh wonderful. Sorry, I'm not able to be there in person. And good afternoon. My name is Marthe Ngwashi. I am an attorney at the Department of Health and today I present a request from the department for the Public Health and Health Planning Council or the PHHPC to reconsider an approval it granted for home care services agency license and generally a potential licensee must agree to adhere to the laws, rules and regulations for its selected provider type. Here are discussing home care services and its licensure and operating requirements are codified in article XXXVI of public health law in Title X, NYCRR parts XVI-XVII and XVI-XVI. And on the department's website. The department requests that the PHHPC reconsider-

Mr. Kraut: Marthe, hold off for one second. I just want to be clear, we're not an executive session now, is that correct?

Ms. Ngwashi: That's correct.

Mr. Kraut: Okay. Thank you. Okay, I'm sorry to interrupt you. Go ahead.

Ms. Ngwashi: No problem. So the ask is the department requests that the PHHPC reconsider an approval for a licensed home care services agency pursuant to its exclusive authority under article XXXVI Public health law, and more specifically Title X, NYCRR765-1.8 A4. In short, this regulatory provision states that an approval may be revoked, limited, or annulled by the pic if the counsel finds that the approved operator has been convicted in a court of competent jurisdiction of a crime. An approved operator is defined as any corporation or a principal stockholder. In this case the approved operator is the corporation Life Quality Home Care Agency Inc. its principal stockholder. Mariana Levin was convicted of a crime in federal court and since we have an approved operator that has been convicted of a crime, the department requests the council's consideration to revoke the approval of the license of Life Quality Home Care Agency. Inc. Thank you.

Mr. Kraut: Okay. Now before we consider the matter, do I go into executive? I just need some guidance when to allow the council members to ask questions about the process. Is this the time to go into executive session?

Ms. Ngwashi: Yes it is. You can call a vote to go into executive session now.

Mr. Kraut: May I have a motion to go into executive session? Dr. Torres, A second. Mr. Thomas. All those in favor of going into executive session please say aye.

Council: Aye.

Mr. Kraut: Anyone opposed or abstains? Hearing none. I'm going to now ask the public to leave the room and we'll go into an executive session. Members of the department, I believe if you're necessary you should stay for that executive session.

Mr. Kraut: Okay, we have returned now to public session, and I would like to have a motion to revoke approval of project number 161281 Life Quality Home Care Agency. I have a motion by Dr. Berliner, a second by Mr. Thomas, I'll turn it over to the DLA for a presentation or should I read the resolution? How do you want me to do that?

Ms. Ngwashi: Yes, you're welcome to read the resolution.

Mr. Kraut: Okay. So we have a motion that's been made, seconded and made, and we are going to consider a resolution for approval of revocation. I'm going to read the resolution that we'll be voting on, whereas on August 4th, 2016, the Public Health and Health Planning Council, pursuant to the provisions of Section 3605 of the public health law proposed to approve application CON number 161281 Life Quality Home Care Agency Inc. Whereas on January 1st, 2019, life Quality Home Care Agency Inc. received an operating certificate for permanent licensure pursuant to the Public Health and Health Planning Council approval of CON number 161281. And whereas on December 16th, 2020, Mariana Levin, the sole shareholder of Life Quality Home Care Agency, Inc. was arrested and charged with a conspiracy to commit healthcare mail and wire fraud among other charges in connection with a scheme to fraudulently bill Medicaid for home health and personal care services that were not actually rendered.

And whereas on June 1st, 2022, Mariana Levin pled guilty to wire fraud, a felony offense and admitted to knowing the acts were unlawful. And whereas on February 1st, 2023, Mariana Levin was sentenced to imprisonment for 54 months, supervised relief after imprisonment for three years, payment of criminal monetary penalties, which is restitution in the amount of $36,328,183 and forfeiture and payment of $1,496,000. And whereas on or around April 2021, Life Quality Home Care Agency Inc. terminated providing home care services in violation of Article 36 of the public health law and Part 766 of Title X of the New York Official Compilation of Codes, rules and regulations. NYCRR. And whereas in June, 2024 and July, 2025 the New York State Department of

Health requested by telephone and mail through a stipulation and order that Life Quality Home Care Agency Inc. surrender its license because it was non-operational and in violation of Article 36 of the public health law and Part 766 of Title X NYCRR.

And whereas Life Quality Home Care Agency, Inc. has refused to surrender its license and is a non-operational licensed home care services agency. And whereas on February 19th, 2026 this counsel reconsidered their approval in accordance with Title X NYCRR 765-1.8 subparagraph A, subparagraph four. After considering factual evidence that the Operator of Life Quality Home Care Agency Inc. was convicted of a crime on June 1st, 2022 and thereafter terminated providing home care services in violation of Article 36 of the public health law and part seven-six-six of Title 10 NYCRR. And whereas the Public Health and Health Planning Council has considered the record, it is hereby resolved that this council after due deliberation and for the reasons stated on the record at its meeting of this council of this 19th day of February, 2026, approve revocation of their August 4th, 2016 approval for application CON 161281 Life Quality Home Care Agency, which was the applicant with a license to operate in the Kings, Bronx, Queens, Richmond and New York counties. And that'll be the resolution that we will be considering. Now I'll turn it over to the Department of Law for any other additional comments. Marthe?

Ms. Ngwashi: Thank you.

Mr. Kraut: Yes.

Ms. Ngwashi: Good afternoon again. You can hear me okay?

Mr. Kraut: Yes we can.

Ms. Ngwashi: All right, thanks. I think that for the most part, Mr. Kraut distinctly outlined what the Council's task is this afternoon. I will go over a few other details and also some procedural matters that the council will consider as well. Life Quality Home Care Agency, Inc. or Life Quality Home Care submitted a licensure application on April 19th, 2016 for a change in stock ownership of an existing Licensed home care services agency. Mariana Levin. Was the proposed new sole stockholder at the time, we are unsure whether or not Mariana Levin submitted this application on her own or she did it with the assistance of someone else. And I'll get into why that is a questionable aspect momentarily.

The application was contingently approved by the EPRC and later the full council on August 4th, 2016. The project received permanent licensure on January 1st, 2019. Almost immediately and prior to receiving permanent licensure, Mariana Levin used Life Quality Home Care to engage in healthcare mail and wire fraud. The criminal activity was discovered and investigated by the Federal Bureau of Investigation. The criminal activity consisted of fabricating home care visits or creating no-show cases, billing Medicaid for the fraudulent services, receiving payment from Medicaid for the no-show cases and thereby committing Medicaid fraud. Theft of public funds. The federal government found that over $100 million was stolen from Medicaid. Of that amount, over $60 million is attributed to Mariana Levin who is the sole stockholder of Life Quality Home Care. Mariana Levin was later indicted and arrested on December 16th, 2020. She pled guilty to wire fraud.

Mr. Kraut: Hold on. Marthe, we dropped. Your voice dropped out. Martha please guys, this is really critical. Can we get what happened?

Ms. Ngwashi: Dollars in restitution and over $1.4 million in forfeiture. Now this penalty that was imposed was because of the egregiousness of the conduct that happened, the abuse of the public funds theft and also the questionable nature as to how Mariana Levin got the license for this home care agency Life Quality... I'm sorry, I don't know if you-

Mr. Kraut: You dropped out for a while.

Mr. LaRue: Indictment in December was where she left off.

Mr. Kraut: Yeah, the last thing we heard the indictment in December.

Ms. Ngwashi: Okay, she was indicted on December 16th, 2020. She pled guilty to wire fraud and admitted to the illegal activity. She was subsequently sentenced to four and a half years in prison and she's currently still in prison also and she's subject to three years of supervised release when she gets out. She's also required to pay over $36 million in restitution and over $1.4 million in forfeiture. The penalty imposed was as high as it was because the judge did want to send a message to people who steal public money in this fashion and very flagrantly. Additionally, they commented on the fact that Mariana Levin started doing this before she actually had a permanent license to operate the agency.

That into question why she submitted the application in the first place to the PHHPC and also brings into question whether or not the information she provided to the department was accurate. Now

the other issue is life quality Home care ceased providing services sometime in 2021. That's a violation of our regulations because we required notice to the department and also as you can imagine, an orderly transition for any patients that are receiving any services there. In 2024 and again in 2025, the department requested the license be surrendered but the agency refused to acknowledge any of the requests and they refused to surrender the license to date.

Now as I mentioned, we are requesting that the council reconsider its approval of this operator life quality Home care agency Inc. And we are recommending that the council revoke its approval of life quality Home Care Agency Inc. Project number 161281. If the council votes to revoke its approval of Project 161281, no approval to revoke the license can happen without first offering the approved operator an opportunity for a public hearing. The public hearing will be administered in accordance with how all of our public hearings are in front of an administrative law judge. If the applicant requests to have this public hearing in a timely fashion, if that happens, it will be undertaken in front of the administrative law judge And after that hearing then the administrative law judge's report and recommendation will be presented back to the counsel for its consideration. Again. Thank you.

Mr. Kraut: Thank you. So you've heard the presentation, you've heard the resolution, you've received the materials about the background of the case, the sentencing hearing and the like. So if there's any questions, please ask them now. If not, I will call for a vote. Yes.

Dr. Ortiz: This is more procedural and Hugh maybe can help me. When Ted Strange was on the Personnel Committee, we would have discussions about our professional liability and responsibility in reporting to the Office of Professions. So Mariana Levin, I looked it up, there's two of them. One has an inactive RN license, one has an active RN license. And so as [inaudible 02:13:03] the only nurse here, what's the responsibility for ensuring that the Board of Nursing and the Office of Professions realizes what has occurred?

Mr. Kraut: So, is there a referral on our action to the board of nursing?

Ms. Ngwashi: So, it doesn't happen from us, however, those requirements are for each licensed individual. So Dr. Ortiz, you should feel free to let the Office of Professions know at the state education Department know about this.

Dr. Ortiz: Okay, great.

Mr. Kraut: Dr. Watkins?

Dr. Watkins: Yeah, I have a quick question. If she was operating this non-operational or this ghost Home Care services, isn't it formality for the department to go in to home care services and do a survey to look at the patients that they allege to have served, looking at their records, following those staff members to the homes of these home care agencies to determine if they're doing their operations correctly? And if this has been happening for so many years, why is that not brought before us as well?

Ms. Ngwashi: I want to just try to, I keep a little bit of a narrow focus on what we're doing today on the fact that we are bringing it forward to you because of a few things. One is that PHHPC has exclusive authority to reconsider an approval vote, an approval action. And that's what we're bringing forward to you today. There is a narrow situation that permits us to do that and the regulation states that you may revoke an approval if an approved operator has been convicted of a crime. And so we have met for of those elements in this today. I'm not taking anything away from what your comments are, Dr. Watkins, and I appreciate them and I know that our Office of Aging and Long-Term Care and Home Care specifically, we'll take that under advisement. However, what I'd like to focus on today is for us to just consider this situation where we have an approved operator that has been convicted of a crime and we're requesting that the counsel look at those facts and determine whether or not a revocation of the approval is appropriate.

Mr. Kraut: Martha, let me just suggest Dr. Watkins, the next time we have a LICSR application coming before us, that'll be the first question that'll be asked. Okay? Any other questions? Hearing none, I'm going to call for a vote. All those in favor of the motion to revoke approval of project number 161281. Life Quality Home Care Agency. Inc. say aye.

Council: Aye.

Mr. Kraut: Anyone opposed? Anyone abstaining? The motion carries. Thank you very much. Thank you Martha for the material. Thank you, the department staff for working on it. The next regularly scheduled committee day is going to be April 23rd and the full counsel will convene here in May 7th. It's in Albany? In Albany. Okay. All right, we'll get back there as soon as they fix the room. May I have a motion to adjourn the Public Health and Health Planning Council meeting? I have a motion. Dr. Watkins. A second. Dr. Berliner. Thank you very much for coming up here. Safe travels and thank

you for the work of all the committees. This was a very productive morning. We are adjourned.

PART 4 OF 4 ENDS [02:17:09]