

NEW YORK STATE DEPARTMENT OF HEALTH
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
HEALTH PLANNING COMMITTEE
July 1, 2025, 10:30 AM – 3:30 PM
ESP, CONCOURSE LEVEL, MEETING ROOM 5 ALBANY
TRANSCRIPT

Dr. Heslin Good morning. Welcome to the Public Health and Health Planning Council Health Planning Committee meeting. We have a robust agenda today. We're doing something a little bit different today than we've done before. Because this is a long meeting we are starting, we are going to run a two-hour meeting and then take a break for everybody to have a little bit of something to eat and refreshment, and then come back in the afternoon and then do a second two-hour session. I'll turn it over to our chairman, Dr. Rugge. In terms of a couple of points of order, the first one is that these mics are hot mics, so remember to turn your mic on and turn your mic off. These meetings are recorded. Your conversation will be recorded if you have your microphone on. This is an open meeting. This is being live broadcast in addition to the people in the room.

Dr. Heslin Welcome, Dr. Rugge.

Dr. Rugge Thank you.

Dr. Rugge Aren't we lucky it's not a three-day meeting. I was going to start with instructions and information that we've all heard many, many times. I think Eugene has done a good job of explaining. We need to stop rustling and speak one at a time. If possible, identify yourself when you first are presenting so the recorder can know who we are, who you are. By way of another starter, this has been kind of a notable year for the Planning Committee. We came up with a new articulation of our mission and our purpose and our charge as a Planning Committee, one that went to the council and was then edited and improved a bit. Here we are under those auspices. Our role is to make specific recommendations to the council in consultation, or as I like to say, in partnership with the leadership of the Department of Health. By this means, our deliberations serve to address emerging healthcare issues and initiatives for the benefit of the council, the department and our public. By preparing this kind of recommendation or preparing for today, we are meeting new needs for review and regulatory adoption regarding PCIs, which we'll get to, and also I think the participation of this committee in doing so is of some benefit to our leaders in government and the team here that we count on for so much work, so much background, and so much information. As we all know, as soon as a new charge was adopted, we had some preliminary discussions about what are the changes in health care that might be addressed? It was a very big and long list of many general topics within the Commissioner and Dr. Heslin coming to say a priority really should be how to determine the process and the guidelines and the terms for allowing cardiac, diagnostic cardiac catheterizations. Together with PCI, percutaneous coronary interventions, something that twenty states have already come to, but not yet for us. In doing so, we have to consider such things as the cost to patients, the implications for hospitals that might be moving these services elsewhere, the convenience for patients, and also the matter of life and death. This is in keeping with our charge, which is to address those issues for which the Public Health and Health Planning Council has full responsibility and authority. We've had one meeting to date in early April that gave us sort of an overview. That we know now that last year in 2024, we had 102,000 diagnostic catheterizations across seventy-eight hospitals. In the course of this, 52,000 percutaneous coronary interventions, mostly meaning inserting stents to open arteries that were being clogged otherwise by

arteriosclerosis. Quality data is available, but was never quite as systematic as we would like to see in part because of COVID, in part, because this was not a tightly regulated system in terms of where we move things. As a matter of fact, in the other twenty states that are doing PCIs on an ambulatory basis, there is even more shaky data. Going forward, we will have data by individual physicians to record and analyze the significance that we're now trying to achieve. At our last meeting, all this information and more was presented. Providing us the background information that we need and the background data. As it happens, we haven't learned everything yet. We are today with a new series in part by the two of them and a part by other people with special expertise to give us the kind of briefing we need to come to the right kind of deliberations and then decisions in terms of how to proceed forward. What we need to do is designate what are the appropriate clinical settings, who are the proper patients, consideration of what constitutes appropriate regulatory overview and analysis, data collection, and reimbursement. So also at that meeting, we discussed the process or the stages for going forward. Number one is education and education. We are to do exactly that today. Secondly, our responsibility is to be sure we have stakeholder input. This is really an interactive of the two stages that the stakeholders with themselves provide us lots of information, lots of education that we'll need going forward. Those blend. But then comes development of formal recommendations by this Planning Committee for presentation to the council with an aspiration to have that achieved by December before year end. Cross our fingers. Subsequently, there are periods of statutorily required time for public input, for stakeholder input, and so the eventual adoption may take something more than a year. Hopefully, we can keep it, or not we, but the department can keep that as short as possible. Along the way, this committee will have the opportunity to consider what other topics should we go forward with as time goes by in this ever-changing health care system of ours. If there are corrections, more advice, we'll have that all along the way but feel free at any time to raise a hand, speak into the microphone, and give us your wisdom.

Dr. Rugge Hearing none of that, I think it is time to go to approval of the minutes of April 9th, three months ago.

Dr. Rugge We have a motion from Lindsay.

Dr. Eisenstein I have a concern about the minutes, please.

Dr. Rugge Please tell us.

Dr. Eisenstein Yes, I would just like the comments attributed to myself to be amended for what I actually question. One of the bullets under Section B on the minute's reads, "Dr. Eisenstein acknowledged that through literature search there was very little information out there aside from what has been mentioned." I think it's important that my question was specific to the safety of doing PCIs. I want that to be reflected in the minutes. I'm hopeful that through this process and what we'll hear today and going forward that my concerns will be satisfied. But my point was, which is not addressed in these minutes, it should say, all you got to do is add two words. Dr. Eisenstein acknowledged that through literature search there was very little information regarding safety out there beside from what's been mentioned. Because my whole point was about the safety and that word doesn't appear. If we could amend that, please.

Dr. Rugge So under way.

Dr. Eisenstein Thank you.

Dr. Rugge It's being done.

Dr. Rugge Any other improvements, changes, corrections?

Dr. Rugge Do we have a second from you, Dr. Eisenstein?

Dr. Rugge All in favor of adopting the minutes as amended?

All Aye.

Dr. Rugge It's unanimous.

Dr. Rugge We're moving on to Roman Numeral I, Part C, the introduction of our meeting topics and Ann Monroe is another Chair. We'll be doing a walkthrough of those topics so we kind of are currently aware of what is coming in the next few hours.

Ms. Monroe Thank you, John.

Ms. Monroe Thank you, Dr. Eisenstein, first of all for reading the minutes, and then secondly for making the correction. Safety is really important.

Dr. Eisenstein Thank you.

Ms. Monroe John mentioned that our first step in this is education. Some of us are clinical, some of us not. I have to confess, I wasn't quite sure what PCI stood for because that's not my area of comfort or significance. I wanted to say a couple of things before we go into the agenda itself. There are two different types of interventions that we are talking about. It's important for us to keep them separate because we may want to move faster on one of them than the other, or not at all on one of them and the other. The first is diagnostic, which means, and I had one of these, they go in and look to see if there's a problem. Simple, no problem, done. That's called diagnostic. The next is PCI where they do something, put a stent in, go in and do some other kind of complicated intervention. Again, as I said, it's important as we go through this to keep the two separate because they go down different paths, sometimes different people do them differently, sometimes locations are different for the two of them. It's that we keep that in our head. This session, I'm going to run through the agenda very quickly. We have pieces of the agenda will be put on the screen so that those of you who are not in the room will be able to track the agenda as we go. John mentioned that the first step is education. It's very important that this committee made up of a variety of different people have a common level of understanding of all of the things we're talking about, how many, where, safety, quality, access, all the various components of what makes a strong and good regulation. We need to all be on the same page for that. I ask those of you who are clinically trained to allow some of the rest of us to learn that, but also for you to look at some of the more population or community concerns that some of us who come from that perspective might have. This whole session is really on education. I want to thank Eugene and Abigail. We have people from other states who are going to be calling in about what they do. We're going to have people give us whatever data is out there and we just need to absorb that, ask all our questions. Make sure that when we leave the room today, we have a pretty basic understanding of both kinds of procedures and what kind of consequences or implications they may have. Is that pretty clear to everybody? We've done Roman I, good for us. We're now going to hear about the New York State regulatory process, hospital regs, and the framework for cardiac quality.

As you look at what I call, we all have in front of us, I call this the mall map. You know, here's the mall. Where are we? I think we're going to hear from you that we're not on here. Oh, we're on there. Good. I just couldn't read it. I just couldn't not read it. Anyway, we are going to hear first about what the regulatory process looks like and what happens after we make our recommendations, and where it goes. For those of us who tend to be more impatient about getting through things, I've learned the regulatory process is not something we can move through quickly. We can follow it and know where our recommendations are. We're going to hear from the department about how the current hospital regs related to this. Currently, as you know, these procedures are only done in hospitals in New York. We'll hear about that and as much as they can tell us about safety, quality, et cetera. We're then going to hear about from various actors in the picture what other data they have. All along the way we want to hear our comments and questions so that they can be summarized and spoke. What else do we need to know about this in order to be successful? I think that walks through the agenda and the topics that we're going to talk about.

Ms. Monroe I'd like to turn it over to Jason Riegert who's the Deputy Director and part of the Program Council Department. He's going to walk us through, for those of us who are not familiar with the rule-making process, anything we do will enter the rule making process. What is that? How long does it take? Who's involved? We're waiting for you.

Dr. Rugge Just as a brief interruption. Over and over again, Ann has told me how important it will be for me to eat the microphone. She doesn't need a microphone at all.

All (Laughing)

Dr. Rugge Anyway, Jason, thank you very much for being here.

Mr. Riegert Thank you for having me here.

Mr. Riegert Thank you for that introduction too.

Mr. Riegert We will talk about the regulatory process, also on the agenda to talk about the PCI regs. One of those, I drew the short straw. We'll see which one now. The regulations, I can say that self-proclaimed expert. The PCI regs, specifically is where I drew short straw. Our attorney that is much more knowledgeable about them is on vacation in Spain. I hope she's enjoying it and hope everybody enjoys it. I don't know who can advance the slide.

Mr. Riegert Just as a baseline, so when we talk about regulations, you probably hear statute, regulations, right, these terms. New York State Constitution is really the overarching authority that provides the legislative authority to the legislature. When we're talking about regulations, we really need to be specific in that we have statutory authority. You might hear that term to promulgate the regulations. Luckily, the legislature is fairly generous, and they give us plenty of statutory authority especially when you're talking about PHHPC in general.

Mr. Riegert If we want to go to the next slide.

Mr. Riegert Yes, thank you.

Mr. Riegert This is where you know the council comes into play because when the Department of Health is delegated the authority to promulgate regulations there typically

are two kinds of regulations. There are regulations where it just says the Commissioner promulgates regulations and then there's ones where either they're the council promulgates the regulations with the Commissioner's approval or the council adopts them or the council is consulted, right? With PHHPC specifically, PHHPC's authority to promulgate the regulations is probably. I don't want to skip ahead on myself here. I'll just kind of finish this slide here. The statutory authority is going to depend on the language that we're looking at. Typically, we have the PHHPC regulations are we like to try to group regulations together just to make it a little more user friendly if you will. We have a lot of regulations in the sanitary code, which you'll probably hear. Obviously, the council should be familiar with that. Some popular ones are like Part 405. When you're talking about Part 405, which we'll dig into in a minute. That's really specific to general hospitals. 415, nursing homes. When you're into like the 755s, that's where you're talking about diagnostic and treatment centers. A lot of the 700 regs are a lot of the CON regs, but basically the way that they're grouped is really just to make it more user friendly and that sort of thing. The example that I have up here were when we did regulations for the general hospital clinical staffing committees because specifically Public Health Law 2805T said the Commissioner shall promulgate regulations. However, PHHPC has authority to promulgate all regulations that pertain to Article 28 facilities, right? That's hospitals, diagnostic treatment center. That's one where even though the legislature says, oh, the Commissioner can do this, we're always sort of looking at we still need to get PHHPC involved because we're relying on that broad authority, which if we go to the next slide, I think that will be helpful for us. When we're dealing with the state sanitary code, that's when we were looking at Public Health Law 225, and that's pretty broad authority there to deal with any matters affecting the security of life or health or the preservation and improvement of public health. PHHPC did some masking mandates back in the day. We do communicable disease regulations through the council. All of those are really coming mostly through that sanitary code Public Health Law 225 authority. Anytime we're doing facility regulations and we're dealing with the general hospitals, the nursing homes, diagnostic and treatment centers, ambulatory, surgery centers, all of those, that's when we're looking at 2803 for PHHPC's authority to regulate facilities. That's just sort of like a very general, quick overview of just that authority.

Mr. Riegert If we want to go to the next slide.

Mr. Riegert As far as the actual process, and we can break down this map. I like that. A lot of the work is done on the front end by the Department of Health. When I say that regulations are promulgated by the councils, different councils can do things differently, but the vast majority of the work gets done by the Department of Health, right? Some councils will make recommendations to the Department of Health, some councils will vote and put things together as sort of rough drafts and bring that to the department. A lot of that work is being done by the department.

Mr. Riegert Did you have a question?

Dr. Soffel I do.

Dr. Soffel Jacob, could you go back one slide?

Dr. Soffel Denise Soffel, council member. I'm noticing the difference in the language between the first and the second bullet. One says authority to establish, amend, and repeal. The other one says adopt and amend. Is there a distinction in the difference?

Mr. Riegert I don't think so. How I would probably write that off would be that the 225 is a little more antiquated. That's sort of like the original that was talking about the Public Health Council. I think that that's really the nuance there. Please don't repeal the sanitary code. You could certainly repeal provisions of the sanitary code. I think you'd still have that same authority. We would say that amend would allow you if there were certain provisions of Article 28 regulations that you wanted to repeal. We could certainly do that as well. As far as how the regulation is developed, there's a lot of work that happens and looking at the mall map in a second, really everything is done internally up till almost like the middle of that mall map there. A lot of the work done with the program staff, gathering that sort of expertise in the field, working with stakeholders, doing all of that. Once there's sort of rough drafts, that's when the program staff will get their office level approvals and then send it over to my bureau, Bureau Program Council, where we're working on them to sort of make sure that terms are consistent, make sure that terms well-defined, make sure we're within that statutory authority to do whatever it is that we're trying to do or. A lot of times if there's a sort of a change in the legislation where it says you have to do regulations on clinical staffing plans. Are we meeting all of those goals of the statute? Once we sort of get that legal approval, everything gets moved up, we'll get the Commissioner, you know brief the Commissioner, make sure that he or she is aware of the regulations and approves it, and then that's when it finally can leave the department. Within the Department of State, there is a Regulatory Review Unit. They're reviewing a lot of the financials, which we'll get into, and ensuring that it applies with the Administrative Procedure Act, which we will get into a little bit. We're going over to the Governor's Office, making sure that they're on board with everything. There'll be communication throughout, but it's definitely, there's a lot coordinating, a lot of planning that goes into that.

Mr. Riegert Now, if we want to go to the next slide.

Mr. Riegert There's a few different kinds of regulations. Typically, we'll just go through sort of the normal process, right? The normal is you're putting it out for a sixty-day public comment period. We are assessing all of those comments, addressing them, and then determining whether or not we can adopt the regulation as is essentially. If revisions are needed, that's where we get into revised rulemaking. If after that sixty-day public comment period, there are additional changes are needed. Sometimes you get a comment, and it says maybe for PCI or something. No spoilers. The current regulation says you have to do thirty-six emergency procedures a year. Maybe if we get comments and people say we think it should be a hundred a year. We sort of are looking at that. Actually, that does make more sense because of those comments that we received that's when we put it out for revised rulemaking. Revised rule making is essentially triggered when there's a substantial revision. Essentially, anything that's more than just clarifying. Anytime we're adding, deleting or changing material terms within the regulation that's going to trigger in addition to the standard sort of sixty-day public comment period, that's going to trigger a forty-five-day public common period. That's all in the mall map that we'll get to next, which sort of makes it extra complicated.

Mr. Riegert The emergency rulemaking, again just thinking back to COVID. I was before the council many times with emergency rule making so that the idea there is that the rule is necessary for the preservation of the public health safety or general welfare and that complying with that sixty-day public comment period would be contrary to the public interest, which is just a really fancy way of saying we need this rule to be effective immediately. When we file that with the Department of State it immediately goes into effect. It's only a temporary rule. It's only good for sixty days. We can sort of renew that. However, that's the idea there is that it's so needed that we just have to skip the sixty-day

public comment period and put it out there. The final one there is consensus rulemaking. I don't think these PCI regs will fall into that, but the idea of there is that if there's such a rule that no one could possibly object, you'd be surprised. Someone can always object. If there's such a rule that no one could possibly object, it allows us to do less of the regulatory impact statement. That's less of sort of the financial analysis, the cost analysis. There's still a sixty-day public comment period. There's still an opportunity for comments. The regulation there that comes to mind we just recently passed... I want to say at the last PHHPC meeting. It was essentially a cleanup type of rule where we went from a two-year schedule to a three-year schedule and then we missed one reference. We already changed that rule last year. We just missed that one additional reference in the regulation. No one objected to it. We were able to use consensus rulemaking in that instance.

Mr. Riegert Now turning to this chart, and I know I'm going kind of quick. Turning to the chart, if you're looking at it, the primary thing you want to look at is the green bar in the middle. The green bar in the middle sort of takes you through the process start to finish. I think it's one, two, three, four, five, six. It's like the seventh, the seventh one, almost right in the middle there is when it's leaving the Department of Health. Everything before that is an internal sort of process of review that it's going through. This is a great time to get input from stakeholders and the council's recommendations. It's very flexible. This is sort of when we're actually developing the regulation. We're doing the legal review. You'll see the RAC, which is the second one which we'll get into in a minute but that's sort of like an internal committee that will discuss the ideas behind regulations. That's all internal. You'll see towards the middle, it says RRU. That's that Department of State Regulatory Review Unit that I mentioned. The regulation is leaving the Department of Health. It's going over to the Department of State for an initial review. It goes up to the Executive Chamber. We're getting Governor's level approvals for the regulation. You'll see that red sixty days right in the middle. That's when we're filing it with the Department of State. It will get published in the state register. Once it's published in the State Register, that triggers that sixty-day public comment period. If you follow the line from there up to the blue box, that's where I said that PHHPC is mentioned. You guys are on that second level there of the mall in the blue box. This is where we're presenting the regulation to the council for the first time. All of our regulations are going to get brought to the Public Health Planning Council twice. The first time is for information or discussion. I always forget which one is which. Essentially, if the regulation has already been filed for the sixty-day comment period it's for information. If it has not yet been filed for the sixty-day public comment period it's for discussion. Those are the ones where we're presenting it. We're bringing it to the Codes Committee. Well, the Committee on Codes, Regulations and Legislation, rather. I'll use the full term. For information, for discussion, that's that first time reading. I think that Jeff Kraut has mentioned it before. I think it's almost more important sometimes to try to get the committee's input and get the council's input at that point because either it hasn't gone out for that sixty-day public comment period or it's about to go out for that sixty-day public comment period. Again, thinking back to the revised rulemaking it's not impossible to change it, but then if we're doing changes after it's already been out for that public comment period, that's when we have to go and assess whether or not a new public comment period is necessary.

Mr. Riegert Yes, go ahead.

Ms. Monroe We have the Planning Committee spending this time on this topic. I assume that our recommendations will go to the council. The council will have those recommendations before this whole process starts. Where do our recommendations enter this system?

Mr. Riegert Sure, that's a great question. I mean, what to me makes the most sense, right? You could certainly make recommendations at any point in time to the council, to department, and then from the council to the department. At any in this process, we always welcome comments. It would be towards the beginning of this green chart is where it's most helpful because that's when we're actually developing the regulation. To the extent that right now we have a blank canvas of sorts. We need to determine what we want this to look like. The earlier in the process we get those recommendations then it's just going to jump start the whole thing. It'll make it easier to actually effectuate the changes. Obviously, the regulations, when they come back will read how you anticipate them to read.

Ms. Monroe Thank you.

Mr. Riegert No problem.

Dr. Heslin Specifically it would probably be in the second and third box.

Mr. Riegert I think that's right.

Dr. Heslin Concept memo which should be our first formal into the regulatory process. Box two and three would be where these recommendations would go for the department to build out the regulatory package before it went to Jason's team for making it legal.

Mr. Riegert Yeah, I think that makes a lot of sense.

Mr. Riegert If we jump to the next slide, right, which is codes and counsels. I have a little asterisk next to the Regulatory Advisory Committee. You just mentioned that Dr. Heslin. The Regulatory Advisory Committee is just an internal sort of group of individuals within various departments or within various divisions and bureaus of the Department of Health that will where if you have a regulation that you're working on and you're developing, then you can present what we call a concept paper or concept memo, which I think would actually be probably similar to the recommendations that you all would make here, right? Where essentially you're saying, this is the current state of affairs. This is what the regulation says. We are in the process of putting together amendments that will do X, Y, and Z. The benefit of that regulatory internal committee essentially is that maybe there are Medicaid implications that the Office of Health Insurance Program can then opine on that the facility folks may or may not be aware of. We'll have regulations that deal with reproductive health. We have a division of Family Health, and they might have opinions on that, and different stakeholders might have opinions or really just to ask questions, right? Not necessarily poke holes, but make sure that people are thinking about the regulations more holistically within the whole department. Sort of taking down those silos and thinking about it that way. I think we got to the Codes Committee within PHHPC and then obviously everything will have to come before the full council for adoption and approval.

Mr. Thomas Good morning. Just a quick question. Hugh Thomas, a member of the council. So, just thinking through this, the Planning Committee, which I don't sit on, but I'm learning is sort of operating within the first two, because it will inform all of you, Department of Health leadership on substantive questions, quality, patient safety, things like that before it goes to the Committee on Codes, Regulations and Legislation.

Mr. Riegert Yes, that's definitely accurate. It'll inform how we're actually developing and drafting.

Mr. Thomas In some respects, and this isn't intended to be provocative, the Codes Committee, in short has the real official first bite at this. Would a sixty-day comment period go out before the Codes Committee had heard?

Mr. Riegert It can.

Mr. Thomas It can.

Mr. Riegert It happens.

Mr. Thomas Likely or not?

Mr. Riegert I think it depends on the need for the regulation, the time, the overall timing. The council, fortunately or unfortunately, depending on how you want to look at it meets five times a year. Sometimes just to kind of get things, we have to put them out for public comment period because there's not going to be another council meeting until September now. That's sort of the unfortunate side of it. I think ideally we would love to be able to bring everything before it goes out for public comment because if there are cuts. There's certain things where we'll say we have to hold this. It's too important too vital to get the committee's input on certain regulations. I think the CON revamping one that we just did was definitely one of them where it's like we want to make sure that every everyone has a voice there.

Dr. Rugge Just as an additional comment, it seems like my experience with the Codes Committee is presented are fully developed regulations. What the Planning Committee is doing is helping to develop the context, the formatting, and details of all that. Not to copy Dr. Eisenstein, but it might be good to add the Planning to this list because it is interactive and part of the process.

Dr. Rugge But differently than the other committees.

Mr. Riegert To go back to Ms. Monroe's question then, I don't know that the Planning Committee is necessarily on the mall map here. I think that that could be something that we could sort of add to.

Dr. Heslin I was just going to say largely the Planning Committee, if you look at the final portion of the agenda today is looking at all the things that are necessary, that it's important to have public input and using Public Health Council's Planning Committee to get that input. It helps to develop the reg. It actually is almost before, because we can do all sorts of things from the internal side. If we don't have external input from a group of people that's sort of a formalized group, as opposed to various interested advocates or stakeholders, that's the real purpose of this is to get that. How are we going to do it? What are the guardrails? How to think about it is why this is so important to do this type of work. We might actually need a box that's parallel to or above program in this chart that is Planning Committee, because that's the real purpose of this is to actually have a formalized group that is educated and has an education that's level for everybody in the room to be able to then give good opinions from an independent point of view as opposed to from a specific advocacy point of views.

Dr. Rugge So in effect, the Planning Committee is something of a distillation of having public input. We represent the entire geography of the state. We represent all the various organizations that are regulated by the health department, and also members of the public with experience. This is a preliminary way of going to the public. We are the public.

Mr. Lawrence Harvey Lawrence, a member of the council. I'm really impressed with the mall map here. I will also admit to being a little lost in the mall. In any event, normally when I'm presented with a flow chart or organizational map, I always ask the question about, well, this is the way things are supposed to work. What's in the background? What's the shadow? What are the points of access that are not specifically indicated? Is there an informal process in all of this in terms of access to the rulemaking? Because I think even if you're doing rulemaking within the department, I have to believe you consult with stakeholders' way before you begin the process. There's got to be a thought process in which you're thinking and you're bouncing these ideas off of individuals. It's not just within the confines of the department, but you're reaching out. Is that reflected? Where is that reflective in this?

Mr. Riegert That's a great question. I'm not sure that that's necessarily reflected in here. I think if we go to the next slide, I don't want to skip ahead. One of the things that we are required to do pursuant to the State Administrative Procedure Act is that outreach and participation. There have been legislative updates to the Administrative Procedures Act that now require more outreach and education than have previously been required. A lot of that happens in that development stage, so as we're developing the regulation. A new regulatory package comes from I don't know I'm going to get say three things. One is the legislature, they pass a bill, they say you need to make regulations to do X, Y, and Z. They sort of give us a general outline and then we maybe meet with stakeholders, meet with regulated entities, and sort of figure that out. Certainly, this committee could have a role in that. There have just been changes, maybe federal changes or changes like here in the actual safety and efficacy or what have you where it's sort of... Now it seems like a good time to update the regulations. That certainly happens as well. It's a sort of little bit of a mixed bag between the two. I think I said there were three, but I think those are probably primary that where the impetus is either some change in the law or just sort of change in external factors. Certainly, outreach and participation has become a much bigger point for the department in recent years. That really happens primarily in the development of the regulation as we're sort of drafting that and doing that stakeholder engagement and stakeholder outreach. I know with the Health Equity Impact Assessment regulations we'd had countless meetings with stakeholders on those before we even started putting pen to paper. In addition to that then there's the public comment period where it's sort of open invitation and anybody can write in and comment. As part of that process, we're required to read and assess all of those comments, respond to all of these comments. If somebody doesn't like something, we have to say either justify it or agree with them and change it or consider that as part a future rule. In that sense, it's iterative, if that makes sense.

Mr. Robinson If I can just sort of add, and in a way add to Dr. Heslin's comments. The role of the Planning Committee is, I think also important because there are things that come out that are something short of regulation that we actually do. Example would be the guidelines for ambulatory surgery and the thresholds for Medicaid and uncompensated care that we develop, and we use, but it's not in regulation. It's a guideline that we put into place. We are forming an Ad Hoc Committee now on long-term care in nursing homes. Likely what we will get out of that is not... Could be some things that might end up in the regulatory funnel, but it could also be guidelines. Ultimately, those things that come out of those Ad Hoc Committees, which I consider to be sort of wings of the Planning Committee

anyway are really intended to sort of... We need to kind of, as we look at this process here, figure out where those kinds of things go, because sometimes it's a kind of like V in the road. Is it a regulation? Is it the guideline? That kind of might not get resolved at the very beginning but could end up like an important issue to consider.

Dr. Heslin I think that's right. Short statement, but I think that's right.

Ms. Monroe Is there anyone else who wants to comment at this point?

Mr. Riegert I'm almost done. How about that?

Dr. Rugge We've got time.

Mr. Riegert There's always more to discuss, but I'm happy to answer any questions. So then as far as the Administrative Procedure Act, right, we talked a little bit about it because that's what dictates the sixty-day public comment period. I think you just touched upon it a little with that comment. That also defines what a rule is, so when that rulemaking process is necessary. We can do guidance to sort of fill in the regulations and sort of say this is what the regulations say, but here's sort of how we are going to be looking at that. That's where the guidance comes in. All of that again is governed by SAPA. As far as what goes with the regulations. Unfortunately, it's not as simple as just amending the text of the regulation and saying, we want it to say this. That's only sort of part of it. We also have to do impact statements. That is a regulatory impact statement, a regulatory flexibility analysis for small businesses and local governments and for a rural area flexibility analysis as well. There is job impact statement, but typically we just do a statement in lieu of, but that's sort of not the point. All of these are where your regulation is going to impact small businesses, which are businesses with 100 or less employees or local governments. We have to do another impact statement. Each of these is looking at identifying the statutory authority, but then assessing the need and the benefit for the regulation, which is kind of akin to sort of like the summary. Why are we doing this? It's very probably akin to sort of when we present the regulations to PHHPC, sort of giving an overview of what the regulation does and why it's needed or will be helpful. We also have to do cost analysis. What are the implementing costs to the state or to local governments? What are the potential cost savings or costs to regulated entities to comply? To the extent that it's optional for them to do that, we'll always throw that in there. To the extent that they actually want to do PCIs in ambulatory surgery centers, what are their potential costs? That could be costs of the regulatory oversight that we might put in there of the space that they're going to have to deal with. We have to try to estimate those costs as much as possible. The impact statements are also looking at paperwork reporting to the department. I know we've moved a lot a lot of things electronically. Any sort of reporting requirements, we would have to explain that. We have to indicate whether there's any duplication or if there's overlap with federal law, so indicating that as well. Also considering alternatives, right? So, there's a section in there where it says essentially we're doing... Maybe we pick a number where you've got to do a certain amount of PCI procedures per year. Did we consider alternatives to that? Did we consider a higher number and a lower number? Why didn't we go with that? All of that information is in the impact statements, as well as what outreach or participation we did with affected parties. What's the potential compliance schedule? Most regulations, we just make them effective immediately, but some regulations, they're sort of a ramp up time. We're identifying all of that information in the impacts statement. I mention that because a lot of times writing the regulation can kind of be the easy part and then now thinking about these broader things and identifying costs and different alternatives that can certainly take a lot of time.

Mr. Riegert Go ahead.

Ms. Monroe I'm not on the Codes Committee. Do they get all of that? The regulation and the impact statements? Are the impact statement in public comment as well as the regulation?

Mr. Riegert All of it gets published for public comment. We make it all available on our website. A nuance is that the state register is a little bit antiquated and can only publish 2,000 words of anything. You've got to do a summary of it. That's a whole other thing. If your rule or any of those impact statements are more than 2,000 words, then we have to do just a summary. We make the whole thing available on a website, which is linked to a couple of slides. The one thing that I just wanted to kind of throw up here about SAPA on the next slide. I think it's important and certainly something that our Commissioner has taken to heart and has impressed upon us, which is to strive to ensure that to the maximum extent practical that rules/regulations are written in a clear and coherent manner, using words with common and everyday meanings. It doesn't always feel that way, but that's the goal there is to try to make regulations sort of simple, concise, easy to read, easy to understand. It's certainly something that we're continuing to work on. It can be very difficult as I'm trying to read some of the terms that are in these regulations. Just something I think I keep in mind.

Mr. Riegert The last two slides, there are really just some resources, websites that I go to all the time. Our Regulatory Affairs Officer does a great job of keeping our website up to date with all of the proposed rules, the recently adopted rules, emergency rules if we have any, so that's always a great resource. Obviously, when looking at the timeline for proposing a rule, we're always looking at the PHHPC calendar because it's so important. We are bringing regulations twice. We're bringing it the first time, again, for information or discussion, and then we're bringing a subsequent time for adoption. Sort of fitting this whole process, fitting the sixty-day public comment period and the presentation to PHHPC twice within those five meetings a year, there's a lot of juggling that happens. At the end of the day, it can just impact the timeline.

Mr. Riegert The last slide just has some, Department of State has some great resources as far as how to actually draft the rules: underlining, bracketing things. It's unfortunately not as simple as just crossing things out and using track changes. It's a little antiquated. We have to use a certain format. I think for purposes of that, hopefully the committee won't have to worry too much about it. Although, if you want to take the pen, I certainly welcome it. It's just sort of another one of the challenges, something else that we deal with. That's the end. I'm happy to answer any additional questions. If you have questions, you can always email me too as well.

Dr. Eisenstein Thank you for that great presentation.

Dr. Eisenstein Larry Eisenstein, committee and council member. Going back to that slide a couple back where you talked about speaking in a coherent and everyday meaning. Earlier in the presentation, you talked the state sanitary code. One of the things that I always found fascinating when I was the Commissioner in NASA for all the years is how much of it is so dramatically out of date. That raises two things. One, an opportunity as the Planning Council, Planning Committee maybe to look in modernizing things like the state sanitary code, which literally there were some rules that were for technique.

Mr. Riegert Milk maids, I see.

Dr. Eisenstein That haven't been used in a hundred years.

Dr. Eisenstein The reason I'm bringing it up is because that's still in regulation, still in law. It could, in a lot of cases impact what we're trying to do going forward. I guess I'm making a plea to... Maybe we can work with the state health department's environmental conference on modernizing things, but I think we also need to be cognizant that regulations that were made in the past don't just go away. Do you have advice as we go forward now? When the state sanitary code was made, cardiac catheterization didn't exist at all. We're trying to build another layer on top of the, I'm going to go back to the mall, to the mall when the foundation may not be able to carry the weight of what we're putting on the top. I don't know. I'm making some crazy analogy now. Do you have any comments on how we as the Planning Committee should be considering what's been done in the past as it relates to impacting us moving forward?

Mr. Riegert I think that's a great point. I don't know that I do, right? I think at the end of the day, you know, it's just a lot of hard work. I think that that's really what it comes down to. I think a really good first step maybe for the committee would be identifying those provisions, right, because sometimes it's sort of like until I'm sort of challenged with an issue and reading that applicable section of regulation it just is sort of sitting there and unused almost in a sense. Or someone's using it at that time. I think the first step really would be identifying those and just saying these are sections of regulation that we've identified as probably needing some update. I think that that could help to at least focus our attention on those areas as a good first step. Really at the end of the day, it's just a lot of hard work of going through the regulations and then figuring out sort of what's the language that makes sense, right? If there's model sort of codes that we can use or what have you.

Dr. Heslin I'll just add to that a little bit. Dr. Heslin, Department of Health. Public Health Law in 1950 was in a book about two inches wide. Public Health Law is now in a library that's about six feet long or seven feet long, if you actually print it all out. Regulation underneath that is orders of magnitude bigger. I agree we have lots of regulations which have the force of law that are old and antiquated. At the same point in time, we'd have to do it certainly in bite-sized chunks looking at where things are important. I sometimes look up regulations from statute, and I'm surprised at what we actually have sometimes that's written down. It's always a challenge to understand how we can try to work on some of these things and also manage new and emerging technologies and emerging ways to do things. Your point is well taken. We have to look reverse as well as forward and then look at how that change would impact all the other changes around it

Mr. Lawrence I guess I'm a little curious about the impact statements because one of the things that I continue to hear around the table is the impact of regulation on long-term care, on hospitals, on the cost of rendering care. With the impact statements, have there been challenges based on the analysis that has been presented in the impact statements? Were those challenges resolved? What happens to an impact statement that someone finds to be, I guess not truly reflective of the impact of the legislation?

Mr. Riegert That's a good question. It certainly has come up. That typically comes up in the public comment period. We'll put the regulation out for public comment. The program will assess what the anticipated cost to the regulated parties will be. A lot of times we get comments that say we're underestimating certain things, right? We're not factoring things

in. What our opportunity in the assessment of public comment is we have an opportunity to go back and update the impact statement or to sort disagree with those comments in the assessment of public comment if that makes sense. Essentially, those typically it comes in the form of a comment a public comment, which is then either addressed by updating the regulatory impact statements or addressed by just sort of acknowledging it in the public comment in our assessment public comment. We feel that our cost analysis is correct, if that makes sense.

Dr. Heslin This is a presentation that we did back in 2017, actually, to the full PPHPC council in their educational session that happened back then. I don't think we covered it in the one this last time. It might be of benefit that we have a more abbreviated full council discussion, because a lot of people here are on the council, but there's a whole other ten or fifteen that are not on the council that haven't had this level of understanding of the entire process. I think it's really important that we have this. What I'd like to try to do is to move Jason onto the discussion of the current regulations that we had for hospitals. It's only in hospitals at this time, in terms of cardiac catheterization and PCI. This is the session that our other council is on vacation in Spain. He's going to do an abbreviated version of that. We may invite back to this committee to do a more in-depth discussion of that exact same thing at the next meeting. Jason, if you could do an abbreviated version of the twenty pages of regulations that got submitted to everybody in full Byzantine regulated language that we've not updated since 2020.

Mr. Riegert I was certainly wishing that this was one of those updated, more abbreviated regulations as I was looking at it for the first time just the other day in anticipation of this presentation. Yes, please bear with me. If you have questions, I will write them down and get back to you as soon as possible as well. As Dr. Heslin mentioned, there's two main provisions that govern PCI, if you will. They're both in Title 10. Title 10, just to kind of continue our other discussion is where all of the Department of Health regulations lie. There's like forty something titles. Specifically, Section 405.29, which sets forth the minimum standards for general hospitals for cardiac services. 709.14, which is more of the Certificate of Need sort of aspect of cardiac surgery centers and cardiac catheterization laboratory centers. I believe both of those were provided to you if you want to kind of follow along. But as far as who, you know, performing PCI, there's essentially two pathways for general hospitals. As you mentioned, it's just for general hospitals. There's the cardiac surgery centers. There's the cardiac catheterization laboratory centers. I don't really have good shorthand for either one, but maybe like cath lab. I don't know. How does that sound? There you go. Surgery centers. The main difference obviously is the surgery centers are performing surgery on the heart, great vessels. They can also do heart transplants if they're approved to do so. Whereas, the cardiac catheterization laboratory centers, again still general hospitals, but they're only performing those catheter-based procedures. There are separate CON processes for each one, which we'll discuss. There's also separate for adult and pediatric patients. Everything is double separated, makes it extra complicated here. That's sort of the general overview. A lot of that you'll find in that definition section of the regulation there and then sort of going down and through the regulation. There's a lot of Department of Health data monitoring, which I think we'll hear from in a bit in a minute. I'm sure will be much better than this presentation. When I say the regulations here, I'm really talking about the 405.29 specifically. This is great. See, you can scroll down a little here. I'll just try to highlight some different things that I think are important. I think the first one is the cardiac reporting system, which is collecting demographic, clinical, procedural and outcomes information for the surgery centers and the cath lab centers on every patient that undergoes a PCI procedure. As part of that, right, these hospitals running these programs are required to maintain any data deemed

necessary by the commissioner of health for cardiac patients that they treat and submit that data to the department, including appropriate case selection and appropriate access to care.

Mr. Riegert Let's see. Going down to the oversight, if we want to go.

Mr. Riegert This is good. This is a good spot. There is the State Cardiac Advisory Committee, which consists of physicians and other professionals. A lot of people want to sit on that cardiac advisory. They do some great work. They are reviewing the existing and prospective services. They really work in tandem with the department. They're also authorized pursuant to the regulation. I can't tell you if they actually do it, but with the department to make site visits, which is unique, and to conduct data and record reviews. The Cardiac Advisory Committee becomes a big part of the oversight here, which I think is fairly unique.

Mr. Riegert Going down to three here. I think this is important.

Mr. Riegert Yep, there.

Mr. Riegert Hospitals that provide these services must comply with, and then there's a cross-reference to 405.22A, which that deals with critical care services. They've got to have critical care services being provided in order to do these procedures at the facility.

Mr. Riegert If we just kind of keep going down, talks about closures.

Mr. Riegert I mean, this just prohibits any of these centers... Centers may be put on probationary status or be subject to withdrawal of approval as these cardiac surgery centers or catheterization labs if they fail to meet one or more of the statutory requirements or are inactive for a period of six months. That's sort of a reoccurring theme here as far as like making sure that they're continuing to do enough procedures and staying active. Inactivity for six months there. There's also language about voluntary closures and just providing sixty days written notice there.

Mr. Riegert If we go down for this next one, is about significant changes to the program and notifying the department within seven days of any significant change to the services.

Mr. Riegert If we want to keep going down, I know, we're going fast. Quality assurance. Hospitals providing cardiac services must have written policies and procedures delineating medical equipment vendor activities in the hospital, that's C9, yep. There's a lot here. They must participate in an organized quality assurance program. For the cardiac catheterization laboratory centers located in hospitals but without on-site cardiac surgery, they have to enter into and comply with a written clinical sponsorship agreement. There's a lot to the sponsorship agreement. We can get back to that too when we go through the CONS provision.

Mr. Riegert Are there any questions? I feel like I'm just like going through it really fast because this is kind of where we're... You tell me when to stop.

Mr. Riegert If you go down to like D, we get into the minimum workload standards. There must be sufficient utilization of the cardiac surgery center to ensure quality and economy of services. The minimum workload standards must be achieved within two years. This is for the surgery centers that the adult cardiac surgery centers have to maintain an annual

minimum of 100 procedures. And for the pediatric cardiac surgery center, they have to maintain annual minimum 75 pediatric cardiac surgery procedures, excluding isolated patent ductus. I think that that is not specific to PCI, because this is for the surgery center. I think it's actually just even more broad than that, if that makes sense. We'll get to the PCI specific in a second.

Mr. Riegert Subdivision E, if we get to there. See, think I did this better for the other part. Subdivision E, yes, it's way down here. That sets for specific criteria for the cardiac catheterization laboratory centers, which I think is more in line or more akin to what we're looking at with the ambulatory surgery centers, at least I hope so. E2 is specific to the cath labs that are PCI capable.

Ms. Monroe You've lost me.

Mr. Riegert I'm not on a page. There is actually where it is. Let me pull it up on here, and I'll see if I can find the page.

Ms. Farrell Jason, can I ask you a question?

Mr. Riegert Oh, yeah.

Ms. Farrell I'm Lindsay Farrell. I'm a member of the council. The source of all of this detail as you're developing these regulations... Are they coming from the medical disciplines? Are they coming CMS? I mean, certainly this stuff isn't all coming from public comment.

Mr. Riegert Oh, no.

Ms. Farrell As you're going to the experts to provide this extensive detail, what would be the experts that you would be relying on?

Dr. Heslin I'll jump in for a second. When these were developed, and this was last updated in 2019. We had gone through what was called a regulatory modernization initiative where we put about 100 people in the room from all walks and venues. I believe Dr. Friedrich was involved with that at the time, involved experts, involved the cardiac advisory committee, involved hospitals, it involved regulators, it involved public advocates, it involved the continuum of everybody. The outcome of that was an update of current regulations that had previously existed at that time. This one was updated in 2019 to reflect changes in the industry that had occurred up to that point. For example, we used to require more cardiac catheterizations in order to stay certified. That number was actually lowered back in 2019 based upon what the industry was saying and also the data supporting quality. The regulation that Jason's going to talk about next, the CON process mainly for the hospitals that do not provide surgical services. In other words, hospitals that do diagnostic catheterization and percutaneous cardiac intervention that don't have surgery on site was updated at the beginning of 2020. That was all an outcome of that 2017 group. What we're essentially doing here this is opposed to running a specific regulatory modernization Initiative in Cardiac Services, which was done then. We're doing that through the Planning Committee. So much like what was done back then, we're going through this committee here to start to get the beginning step of this process. Since we're bringing people in from the outside world, experts, et cetera, we're going to have a robust public comment period that'll probably be at the next meeting to be able to have different stakeholders come in to give their opinions and thoughts so that we can continue to move this forward.

Dr. Heslin Dr. Eisenstein, you look like you have a question.

Dr. Eisenstein A quick comment. It's clear that the Cardiac Advisory Committee is going to have to play a key role. They're the experts. I've been unable to find the list of members on the state website, and for the Public Health and Health Planning Council, you could see all the members who we are, what we represent. For transparency, I think it's going to be going forward really important for us to have, and more important, for the public. We could just ask the state, but for the public to be able to know who this Cardiac Advisory Committee is. It could be I just missed it, but I've tried to look a couple of times, both home and this morning, and I've been unable to find an updated list. I found one from like 2017, but for transparency, I think the public should know who's advising us on this. I just want to put that out there.

Dr. Heslin Sure thing. I'm pretty sure I've seen a more updated list, but we'll take that back.

Dr. Eisenstein It's possible, just if you Google Public Health Planning Council, all of us pop up. If you Google Cardiac Advisory Committee, it doesn't.

Dr. Rugge Harvey Lawrence.

Mr. Lawrence I guess along those lines...any plans to integrate artificial intelligence in this effort?

Dr. Heslin What we're doing is complicated enough to start with. New York State is currently got an artificial intelligence policy, which you can go out and read as a state policy. The Department of Health is currently developing their artificial intelligence policies, and that has not actually been completed just yet. It's being looked at in terms of artificial intelligence. You know, how far is the reach and scope both for our internal use and also external use. There is a whole process being developed more to follow on that. Artificial intelligence is a term of art, I would say. It's an Excel spreadsheet that does formulas, artificial intelligence. Some people would say it is. Some people say there is no decision making there, and therefore it's not. There's a lot of definitional things that have to be defined before you can use the term of artificial intelligence, that's all part of what has to be completed to answer your question in sort of a long-winded way.

Dr. Rugge Just as another quick question.

Dr. Rugge From 2019 to 2020, were referred to various groups like the RMI by the Commissioner. Now, the Commissioner has referred to PHHPC consideration of PCIs in the settings rather than that being a necessary statutory requirement that PHHPC does that address? Is that the case?

Mr. Riegert Specific for PCI, is the question?

Dr. Rugge PCI seems like a natural thing for us to address. I guess what's the source of the authority to delegate it to us. Is it statute or is it the Department of Health?

Mr. Riegert Well, PHHPC has broad authority over the Article 28 facility, so you can always make those kinds of recommendations.

Dr. Heslin This was referred because in the categories that Jason mentioned earlier, you have the statutory change that would have that. There's the second category that there was something that changed either in federal law or in some sort of system that generated a need for a consideration for a service. The change that occurred was in 2018, Medicare started paying for PCIs to be formed in ambulatory surgery centers. The department's been approached by both hospitals and also by cardiologists about the opportunity to have this happen. The decision was made that we would bring this to Planning to flesh out not that it is going to happen because it's already happening, both nationally. We have examples of a micro hospital that has two beds that essentially is starting a cardiac catheterization lab, which we've already approved as Public Health Counsel. What are going to be the guardrails necessary to be able to have that happen. Instead of establishing a separate standalone process that would be outside of the Public Health and Health Planning Council, it was decided that this would be important to do it through our what would be considered a normal and useful process as opposed to a separate Ad Hoc group.

Mr. Friedrich Marcus Friedrich, member of the council. I think this is like a committee.

Dr. Rugge And the committee.

Mr. Friedrich Yeah, and the committee.

Mr. Friedrich This is a great and important question because as I understand that the department does not regulate ambulatory surgical centers, but we are going this route because there is implications on the hospitals. We want regulations around that. The idea is not to regulate ambulatory surgery centers. Do I get that right?

Dr. Heslin No, actually, ambulatory surgical centers are Article 28. As such, they are regulated. We actually at Public Health Council have to approve the CON for an ambulatory surgery center to be able to be built. We do not regulate office-based laboratories as a regulation. We defer to the federal and then can speak a lot on that because I believe her group actually does the office-based laboratories. In fact, ambulatory surgical centers are Article 28's. As such, we do have CON authority. We do, through the Public Health and Health Planning Council approve all of their CONs in order to be able to provide services.

Mr. Lawrence You collect outcome data from all of these ambulatory care centers as well?

Dr. Heslin SPARCS data is collected for the hospitals. It's collected for ambulatory, but it's not in the same level of robustness. We'll talk a little bit about that data collection tool that we have. It's not as robust in the ambulatory world as in the hospital world.

Dr. Rugge Who knew the legal basis for all we're doing is this complicated? Takes this many pages and that long a discussion. Thank you very much.

Ms. Monroe May I suggest that we let you off the hook so that you don't have to go through all of this. We'll look at it carefully and see which pieces seem to apply the most to us and kind of create a higher-level document than these two very well written but very dense pieces of the regulatory book. Is that all right with you?

Dr. Heslin I was hoping Jason would spend thirty seconds on PCI, because that was the part that we were actually going to function on. In terms of the CON for PCI under 709.14, that's where you want to spend a lot of time thinking about because that's going to be the regulation that most reflects what might be considered in ambulatory services.

Ms. Monroe Would you please tell us where that is in these two documents?

Dr. Heslin Jason.

Mr. Riegert I will just high-level touch finish off this last one. Because you're right. I want to get to where it's more applicable. I think as far as the staffing requirement. Without even following along looking at the staffing requirements for these PCI cardiac catheterization labs. They've got to have board certified physicians. Each physician is supposed to perform 75 total PCI cases per year. They'll have to have at least three cardiac interventional cardiologists. Those are all performing 75 PCI cases a year, 11 of which are emergency cases. They also have to have a data manager. I think that's sort of important with what we're talking about. Those are probably things that you'd be looking at. They've got to have set patient selection criteria. That's probably another thing that would be important to consider having appropriate policies and procedures in place for determining appropriate care and interventions. The big one, too, right, is that the PCI capable cardiac catheterization laboratory centers must maintain a volume of at least 36 emergency PCI cases per year. I think this is what you referred to, Dr. Heslin, where the 2019-2020 regulatory update changed that to really focus on the 36 emergency PCI cases per year. There's also a provision within that same 405.29 regulation that talks about if the centers are experiencing an annual volume of less than 150 cases per year or less than 36 emergency PCI cases a year for two consecutive years, then they have to procure the services of an independent physician consultant. I believe that the old regulation that once you fell below the threshold, that was sort of it. That's also like a newer nuance to it.

Dr. Heslin I think that you're right. We should move on, but I think it's important to understand that there'll be differences between these and what might be considered an ambulatory surgery center, because typically ambulatory surgery centers would be scheduled. They don't do 24/7 work, so there'll be material differences to consider. This could be considered a good general template of where we could start to build. But in lieu of time, I want to thank Mr. Riegert for doing a yeoman's job of presenting something that he learned two days ago. I'm not sure that I could have done that, but very, very appreciative of. We will take back for consideration for the full council going through the full mall map with maybe some additions on where Planning might fit to the full council for an educational session.

Dr. Heslin I'd liked to introduce Dr. Alda Osinaga and Kimberly Cozzens who are from the Office of Health Service Quality Analytics and our Cardiac Services Program. They're here for a repeat performance. Last time when they presented they presented some interesting information regarding cardiac catheterization, PCI, percutaneous cardiac intervention. There were a lot of questions. We hope people enjoyed and digested some of what they gave us last time. They're going to give us some more information today, both about the program, some of the definitions, some of history, and then also how the program had operated. They're also gonna present to us constraints as to what they can do now different than what they could do based upon the sunset of both grants and also programs that don't exist anymore. As with everything, we have lots of information, we have changes, and there are constraints on what we can and cannot do. It's important that

people understand what we do and what we cannot do because that's gonna make a difference in terms of how we build out rule sets.

Dr. Osinaga Hi again, everybody. It's nice to be back here. Thank you for having us back.

Ms. Monroe Could you move the mic closer, please?

Dr. Osinaga If we can go to the next slide.

Dr. Osinaga The one before that.

Dr. Osinaga Just wanted to introduce ourselves again. Thank you.

Dr. Osinaga My name is Alda Osinaga. I'm the first person listed on this slide. I am one of the Medical Directors in the Department of Health. I'm a Chief Medical Officer of our Office of Health Services Quality Analytics. I'm also the Director of the Clinical Center there. The clinical center is the center within this office that works closely with our cardiac services program.

Dr. Osinaga I going to have Kimberly Cozzens introduce herself next.

Ms. Cozzens My name's Kimberly Cozzens. I'm the Program Director for the Cardiac Services Program. I'm at the University at Albany College of Integrated Health Sciences.

Dr. Osinaga Remember, this is a partnership that the Department of Health has had with SUNY for many, many, many, years and so we'll be presenting again today. I'll start the presentation. I'll hand it over to Kimberly and then I'll close the presentation. What we wanted to concentrate and thank you Dr. Heslin for introducing us is to speak about when we think about moving, if we think moving PCIs or diagnostic catheterizations into ambulatory surgical centers what kind of things we have to think about in terms of quality and safety. We're going to present today. We're going to start with a background again on just what are catheterizations. Kim will then go on to give some data on that. We figured that it would be nice to give you a sense of what we do currently regarding monitoring quality. Go into that into more detail, then we will speak about the history of the waiver program that happened more than twenty years ago when it was decided that PCIs could be done in a hospital that did not have surgery staff on site and what was done then. Because we figured that if we could give you a little history of what was done before, and this is where Dr. Heslin said we'll talk about what we did then and what is not available now. There were certain circumstances then that had different programs available. We did want to provide that historical insight. We'll close with things to think about. We wanted to start thinking about what we need to think moving forward. We'll go through things that we think all of us should be thinking about as we think about moving a service outside against ambulatory surgery centers.

Dr. Osinaga We can go to the next slide.

Dr. Osinaga Again, we're going to start with some background. This is just a recap. I think we already spoke about this earlier. We wanted to talk about again what we mean when we say cardiac catheterizations and what we what we means by this when we're presenting. Cardiac catheterization is a general term for a procedure where a catheter, and that's this thin flexible tube is inserted in a blood vessel. It usually goes in the arm, usually in the wrist or in the groin. It gets passed up to the heart. It is either used to

diagnose or to treat heart disease. I'm going to give one more nuance than what was discussed earlier. When we think about diagnostic catheterization, we say it's to diagnose heart disease. One of the things that can be used to diagnose is coronary heart disease so that's a disease in the coronary arteries. The coronary artery are the arteries themselves that feed the heart muscle. That's one thing that the diagnostic catheterization can be done. It can be gone to go in and look at those coronary arteries. It can be down for other things. It can be done for things that aren't even looking at the coronary artery. You can look at the right heart of itself and then look at pulmonary arteries to see if you have any pulmonary disease. You could just look at left heart to see how your left heart is pumping or your valves in there. The reason I stress this is because when we think about diagnostic cath, I think there will come a point where we will say if we allow diagnostic catheterizations to happen in the ambulatory surgery center, are we going to say any diagnostic catheterization, or are we gonna limit to specific diagnostic catheterization? In the context of PCI, PCI is only an intervention. It's to treat a specific kind of heart disease. That is to treat heart disease that happens in the coronary arteries. Remember, the diagnostic cath can go in and see the coronal arteries and see if there's any blockages. The PCI is an intervention on that. You can do a balloon angioplasty. You can put a stent in. Again, that PCI is an intervention of coronary artery disease. It is one part of the diagnostic cath in a catheterization. I'm gonna pause there and see if anybody has questions. If not, we're going to go into some data next.

Ms. Cozzens Thank you.

Ms. Cozzens To give a little bit more thinking about the diagnostic cath and the PCI, a little bit of the landscape here. For diagnostic cath hospitals, there are 85 hospitals in New York State that perform diagnostic catheterization. Eight of them, to the best of our counting are diagnostic only, meaning those are hospitals that have a cath lab but do not also perform PCI, strictly diagnostic. We have 77 hospitals in New York State that perform PCI. 37 of those have cardiac surgery on site. Thinking about our number of procedures for 2018, this is the last time we had a sort of overall. We had an aggregate cath summary, where we did an annual survey of diagnostic cath hospitals. That was discontinued after 2018. These data are a little bit old. At that time, what we gathered was that there were almost 103,000 diagnostic cath procedures without PCI. At that time, about 46,000 were the PCI and the diagnostic cath were done at the same time in the same visit to the cath lab. That was just about 150,000 total diagnostic caths. Looking at the PCIs in 2024, which we get this data from our clinical registry of the PCIRS reporting system, there were about 52,000 PCIs in 2024. Another difference between diagnostic cap and PCI that's interesting or important for our purposes is what data we have available, which we've already touched on. In New York State, we do not have a clinical data registry for diagnostic cap. We do for PCI, which means that for PCI, every single one of those procedures, as Jason described from the regulation, there's a requirement to report data for every reported case. We will talk about that in a little bit more detail. We have rich clinical patient level data, facility and physician level data for all PCIs. We do not for diagnostic cath.

Ms. Cozzens Next slide, please.

Ms. Cozzens This is just to give you a sense when we're talking about PCI of a little bit more about just the overall mortality rate. We've used our draft data from 2024. PCI is done for a variety of indications. There are patients that come in with really an elective presentation all the way up to patients in a very critical life-threatening situation, very high-risk emergency situation. The outcomes obviously depending on the kind of presentation for the patient are very different.

Mr. Friedrich Can I just jump in for one second?

Mr. Friedrich Marcus Friedrich, member of the committee. Since we don't have diagnostic numbers, and I feel this, you know, double the number of diagnostic and then like the total number is like a third of PCIs. Is there any reason for us to think that this ratio will change in 2024? I'm asking maybe Dr. Puma or whatever, because like whoever I talk to in the PCI community, they say this ratio is still probably relevant, that they are about twice the number of PCIs on the diagnostic side. I'm just curious, even though we don't have like very detailed data...do you think this might or might not be like a real number?

Dr. Puma That's an excellent question, Dr. Friedrich. Kim and Dr. Osinaga presenting pretty robust data because New York State was the first. It's been over thirty years now that we manage this data. The reason initially cardiac catheterization wasn't monitored is because cardiac catheterization was considered a low-risk procedure at the time. It was never part of the data sets. PCI data has been collected since 1991. I'm gonna present a little bit later that as Kim was saying, we do PCI for coronary heart disease for multiple reasons. As we see here, about 5% of PCIs done in hospitals today are for acute heart attacks, ST elevation, or very critical non-ST elevation MIs. What I suppose we'll see, or I'll show you is about 40% are done for patients who get admitted through the emergency room with an acute coronary syndrome, but then the remainder are elective outpatient procedures. Of those, as I'll you almost 40% are either normal or less than 20% coronary disease. That may be the underlying reason. If you see this data, which is incredibly robust, non-emergency PCI in this state, this to me is a success of the Department of Health in New York State that the monitoring program and the data collection, nonemergency PCI in hospital mortality is 0.35%. That's quite low and suggests that the quality has significantly improved. If we looked at the 91 to 93 data, it would be a very different data set.

Dr. Heslin I just wanted to finish with Dr. Friedrich, there's going to be a presentation a little bit later today by Beth Israel Deaconess Medical Center from Harvard. They looked at the entire Medicare data set for 2020 to 2022 for PCI and PCI for ASC. They may actually have an answer to your question because they also looked at the data set for diagnostics. They could give us, at least through the Medicare data, as a take back question because I don't think it's in their presentation, the ratio of diagnostic versus PCI for the entire Medicare data set, which would be a useful proxy.

Dr. Eisenstein Just to clarify on the data, so somebody is brought to the emergency room with excruciating chest pain, and the decision is made to do catheterization on them. It turns out to be completely clean heart. It's gastroesophageal spasm or whatever. Is that counted as emergency or non-emergency, because they present it as an emergency, but it turns to not be a heart emergency? I know a lot of people who have had that experience especially in our 50s. Where does that go?

Ms. Cozzens In that case, the patient did not have an intervention. They didn't have coronary artery disease, so they didn't need a PCI, and they would not be included in these data that I'm showing here because they had only a diagnostic cath.

Dr. Eisenstein Okay, and I get that, and it makes sense, but there's a lot of those. I think when we look at the big picture, we do need to consider the role of the emergency presentation, regardless of how it turns out.

Ms. Cozzens Yes, and I think that's something that the committee would think about in terms of patients that are appropriate for even consideration of treatment in an ambulatory surgery center. A patient that comes with that kind of presentation and symptoms, probably they should not go, they would go to a hospital where there's a full range of services available for whatever that diagnostic procedure shows because they're in an acute situation.

Dr. Eisenstein Maybe part of what we've discussed is we're talking about access. This is an access issue. In places like on Long Island where you can trip and fall into a hospital, that's fine. In more remote places, I think we were talking about what's the role for non-hospital scenarios?

Dr. Heslin I think these are all really important questions, but we still need to get through the rest of the education. And as Dr. Rugge said earlier, we have to go painfully slow to, or no, as Ms. Monroe said earlier we have gone painfully slow to get everybody educated at the same level before the doctors in the room can start.

Dr. Eisenstein I'll be quiet.

Dr. Heslin No, no, no. Don't be quiet, but we doctors are not known for our patience, just let's say, but others are better at that.

Ms. Cozzens Picking up from there, this is really just to demonstrate that there's broad differences based on patient presentation and the outcomes for patients. Our non-emergency, when I talk about non-emergency here, this means a patient that has not had a heart attack in the last 24 hours, has not had cardiac arrest and is not in cardiac shock. There's still some very sick and very acute presentations within that group of patients. It's clearly not just elective PCI. One of the things that we have been doing with our data is trying to look at what is the group of low-risk, non-emergency PCI within New York State right now that may be meeting those criteria for ambulatory surgery center patients. We've been using the Society for Cardiovascular Angiography and Interventions Expert Consensus Statement among other documents and beginning to gather input from our Cardiac Advisory Committee to develop some criteria that we could apply to our data and then have a cohort. We can look at outcomes specifically for these low-risk PCI patients. These are patients that are suitable for planned PCI. They don't have acute coronary syndrome, meaning they're not having a heart attack. They don't have a recent heart attack or unstable angina, which is chest pain that's new or getting worse. They don't have co-morbidities that might require that extra support that's available in a hospital. They don't have complex lesions that suggests should be approached with caution. We've built this sort of low-risk, non-emergency cohort of patients based on real patients that receive PCI in New York State. Again, this is quite preliminary. We're still working on these criteria. I wanted to give you a flavor of what the outcome for those patients appears to be. Using our data from 2022, there were about 6,600 PCI patients that met these criteria. That's 13.7% of all the PCIs that were performed. They also have very low rates of in-hospital death or complication, as you might expect, based on the way that the group was defined. In our cohort, we saw one death. That's 0.02% observed mortality. That's two in 10,000 patients, roughly. There's rounding there. We saw that there were 52 patients or 0.89 less than 1% of patients had a reportable complication such as stroke, myocardial infarction, that's a heart attack, coronary occlusion or perforation, bleeding, or an emergency cardiac surgery or PCI. Quite a low rate of complications as well. In our data, we see that 59% of these were discharged on the same day as their PCI. This is an area that we're continuing to explore. We have some very recent analyzes. We've looked at were these patients already

in the hospital when they had their PCI. Maybe there's another reason that these were not. We don't have intention to treat. We don't have intention to treat as a same day discharge. We only know that they were a same-day discharge. We're using our data to look for some other clues that might help us better understand what characteristics of these patients predict a same-day discharge. Things like clearly not being admitted the same day as their PCI. That would not be a group that we would include in here. We're revising this. We're also looking at things like time of day. So, for example, these patients had their procedure starting from very early in the morning all the way up until after 6:00pm. Clearly, that's very much related to if they're going to spend the night, which is what we were looking at. This length of stay is very much evolving, but something we continue to look at. We're also looking at the access site, whether it was a femoral access through the groin, or whether it is radial through the arm, which is related to whether these patients spend the nights. Again, we don't know that the hospital intended to release them in the same day. There's a lot of variation around that, but to give us just a little bit of a sense of just based on how it's been defined less than sixty percent stayed over.

Dr. Osinaga Before Kim moves on to the next slide, just want to make sure there's two take home points, I think, from this that I want to stress. We start out, when we think about all the PCIs that were done in the year. You started with 48,000. Try and think about who an appropriate patient for an ambulatory surgery center might be. You get down to something about 6,000. Just to think about what percentage. Does that mean that those 6,608 patients were appropriate? We can't say for sure. This is just trying to think about what we have in our data and trying to estimate here, but just to give an idea, it's not everybody who goes for a PCI that we think would be an appropriate candidate to go to the Ambulatory Surgery Center. Again, just on that last note here, about the 59% were discharged the same day. Remember, if you're going to Ambulatory Surgery Center, you'd want to be able to go home the same day. There's a percentage there even of these that we try to find in our data that stayed overnight. We're trying to figure out more about that to understand that a little bit better, just to try to characterize this more. I wanted to give that sense of an idea about how many PCIs might be able to go over to an ASC.

Ms. Cozzens I'll move through this part fairly quickly about our data collection validation feedback. The PCI system, as previously mentioned, was established in 1991. Our process, there is a two- to three-page form that is completed for each case by staff at the hospital. That data collection includes patient demographics, clinical risk factors. We know the cardiologists that perform the case. We know information about the areas of the heart that were treated and how they were treated, as well as complications that were experienced during the hospital stay. The data are submitted quarterly through a secure DOH data collection system. It is due to us thirty days after the end of the quarter that the patient was discharged in.

Ms. Cozzens Next slide, please.

Ms. Cozzens For validation, we have very robust validation processes. We look at completeness and accuracy of the data in a number of ways. This includes checking for inconsistencies in the data as it's initially presented to us, as well as fields that are missing. We report the data that have been reported to our registry to that that's been reported to SPARCS for a bit of external validation for completeness and accuracy. We review medical record documentation to assure that the risk factors have been reported accurately. We also obtain our primary end points of in-hospital or thirty-day death and readmission from the New York State Vital Statistics and SPARCS. We use an external source for those final end points.

Ms. Cozzens Next slide, please.

Ms. Cozzens One of the things that we really try to do with the data throughout the entire life cycle of the data from when it's first collected until that final publication as we try to use the data and work with hospitals so it can be a QI Quality Improvement tool. We have some immediate feedback reports that we do with raw data. As soon as the data is committed to us, hospitals receive what we call patient profiles, which allows them to benchmark their results against New York State results. We do quarterly or semi-annual reports for STEMI patients. STEMI is a certain kind of heart attack that's been very well documented as time to treatment being really important for outcomes. We look at some processes that may be opportunities for improvement within hospitals. We feed that back against statewide benchmarks to hospitals. We will also periodically do other feedback reports. A fairly recent example had to do with Ad Hoc PCI. Ad Hoc PCI is PCI performed at the same time as diagnostic cath. Based on a study that we did, we provided hospitals with some information about their rate of Ad Hoc PCI for some patients that guidelines suggest may benefit from consideration of cardiac bypass surgery. Ad Hoc PCI, there are some questions about if there were treatment choices that were fully explored when Ad Hoc PCI is performed. That's an example of how we use the data to feed it back to hospitals immediately or relatively soon after collection. We also do a fairly extensive quality improvement work around what we call our alert letters. Twice a year we look at raw data that's been reported to us. We notify hospitals when we see that the observed mortality rate for that hospital is two and a half times the New York State rate. There's many reasons that that may occur. This is not risking adjusted data. This is just completely observed mortality rates. We send that to the hospital. We notify them. We ask them if they've identified any issues within their own data review that may have contributed to this elevated mortality. We ask that to see the summaries of their mortality reviews. We collect patient level specific data information about those cases. That's reviewed by the Cardiac Advisory Quality Improvement Subcommittee. One of the key things that we're asking our QI Subcommittee to do there is say based on the material that we've received from the hospital... Is there evidence that they have a robust QI process in place? That if there were an opportunity for improvement, they have done a thorough examination to be able to identify that? We provide feedback to the hospital based on any findings from the Cardiac Advisory Committee. That may be questions, that may be follow up, suggestions. We can have continued monitoring if there are concerns that may not have been addressed.

Ms. Monroe Is that data or that publicly available, so as part of a report card or patient that patients can look at?

Ms. Cozzens The publicly available data is, and I'll speak to that in a second, we do have publicly available data that assesses hospital outcomes for PCI. We look at mortality and readmission for every hospital that performs those cases. There is a little bit of a data lag on that. Before we put anything out in the public domain, we want to make sure that we've done all our validation and confirmed that and gotten that very reliable outcomes information. That information that's available is more statistically robust. It is completely validated. That's what we make available to the public. There is a lag. Right now, we have the 2021 data is in production process to be released, 22 will follow shortly after. It's usually a couple years of lag between the data that's reported and what's published.

Dr. Soffel As I understand it, what you do is you verify that there is a QI process in place that is adequate. You don't look at what quality issues might have been going on at that facility that led to poorer outcomes.

Ms. Cozzens It's really both. It is reviewed by cardiologists and cardiac surgeons. They will look at those specific cases. Their first question really is... Has the hospital done a good job of reviewing these cases and exploring all possible contributing factors? They'll look at that. If they feel that that hasn't been addressed, then they may have questions or suggestions or concerns. It may have to do with preoperative assessment and procedural planning. Sometimes they will look and have some technical concerns about choice of approach on a particular procedure. They may also look at things about post-operative care. They do look at those things, but really it's first through a lens of have they been able to demonstrate that the hospital is engaged in this QI review.

Ms. Monroe Just a comment. If I need a PCI, I guess, and I live in a place where there's more than one option. I look to see performance, I'm gonna see performance from four to five years ago. Three to four years ago, right? There's no way of knowing that that's reflecting the performance of today.

Ms. Cozzens That is one of the limitations. We do feel that that information... It's a good starting point for those kinds of conversations that then can take place with your referring physician, your care team.

Mr. Perry Just have a quick question.

Mr. Perry Stanford Perry, member of the committee. Is there a look back from the advisory committee to determine if the feedback was actually implemented by the hospital?

Ms. Cozzens There are, depending on the findings from the Cardiac Advisory Committee, we will ask for a follow-up. It might be in six months. It might an immediate follow-up about sometimes a hospital will say, we're implementing this new process. We will follow up. Did you implement this process that you've planned? How is it going? We do these mortality reviews on a semi-annual basis, will be able to observe if the mortality rates have improved over time.

Ms. Farrell Lindsay Farrell, member of the council and the committee. Have you ever asked the hospital to cease performing the procedures as a result of poor review of their data?

Ms. Cozzens There have been a number of situations where hospitals have sometimes voluntarily or sometimes in another manner had to suspend or change their program activity. Typically, that does not happen through the cardiac advisory committee and QI work. If there are very serious and grave concerns that the Cardiac Advisory Committee observes through this process, they will be handled through the Office of Primary Care and Health Systems Management. When it really becomes a regulatory enforcement, there might need to be a site visit looking for certain sightable problems.

Dr. Heslin The short answer is yes.

Dr. Heslin We're approaching time. I would ask for discretion so that Ms. Cozzens and Dr. Osinaga could get through the rest of their presentation and then we might be a little bit late for break if that's okay. Thank you so much.

Ms. Cozzens Next slide, please.

Ms. Cozzens This is referencing our public reports that we've already spoken about that are available online. Also, at the time that a new report is published, any hospital that's a high outlier, meaning has been identified with mortality or readmission that is statistically higher than the New York State rate, we do notify the hospital CEO and Program Director, so that they are aware that those findings have been found and made public.

Ms. Cozzens Next slide, please.

Ms. Cozzens We wanted, as Dr. Osinaga mentioned, to give a little example of a historical process that was used.

Ms. Cozzens Next slide, please.

Ms. Cozzens This is during the period from 2000 to 2008. We had, when there was not regulatory authority for PCI at centers without cardiac surgery on site, the department issued time-limited waivers that was first for primary PCI and then for full-service PCI at these hospitals, and that's what I'd like to just talk about for a moment.

Ms. Cozzens Next slide, please.

Ms. Cozzens This started with primary PCI. Primary PCI is a reperfusion. PCI is the primary reperfusion strategy for ST segment elevation MI, which as I said was a specific kind of heart attack where very rapid treatment is shown to improve outcomes. It might seem a little bit counterintuitive that the first group of patients that were allowed to be treated with PCI Centers without the cardiac surgery backup were these high-risk, more acute cases. The rationale behind that is the risk-benefit ratio. It made sense at that time. This was sort of an uncharted territory. The benefit to these patients of closer access and more rapid availability of getting that intervention outweighed any risk, was more in balance without weighing the of having PCI at a site without cardiac surgery. That's where that began. At the time, very much involved with this process was the Atlantic Cardiovascular Patient Outcomes Research Team Registry, CPORT, as it was known. This was sort of happening in multiple states. There was a movement to be able to do PCI in hospitals without cardiac surgery on site. The CPORT participation was central to the development of our waiver process as well as the subsequent monitoring. The way this worked is there was a Cardiac Advisory Committee work group convened to develop recommendations and guidelines. That was Cardiac Advisory Committee members as well as a couple of consultants, which included the principal investigator of the registry as part of that group. They looked at recent studies. They discussed models about how it was being done elsewhere in the country. At that time, there were only recommendations in the proposal stage from American College of Cardiology. They looked at those guidelines as well. They came up with a recommendation for a six-month time-limited waiver to allow primary PCI at hospitals where very specific criteria were met. They also developed patient selection criteria, implementation requirements, and a monitoring plan.

Ms. Cozzens Next slide, please.

Ms. Cozzens That criteria was quite detailed. Some of the things, these were only, the only sites considered were those with existing diagnostic cath programs that had been in existence for at least three years, had good results, and at least 400 diagnostic cath a year. They needed to be able to provide the appropriate equipment, they needed the administrative support, and they needed to demonstrate sufficient anticipated volume to perform at least 36 PCIs in a year. They also needed to have a plan and a commitment for

primary PCI as the routine or preferred intervention for STEMI on a 24/7 basis. That was really quite an administrative, that's very resource intensive program to launch and maintain, as you can imagine.

Ms. Cozzens Next slide, please.

Ms. Cozzens Other parts of the waiver criteria. They needed to have in place a plan for immediate surgery backup with a maximum transport time of one hour. They needed to test and demonstrate that that plan worked. They needed have an affiliation agreement with a high volume, high quality cardiac surgery site which included issues of credentialing and training, quality reviews and a transfer agreement. There were specific requirements about physician experience in volume to be performing PCI at those sites. They also, importantly, needed to agree to participate in the CPORT Registry with all of the associated data reporting and requirements of training for CPORT. Of course, they were also reporting to the PCIRS registry.

Ms. Cozzens Next slide, please.

Ms. Cozzens When this was implemented, the waiver was reviewed by DOH staff and the clinical consultants, which is that CAC Subcommittee. If those criteria were determined to be met, the hospital could proceed to the enrollment. That involved two to six months of training and protocol initiation before they could even begin performing the PCI. Once they said that the hospital was ready to begin, then the department gave the all-clear that they could start performing cases. They performed 10 cases initially. If they could demonstrate 10 cases with good results, as agreed by review performed, then they began unrestricted recruitment.

Ms. Cozzens Next slide, please.

Ms. Cozzens Once they were performing primary PCI without cardiac surgery on site, there was an extensive monitoring program in place. We looked at processes like door to balloon time and door to thrombolytic time, that's time to treatment for patients that were and were not eligible to receive PCI. We looked overall institutional volume. We also looked at outcomes, death, myocardial infarction, or heart attack, stroke, and significant bleeding. Any adverse outcomes needed to be reported within 72 hours of the event. Other data was reported on a less time-limited or immediate to time basis. Data were also reported to the PCI reporting system. Every six months, these results were reviewed by CAC and DOH.

Ms. Cozzens Next slide, please.

Ms. Cozzens There was also mechanisms for termination. At the discretion of the Department of Health, based on the recommendation from that CAC group or the Project Chairperson, the program could be terminated for any number of reasons, volume, outcomes, non-compliance with the requirements, et cetera.

Ms. Monroe What result was there from all of this?

Ms. Cozzens After a number of years of primary PCI through a waiver program, then it was expanded to allow full-service PCI or elective cases as well at centers without cardiac surgery on site. That also began as a six-month time limited waivers. And then in 2009, there was major regulatory changes that provided a regulatory pathway for hospitals to be

able to obtain operating certificate, have cardiac cath on their operating certificate without PCI on site. They no longer needed to go through that waiver program. We maintain now the monitoring piece, PCI sites with and without cardiac surgery. We monitor in the same way, that six-month review that I mentioned.

Dr. Osinaga This is our final section here. These are the things to consider for cardiac catheterizations and ambulatory surgery centers. Just before I begin, I wanted to mention that we have already met with a Cardiac Advisory committee just once with some of the members to start this conversation. We've asked them two questions. We've asked them who are the appropriate candidates to be in an ambulatory center and what safety and quality guard rails would be needed to be put in place? We don't have recommendations on them. Like I said, we had just one meeting, but we plan to continue to meet with them and ask them those questions. Those are the recommendations we've asked them to come up with. What I did want to talk about today are already the things that we think we need to ask ourselves and ask about. A lot of these came up during these meetings with the Cardiac Advisory Committee. Some of these things are a reflection of what was done in the past. Some of these things are things that I already mentioned in some of the guidelines out there. We're going to talk about three things; case selection, program requirements, and then monitoring.

Dr. Osinaga This is the case selection slide. When we think about this who are the appropriate candidates for catheterization in ASCs? Things that we'll need to consider are the type of procedure and the approach. We talked about this a little earlier. Is it diagnostic catheterization? Is it PCI? What kind of diagnostic catheterization? The approach is talking about whether you go in through the wrist, through the arm, or whether you're going through the groin, because there's different recovery times from each of these things, so those are just different types of things, and thinking about timing and how long a patient will need to be monitored afterward. Thinking about patient risk factors and comorbidities because that determines what risk you might have for a procedure. Are there some patients that would be safer to do in a hospital setting versus an ambulatory surgery center? The type of lesion. This is also sort of similar to patient risk factors and comorbidities, depending on what lesion is suspected that you have in your coronary arteries. Perhaps, you would want to do the procedure in a setting where a person can be monitored overnight. Thinking about post procedure, and this is the care and access to further care, thinking about patient selection and does the person have somebody to take them home after the procedure, to be with them for the time right after the procedures and the access to the further medical care. If something happens and a complication happens, where is that person located and where is the nearest hospital and how far is that? Those are sort of things to think about in case selection.

Dr. Osinaga For the next slide, that's for program requirements. What will we require of the ASCs in terms of, should we think about the experience of the interventional cardiologist? Will there have to be a level of experience of the people working of the cardiologists working in the ambulatory surgery centers that we want to have as a minimum floor? What equipment will need to be available? Staffing, and the regulations themselves right now talk a lot about staffing. We spoke about that earlier. Volume threshold will there be some sort of volume, minimum volume for physicians and for the ambulatory centers themselves. Will there be a requirement? What kind of requirement for transfer agreements and transfer time or distance to the hospital with surgical backup? Thinking about surgical consultation. When you're doing a cardiac catheterization depending on the results, you may want to speak to a cardiac surgeon to see is this person more appropriate for cardiac surgery instead of having a PCI, and how will that

happen, and the timeliness of that, and who will you be working with? Data reporting, this is a big one. What kinds of data are we going to be asking for at what interval? Who's going to do it? Quality assurance, thinking about will there be anything that we say about ambulatory surgery centers, and what kind of QI activities they're going to have, who they're gonna have that with, what kind monitoring they should be doing.? Should they be doing case reviews and for what and how they're going to be looking at that? Thinking about credentialing of the providers in the ambulatory surgery centers. How is that going to happen? Details on that. Thinking about program requirements, these are what we think are the questions to think about establishing as we think about this program.

Dr. Osinaga The final slide is about monitoring. What will be monitored? How will it be monitored? Things to consider our outcomes. What kind of outcomes will we be monitoring in for procedures that are happening in an ambulatory surgery center? What data will we need to be able to produce outcomes and outcome results? How will we monitor that the centers are adhering to patient selection criteria? One of the things they'll have to establish is who can go there, right? We talked about that earlier. How will we know that the centers are following that and also following any of the other program requirements? How is that going to be monitored? How often? By whom? Thinking about volume, especially if there are thresholds being if their thresholds in place how will we be monitoring the volume. Those are some of the questions to think about. Like I said, we don't answer yet. These are things that we are working toward.

Dr. Heslin Thank you so much. We're going to break for a break for little while. I just want to preview the afternoon just a little bit so that people know what we're looking at. At 1:30pm sharp, we're gonna have a group from the Smith Center for Outcomes Research from Beth East Real Deaconess Medical Center speaking. The reason why that's added in at that time. Dr. Dangus is an intern who is a research fellow over there. She's taking a break from her internship for the doctors in the room. It's hard to take a break from an internal medicine internship when you're on a floor to be able to do a presentation to New York State from Boston. We're moving things around just a little bit to accommodate to Dr. Dangus' schedule. That'll be at 1:30pm. And then after that, Dr. Puma, whom is at the table with us will be presenting. We have a group from Indiana who runs a freestanding ambulatory surgery center. They've done about 1,000 cardiac catheterization procedures since they started. They're gonna give us their experience on how they got started, how they work with their local hospital. What they look like in terms of their data, complications, et cetera, as at least an on-ground experience of a currently existing center. I'm going to present a little bit on what we have in terms diagnostic catheter utilization in New York State by region, and then a quick look on that. That's gonna look like what the afternoon's gonna look like. It is a revision to the Ambulatory Surgical Center Update Agenda. Given that we're a little bit delayed in our break, I'd ask if people were back in the room by 1:20pm if possible, an extra five minutes on that end, and then we'll get started at that time if everybody's okay with that. Thank you.

Dr. Heslin Good afternoon. We're gonna be resuming the Public Health and Health Planning Council, Health Planning Committee meeting. I know people are still enjoying some of their lunch and thank for getting back here. Just to recap this morning, we had Mr. Riegert present on hospital regulations, and then we had Dr. Osinaga and Ms. Cozzens present on our Cardiac Advisory Committee and some of the work that they're doing more to follow. Briefly, I just wanted to start over the next four or five minutes to talk a little bit about what we started to talk about this morning, which were some of criteria and questions that you might think need to be addressed. We don't have a lot of time at this moment to go through that whole piece. What I'd ask you to do is to start to write down

things that are of interest. Anecdotally, different people have brought things to me. Dr. Eisenstein had talked to me a little bit about how we might look at where this would be done and how this might impact hospitals and systems. Dr. Friedrich brought up the concept of having some Ad Hoc groups working on different aspects of how we might pull all of this together. So, write down your questions. Start to think about not only how we will manage this, but as you listen to the presentations that we have this afternoon, starting off with the presentation from Harvard, the Deaconess School, think about what might be questions we want to ask that group, same for Dr. Puma and his presentation, then ultimately the same for the Quincy Medical Group, which is a group from Indiana that will be presenting about their cardiac catheterization experience. One note, I did put in front of the members one presentation that I had forgotten to print. I apologize for that. That was the presentation that appeared during lunch. There is another presentation in front of you. Someone asked me why all the paper. I hate when electronics goes away. Therefore, I print a lot. I apologize for the environmentally unfriendly way of doing this, but better to have the information in front of you. I do see that we have some of the members of the team from Harvard on the line. Can you pull up the entire?

Dr. Rugge I will confess that I took a quick look at this, and I thought it said, oh my god, ASC.

All (Laughing)

Dr. Heslin There you go, it stands for Quincy Medical Group. We have about four minutes before we expect Dr. Dargas to be able to be on the line to be able work and do her presentation who is currently online and waiting. If there are any specific questions or thoughts, we'd be happy to entertain them at this moment.

Dr. Soffel Hi. Denise Soffel, committee member. I was just at the end of the last presentation because she kind of got rushed through it at the end. She went through a list of issues that you might want to consider as we consider the issues around moving PCI to an ambulatory setting. I was wondering the extent to which all of the items that she had flagged in terms of the program requirements, the monitoring, if that, all of that information is currently being collected for the hospital-based programs so that we have in fact a sort of a real template that says this is how we ask the hospitals to do it and that would be a jumping-off place.

Dr. Heslin The answer is yes, and that is done with the disclaimer that that is for PCI, percutaneous cardiac intervention, and no for diagnostic catheterizations. One scenario could be that if we were to expand this to ASC, whether they're part of hospital or not, those data feeds into that type of data set could potentially be possible, that's one way to consider how this could be looked at.

Dr. Eisenstein Just very quick, I think we also have to remember, I enjoyed the presentation earlier, but when they made the list of things to think about, it was focused specifically on the cardiology patient and the cardiologist center. I think that we also should be thinking about the impact on healthcare in the community as a whole. There's a limit on nurses and catheterization nurses are specially trained. These are highly desirable. If you have an area of shortage of nurses in the communities and you're pulling them away from the safety hospital, what's that impact? I just want to add as a thought to think about the impact on healthcare as a whole in the community.

Ms. Farrell Yes, I have a question regarding alternative diagnostic modalities. I'm thinking of colonoscopy, for example. There's Cologuard, which is a new diagnostic test that, in some cases, obviates the need for an initial colonoscopies for certain groups of people. Are there other ways to diagnose coronary artery disease? Do you really have to go in and take a look?

Dr. Rugge This is not the last bit of change. It goes on and on.

Dr. Heslin The answer is there are many ways to diagnose cardiac disease, but still, this is a procedure that will not be going away in the near or distant future. It would be one of many tools in the toolbox to be able to look at probably our most, our leading cause of death actually, right?

Dr. Heslin Mr. Lawrence, I thought you had your hand up, but I'm not sure.

Mr. Lawrence I guess when I was listening to the presentation, I had this thought that the presumption, the underlying assumption here is that this is all going to be profitable and so that there will be a rush of people, or I guess physicians going into forming these ambulatory surgery centers. I guess that's one part of it. I guess it will be profitable. The other part of it gets back to this whole question of equity and the distribution of those services, because if in fact we're going to experience a large share reduction in Medicaid and funding for services for underserved people, then who will these ambulatory care centers serve?

Dr. Heslin I'm going to go really quick because our presenter has arrived, but the topics that you bring up are exactly right. In our last phase of the meeting, next steps, we talk about how the Cardiac Advisory Committee might interact with us. You know, what might be a preliminary framework, for-profit, not-for-profit, demonstration versus full state, what are the criteria for that, what would be the Medicaid criteria, how much percentage, those are all questions that we need to flesh out. You're spot on in thinking about those pieces of the thing. We're gonna move very quickly now because of time limitations.

Dr. Heslin For our first presentation, which is Percutaneous Coronary Intervention in Ambulatory Surgery Centers. Dr. Katerina Dangas is a research fellow at the Smith Center for Outcomes Research at the Beth Israel Deaconess Medical Center and a resident in internal medicine at Massachusetts General Hospital. She's an intern right now, has graciously given up a portion of her internship time. I think she's actually in a general medical floor to present to us today. With her is Dr. Robert Yeh, who is the Director of the Smith Center of Outcomes Research and Section Chief of Interventional Cardiology at Beth Israel Deaconess Medical Center and Professor of Medicine at the Harvard Medical School. They have, to my knowledge, got the first data set from Medicare, inclusive of all Medicare patients, regarding percutaneous cardiac intervention and some early data on outcomes in ambulatory surgery centers. I will turn it over to Dr. Dangas and her team to do their presentation today and answer any questions.

Dr. Dangas Thank you so much, Dr. Heslin, for that wonderful introduction and for inviting us to share some of our work with you. I'm Katerina. I've had the privilege of spending a large part of the last year with my mentor, Bobby Yeh, studying cardiac procedures and ASCs. I'm really excited to share some of our preliminary findings with you all today.

Dr. Dangas So for a bit of an introduction, ASCs, as you probably all know, are freestanding centers that provide outpatient procedural care with same-day discharge in

low-risk patients. While they've been around since the 70's, mostly providing surgical care, the reason they're so important now for the cardiovascular community is that the number of cardiovascular procedures in ASCs is growing as technological advancements and optimization of carrier delivery really have improved the safety profile of many of these cardiovascular procedures, including PCI. Just for a little bit of background of what do ASCs stand to offer us. Probably you all know this already. I like to think of it from each stakeholder's perspective; so, physicians, patients, and payers being the main ones. For physicians, ASCs offer more control over schedules and resources that they use, including device selection. They can allow for more procedural efficiency so that more procedures can be done in a day, potentially. The second pillar here is really that they may have an ownership stake in the facility, which might give them some financial stake in the success of the ASC. For patients, they're often lower coinsurance costs and also potentially more convenience associated with accessing procedural care outside of a hospital. For payers like Medicare, they pay less per procedure in an ASC as compared to the hospital, which theoretically promises some cost savings. Most recently in 2020, following the emergence of evidence supporting the safety of PCI with same day discharge in selected patients Medicare has begun reimbursing for a set of PCI procedures and ASCs, namely stents and balloon angioplasty. To begin to establish some guardrails around ASC/PCI has issued statements to guide patient selection, operational standards, as well as provider criteria for PCI and ASCs. They have emphasized that patients having their PCI in an ASC should really have a favorable clinical and anatomical risk profile and should be generally lower risk than those having PCI in a hospital. Nonetheless, the evidence base for ASC/PCI is really exceedingly thin. We sought to evaluate three key issues using Medicare claims. First, this is like the procedure volume trends of outpatient PCI from before and after this policy change and then also looking at the types of patients, the types and procedures, and also the thirty-day short-term outcomes for patients undergoing elective PCI in an ASC compared with a hospital outpatient department. To do this, we used all Medicare claims from both fee-for-service and Medicare Advantage. We use CPT codes to drive our population of patients who underwent PCI. We excluded those patients that had PCI before 2020 and those with codes not reimbursed in ASCs to form a more even outcomes population for ASCs in hospital outpatient departments. Our outcomes of interest at thirty days were standard, all-cause mortality, myocardial infarction, stroke, effusion, hospitalization, oxycyte bleeding, transfusion, and repeat intervention. We have the temporal trend. We can see that from 2018 to 2022, the rate of ASC/PCI, which is the one in the red, is increasing steadily, but it's really small when compared to the number of PCIs performed in outpatient hospital settings. Since the policy change in 2020, actually less than 2% of outpatient PCIs were performed in ASCs, as you can see here. There was significant geographic variation in the rate of ASC/PCI by US state. The darker red states have more procedures. We see that states with higher rates are often those that don't have state regulations restricting ASC/PCI such as Arizona, Louisiana and Texas. In terms of patient characteristics, our populations were pretty similar in regard to age, sex, and race when comparing ASCs to hospital outpatient departments, but more ASC patients were located in Southern and Western regions, and there was also a higher proportion of socially vulnerable patients, which we evaluated using a community level of socioeconomic stressors. It's possible that this is related to the geographic distribution, but we're investigating that still. In terms of the comorbidities, our populations were pretty well matched, but we do see that when we look in the year prior to the index procedure, so right before the PCI, we see that there were some more patients with an MI within the year before their PCI in the hospital outpatient group, but this was still low in both groups. Patients in ASCs were less likely to have had an inpatient visit within a year of the procedure. There were some important differences in the procedural characteristics. So, for example, hospital outpatient patients were more likely to have had atherectomy and

IVAS and FFR. This is really related to the lack of reimbursement for these therapies in ASCs, which makes sense than that they would be more commonly seen in the hospital outpatients setting.

Dr. Dangas We have some of the outcomes. These are just absolute event rates for the outcomes that we've discussed in following PCI in the thirty days after a procedure for patients in ASCs, as well as patients in hospital outpatient departments. ASCs are in red and hospital outpatients is in blue. What we can see is that we saw low rates of all-cause mortality, myocardial infarction, stroke and effusion and tamponade in both groups. These were less than 1% in both group. We do see a slightly higher rate of all-cause hospital admission in the thirty days following PCI in patients in the hospital outpatient group. We do see low rates of axocyte bleeding and transfusion in both groups to less than 1 percent, which is promising. Interestingly, when we looked at repeat PCI, so this is the need for second intervention after the first intervention. We see that the rate is higher in an ASC than in a hospital outpatient department. It's important to note here that in this analysis, we didn't look at whether they were in the same vessel. It's our hypothesis that given the low rate of myocardial infarction that we think that these could be related to staged procedures, which may be more likely to happen in an ASC setting where, for example, a doctor might choose to, if a patient has two vessel disease, they might choose to defer the second vessel to a different day to reduce risk potentially. That's our hypothesis. We then performed some adjusted logistic regression analyzes, which we adjusted for important things such as patient demographics, comorbidities, and procedural characteristics. We found that the outcomes for our adverse outcomes, so mortality, hospitalization, MI, and bleeding, for example, we don't see higher adverse event rates in ASCs. Now, it's important to note that we don't interpret this to mean that high-risk patients would have better outcomes in an ASC than in a hospital. Rather, I think this supports that there currently is sound patient. There may be sound patient selection of lower risk patients for PCI and an ASC in our cohort. Importantly, we do see this higher rate of repeat PCI in the ASC group even after adjustment. Again, we think that this could represent stage three vascularization. We have some important limitations. First of all, residual confounding due to unmeasured covariates is really a significant possibility. We think that patients in ASCs are supposed to be selected to be the lowest risk patients. We tried to account for this where possible, but we aren't able to account for things like anatomical risk and angiographic risk using claims here. This is an analysis of Medicare claims. There's a risk of misclassification error. We only looked at patients who were over 65 and insured by Medicare. Overall, what we can conclude is that the rate of PCI and ASCs is increasing from before and after the policy change, but they still represent a small proportion of outpatient PCIs. Patients in ASCs were more often from socially vulnerable areas and from the South. These procedures, these PCI procedures in ASC's less frequently involve atherectomy and FFR. In terms of outcomes, there were low absolute event rates following PCI at thirty days in both ASCs and hospital outpatient departments, which may suggest sound patient selection. Finally, there's this increased rate of repeat PCI in ASCs, as compared with hospital outpatient departments. Looking forward, national registries may be a helpful mechanism to gather more data from cardiovascular procedures in ASC's that can then be used to evaluate key metrics of quality and clinical outcomes. I want to acknowledge my incredible mentors who really made this possible. I'm glad we were able to share it with you today.

Dr. Heslin Thank you, Dr. Dangas.

Dr. Heslin Are there any questions from the committee?

Dr. Heslin Ms. Monroe.

Ms. Monroe Thank you very much.

Ms. Monroe Very interesting. I was looking at the map of where the states were that these patients and ASCs came from. You can take that back. I assume that those are states that allow ASCs to do PCIs, because most of the states they don't. That's accurate, right?

Dr. Dangas Yeah, that should be accurate. States like, for example, Texas and Florida, as well as Louisiana have no restrictions on ASC/PCI. You see that these are the states with the higher rates here.

Ms. Monroe The rest of the country really wouldn't be measured because they don't allow it?

Dr. Dangas I think that's not the case globally. I think some of the states do allow it, but there are other reasons that it... There are the restrictions. Some states have absolute prohibitions on ASC/PCI as you've alluded to. Other states have Certificates of Needs requirements and other states have restrictions on cath labs that are specific to the state. It's really a state-by-state basis.

Dr. Heslin I'd also add that this data goes through 2022, and that the law was enacted, and this data is from 2020 to 2022, so there's been three more years of advancement since then for the data set. This is work in progress. I wanted to just point out there was another slide in the deck that does talk to the cost slide. I know that was just thrown in for us to look at after the presentation or if there was any commentary.

Dr. Dangas This was an image that I just threw it in in case the issue of cost came up just to give an idea of the per procedure cost to the payer. This is Medicare in this case, would pay for these common cardiovascular procedures in an ASC versus a hospital outpatient department or indeed an office-based lab, which is in green. So, you can see, for example, if you look at coronary stenting or coronary angioplasty in a hospital outpatient department. For a stent, the Medicare will pay about \$10,500 and then in an ASC, it'll be about \$6,600. This is just per procedure. I think we still have to evaluate overall cost-effectiveness as well. This is per procedure what they would pay.

Dr. Heslin Mr. Lawrence.

Mr. Lawrence I'm just a little curious. Did you have any problems with the aggregation of the data across the multiple states? Is there a source of this data that is common to all states?

Dr. Dangas We use Medicare claims. It's a national database. We didn't have to do aggregation of data by states in this case.

Dr. Friedrich Thank you.

Dr. Friedrich One thing to consider is also the influence of COVID. New York State, where there were severe restrictions doing most of like beginning of 2020 or the Summer of 2020 to almost 2021 on at least like elective procedures, especially these years, 2020 to 2022, I feel like at least from data that I've seen in a lot of states are questionable at best. I think like the, the more you look into the data and compiling the data COVID should play less of

a role. I think in these two years, there might be an influence. I don't know how the other states or Texas handled that. If there was at all, any restriction on ambulatory surgical centers or maybe elective PCIs or something like that. That is something when I saw that, I just wanted to mention that.

Dr. Dangas You're 100% correct, and I think that that is definitely a contributing factor for the relatively slow, slower uptake of ASC/PCI. Usually, we do expect a lag from a policy change to the change in practice. It's not completely unexpected that there are certain pockets of the country that have been a little bit faster than others in implementing changes to allow ASC/PCI. This is a moving target. Many states are in the process of making reforms right now. I expect this to only, as you said, as we get further out from the pandemic, we're likely to see more and more procedures moving into the ASC setting. Thank you for that comment.

Ms. Farrell Could I ask about the social vulnerability index? What is it? What are they measuring?

Dr. Dangas The Social Vulnerability Index is a measure of community-level socioeconomic stress. It's at the level of the community. It's a validated measure that the CDC has developed and endorsed. It doesn't really account for individual socioeconomic status, but it accounts for things at the community level.

Dr. Heslin I understand that this was done as an abstract about a month ago, and I understand that a manuscript will be coming out somewhere in the next few months. I don't remember exactly when that was from our conversation earlier last week. I'm looking forward to seeing the full manuscript as you get the data hardened up a little bit more. We would welcome you to come back and if you have more data or more hardened data to do a short update at one of our meetings.

Dr. Heslin Dr. Yeh, do you want to add anything to Dr. Dangus' presentation?

Dr. Yeh I was going to say that Dr. Dangus and our team have a manuscript that will be an overview of the policy and the regulations around cardiovascular procedures in these outpatient settings. That should be coming out within the next two weeks, but it really sets the backdrop for what are the health, policy, ethical, equity considerations for expansion of cardiovascular procedures in these settings. You can tell this is still a work in progress. We're still putting this together. We'll plan to submit the manuscript later. You will have something to look at, it'll be in the Journal of the American College of Cardiology in the next two weeks. And then just your question about the Social Vulnerability Index, it's really derived from measures that come from the American Community Survey. It has several domains, including the socioeconomic status of the population in the community. Some characteristics like single parent households and English language proficiency, the housing and crowding in those areas, as well as the percent of any community that has of racial and ethnic minority status. Those four domains contribute to... Well, don't we go into this community level measure, Social Vulnerability Index, and next to my colleague, Eric, who actually happens to be sitting over my right shoulder here. We're in the middle of doing a procedural day. Has led research that has looked at cardiovascular procedures, specifically the expansion of peripheral vascular procedures into those outpatient settings, which has really been a large movement of those. In fact, I think it might be even the majority of these procedures are done in these office-based labs. In his analysis, those laboratories have really served socially vulnerable communities. It has been one of the things that has been a step forward, we think, was that these outpatient facilities have

increased access to procedures that patients may not otherwise have accessed. Thanks very much for the opportunity.

Dr. Heslin Ms. Monroe has one more question.

Ms. Monroe This was great. One of the things we talked about before you got on the screen was the role of volume in determining outcomes. Maybe I just missed it in the presentation. Did you talk about volume at all today? Will you be talking about in the actual paper?

Dr. Yeh It's a great question. Right now, the volumes of outpatient procedures of this particular procedure are quite low. I don't know if we are there to be able to look at a volume outcomes relationship, but I think it's absolutely germane to our field, which is that the volume outcomes relationship holds for our procedures just as they do for surgical procedures. It will be an important dimension to look at. One complicating issue is that there is a facility volume and then there's a provider volume. Almost every provider who delivers these procedures in an outpatient setting also delivers these procedures in some other hospital. They might take their complex patients to a hospital. They might do their lower risk patients in one of these ASCs. There's kind of two factors. There's the volume of that operator, that procedure list which may be a high volume, even if they have a low volume that they conduct at an ASC. There's the institutional volume or the facility volume of an ASC where the staff may be an issue in their training and just how they do things. It's not something that we've looked at. I don't know that the volumes are high enough for us to start looking at it, but it will be, I think, a really important question to answer.

Dr. Heslin Thank you.

Dr. Heslin Any other questions from the committee?

Dr. Heslin Well, we thank you so much for being here with us today and really appreciate data that is literally hot off the presses and hasn't even been published yet. We feel very privileged that you were able to share that with us and look forward to both of your papers. You're welcome to stay for the rest of the meeting if you'd like to, or if you have any colleagues that would like to be online. Again, thank you.

Dr. Yeh Thanks very much.

Dr. Heslin It's such an emerging field at this point in time that literally I found it the same day that Ms. Cozzens found it. We emailed each other within ten minutes of each other going, gosh, did you see this? We sent out emails. They were gracious enough to answer the emails. We're just fortuitous to be able to have such good community that we can actually have these type of discussions. It really is a testament to how the health community supports each other regardless of what the other noise in the world is. We'll just say that.

Dr. Heslin We're going to move on. Next Dr. Puma is going to be doing a presentation on advancing cardiology procedures in ambulatory surgery centers. Dr. Puma is the founder and president of Sorin Medical with over thirty years of clinical experience. He has published over 100 peer-reviewed articles and has written textbook chapters on this subject. He has held multiple positions, his most recent one is as an Assistant Clinical Professor of Medicine Cardiology at the College of Physicians and Surgeons at Columbia

University Medical Center. Dr. Puma founded Sorin Medical in 2013. It is the city's largest private interventional cardiology practice. We welcome Dr. Puma here today.

Dr. Heslin Thank you, Sir.

Dr. Puma Thank you, Dr. Heslin.

Dr. Puma Thank you for a kind introduction. For inviting me, Dr. Rugge and Ms. Monroe and the rest of the committee for inviting. I come today as the President and Founder of the New York Ambulatory Cardiovascular Society. We are very appreciative to be part of the discussions to help the committee and the Department of Health make decisions on what's the most appropriate use of cardiac catheterization and percutaneous intervention in outpatient center. The society is not an advocacy group. The purpose of the society is actually to educate the department, community leaders, hospitals, and physicians, and actually trying to reduce advocacy because oftentimes advocacy is led by singular issues and not necessarily what's best for the patients in our environment in our community and in our state.

Dr. Puma With that, just some background. I was asked by the committee to do to some degree, a rudimentary background on ambulatory surgical centers. Ambulatory centers are designed for outpatient surgical procedures that do not require hospital admission. Procedures are generally low to moderate risk. That's the expectation. They generally have short recovery times. Patients are all discharged within twenty-four hours. There's no overnight stay.

Dr. Puma There are a number of significant federal and state requirements for ambulatory surgical centers, as you can see. New York State has a Certificate of Need process and a very robust accreditation process of which this committee primarily makes the decision for New York State's process is extensive, both for certification as well as documentation, including architectural designs, the Article 28 license, policies and procedures prior to opening, staff training records, informed consents, transfer agreements with hospitals. This is for any ambulatory surgical center. Emergency management plan, credentialing file. This slide, I could keep reading through it and give you the guideline, but then I'll feel like that very nice lawyer that started this whole thing off. I don't want to hand out three packets worth of information. This should give you a sense of how regulated ambulatory surgical centers already are in New York State.

Dr. Puma ASCs continue to grow nationally. This is just a slide to give a sense of how many procedures. There is clearly a shift as healthcare has shifted from inpatient care, open surgical procedures to largely outpatient, minimally invasive procedures as there have been advances in medical therapy, interventional treatments, laparoscopic surgery, robotic surgery. You can see that in 2022 and 2023, there were more procedures done nationally in ambulatory centers that are done in hospitals. Hospitals are in fact really the industry that's undergoing great change and a great transformation. By 2033, over three quarters of surgical procedures will be done in ambulatory surgical centers in the United States.

Dr. Puma How did this start? Where are we going? I think most of us that have been in healthcare may remember if you're old enough, if you were as old as me, we used to see ophthalmologists and orthopedics in the hospital, but they became dinosaurs in the hospitals over twenty years ago. That was really the initial charge out of the hospital and then gastroenterology and pain management right behind. Many ambulatory surgical

centers started as single specialty ophthalmology centers, orthopedic centers, or pain management, or GI centers. They have an incredible track record of high quality, low complication care. As years have gone on, this is now established, GYN centers, GU centers, ENT, plastics, and podiatry. Current emerging trends, as spinal procedures are becoming far less invasive and minimally invasive, cardiology procedures and interventional radiology procedures. One of the fastest growing procedures, for instance, which are done now in ambulatory centers for patients with knee osteoarthritis are genicular artery embolization's for pain relief as opposed to knee replacement. That musculoskeletal embolization's in an outpatient center are the fastest growing vascular procedure right now in the U.S.

Dr. Puma Where does New York State stand compared to the rest of the country? On this slide, I just took a mix of states that either was similar to New York in size or governance. You can see on the right, per capita, New York is the lowest in the country in in terms of ambulatory surgical centers per capita. We are quite far behind in terms of the number of centers. As I'll show in a minute, in terms where we are procedure wise.

Dr. Puma This slide, and then I'll just go to, this is the yes slide, and this is no slide. If we go back to the yes side, I want to go back the Beth Israel presentation, because I think the timing is critically important here.

Dr. Puma We'll go one more slide past the no slide, please.

Dr. Puma One more.

Dr. Puma Timing is very important. November 2018 CMS added a number of codes to their---

Mr. Robinson You're absolutely right in terms of the number of freestanding ambulatory surgeries centers, but my sense has been that hospitals have created on-site ambulatory surgery centers that mimic the way off-site ambulatory surgeon centers work. Therefore, you know what I'm getting at in terms of the...

Dr. Puma Yeah, no, you're exactly right. This is actually all ambulatory surgical centers. The largest growth, however, is in HOPDs, Hospital Outpatient Departments. That rises faster than independently owned, whether those independently owned are syndicated in a for-profit manner or in some not-for-profit matter. You know, just to give you, for instance, in our society, we have physicians that are independent on their own. We have physicians that now work for private equity. They're in large practices, work for private equity right here, actually in Albany. We have positions that are academic and full-time. Colleagues of mine at Columbia, as well as full-time at other medical centers. You can see that there's really now an entire array of types, but we are still the lowest per capita. The majority of hospital outpatient HOPDs, as this committee well knows is their justification is typically to reserve the hospital for the higher acuity cases.

Dr. Puma We'll move on. This is the yes list. This is to put in perspective the Beth Israel presentation. November 2018, CMS added diagnostic catheterization codes to their approved procedure list for ambulatory surgical centers. In 2019, they added PCI codes to them approve procedure list. In January 2020 was when they approved payment in ambulatory surgical centers. The 2020 to 2022 data, A, there were no ambulatory surgical centers doing PCI in 2020 the initial portion of the data. They used that start time because that's when CMS paid for it. B, Dr. Friedrich is exactly right. That is right in the meat of

COVID. But then, C, we also got to recognize, and I think Dr. Osinaga there mentioned part of it. The startup cost for an ASC, whether it's an HOPD or an ambulatory surgical center are significantly more than a freestanding ASC because of the facility that's required, the cath lab equipment. It's not just a typical operating room. The states that started early were all non-Certificate of Need states. On this list I have in the second column, whether CONs were required or not. There is a significant delay, first delay because of COVID, and then delay because a regulatory and build out. You're gonna see that curve kind of scoop right up now between 2025 and 2030, as many of these states haven't even started. They've approved but haven't started PCI. This is the no states.

Dr. Puma Next.

Dr. Puma We wanted to get back to what percentage of cases in a typical cath lab get PCI. You know, the standard is about 28% of all comers in a cath lab are PCI, 72% are diagnostic only, and 39% are normal, which is defined as either normal coronaries or up to 20% stenosis. The other key thing is even historically, patient satisfaction for ASCs is much higher. I'm not sure if the slides are still in here, but when we talk about equity for patient care, the number one reason underserved patients in data that I have do not enter the healthcare system is fear of the health system itself. Pay an interaction with their healthcare provider. Providing a more satisfying environment that patients would recommend and return to may be one of the underlying reasons the Beth Israel folks are seeing the fact that ambulatory surgical center cardiac procedures are providing equity of care to socially vulnerable patients.

Dr. Puma Next.

Dr. Puma I think the Department of Health actually has all the data, but I wanted to go back to some of the older data because the key here is really understanding the evolution of catheterization, PCI, and what were initially very high complication rates, especially in the pre-stent era in the 80's and 90's, and as well as in an era when we didn't know what anticoagulation to use for patients. I remember when I was a young attending in Durham. The worst service you could be on was the pull service after PCI. You'd go home and your fingers were like a swan's neck from laying on groins all day after you heparinized patients all day long and overnight. The medical therapy has improved. The anticoagulation has improved, the use of stenting and much smaller access sites, much smaller sheaths, and the conversion now, which has really taken place across America from femoral access to radial access. What you can see is that outcomes, whether there's on-site surgery or not are essentially no different.

Dr. Puma Next.

Dr. Puma They're essentially no different. The Department of Health earlier, Ms. Cozzens mentioned the trial. That was literally the pivotal trial that changed PCI in America. And in fact, in our state, with the data that our Department of Health presented, more PCIs are done in facilities without surgical backup today than are done in facilities with in-hospital cardiac surgery. We have more hospitals doing PCI right already in New York. Soon we're gonna have essentially an HOPD, but a mini hospital doing PCI in Lower Manhattan, in Greenwich Village, which by the way, is like a health desert right now. There's about two million people between one cath lab to the next as hospitals have closed in the Downstate area.

Dr. Puma Next.

Dr. Puma This is a summary of a meta-analysis, summary of all evidence for safety of cath and PCI in the outpatient center. As you can see, whether or not there's on-site surgery, the incidence of mortality, or the need for emergency bypass is quite low. In fact, the need for emergency bypass is a thing of the past. Emergency bypass, when the need for emergency bypass or a major complication to interventionalists like me were visceral. When I was a young interventionalist to Dr. Yeh from Beth Israel, that's something he read in a book. It essentially just doesn't happen anymore. In addition, we already have, and SCAI, which is the Society of Cardiac Angiographers and Interventionalists is already far advanced in determining patient selection admission criteria for PCI in the ASC, clinical characteristics that would be contradictions. As you can see, high potassium, high creatinine's, morbid obesity, significant anemia. INR is over 1.8, untreated infections, and the list goes on. These are all pretty well documented. There has been no specialty in medicine more regulated than cardiology and cardiac surgery. In fact, I'm not aware of any other specialty that this state regulates for the last thirty years on every procedure than cardiology and cardiac surgery. My point being is that understanding both the clinical characteristics of the patient and the anatomic characteristics is all well understood in terms of who's high, low, and intermediate risk, who's appropriate for hospital inpatient procedure, and who's for an ambulatory surgical outpatient procedure. This is why we were here. This is what kind of changed the world. Now, let me be clear. In November 2018, CMS added many codes across many specialties. Cardiology is very emotional. When gastroenterology codes change, we don't have big meetings like this. No offense to any gastroenterologist that might be here. When cardiology codes changed, it is very emotion. In part, because it's almost always invasive. It is the leading cause of death in the United States and in the Western world by a long shot, I will add. There is a lot of emotion to it. These are the codes that change things. Less than two years later, they were billing for it. There was reimbursement for it By state, again, going back to states similar in size, but here not necessarily in government governance. Florida and Texas considered red states with no CON laws. Michigan and Illinois, however, blue states, but also approved by regulation. Michigan has already started doing PCI in ambulatory surgical centers. Illinois approved but not yet started, again lending to the delay between this process and then the development and build out of ambulatory surgical centers or the up fit of existing centers with appropriate equipment and the cost to do that.

Dr. Puma I think the Department of Health team, the cardiac team, already discussed some of the issues, but there are significant issues, structural issues that need to be addressed, staffing issues, staffing issues which are already an issue, and we have to acknowledge on the hospital side, although part of the staffing issues on the hospital side while ambulatory surgical centers have anesthesia staffing issues. Interestingly, in this state, we don't have nursing staffing issues because many nurses are leaving hospitals to work in an ambulatory surgical center environment. Again, an issue. The other issue in training, a typical surgical scrub tech in an ASC right now is not a cath lab scrub tech. They're very different. In fact, cath labs have RCIS trained techs, gone through a training program to understand cardiac hemodynamics and valve disease and different issues of that nature. All of these things need to be worked out. Again, as I see this afternoon from this meeting are being thoughtfully worked out by the department. Of course, safety. ACLS certification of staff, which is already a guideline, crash cards, defibrillators, already guidelines. Most important probably, a little firmer transfer agreements and policies.

Dr. Puma Next.

Dr. Puma What are the benefits to hospitals? I think that's really the key thing. I think right now, as many people look at this nationally, and the concern is what will be the effect on already stressed hospitals and hospital systems? They look at it as if it's a zero-sum game. As Dr. Yeh mentioned, and I'm glad to hear my colleagues in Boston looking at these issues, Most of us, at least in the practitioner side of the world on the ground are looking at ways to gain access, or to give access to underserved communities. It's gratifying to see. It's not the number of procedures that are being done today. It's the data we have on the number of patients with disease that aren't getting treated. In fact, if you're able to enlarge your treatment sphere, it would be quite beneficial to your community. Hospitals would benefit just like they'd benefit from any HOPD to higher inpatient capacity, and they could focus on complex interventions and emergent care. It would give them greater financial sustainability.

Dr. Puma Right now, the last slide on the Beth Israel slide, actually I would suggest everyone take a look at that. The cath lab is a low margin high resource utilization center for the hospital. Eliminating especially low margin diagnostic caths and low risk PCIs that don't stay overnight would actually be beneficial for hospitals if they can improve their acuity levels and improve reimbursements. That would also help them solve some of their staffing issues. In the two years after COVID, when I was the clinical chief at a hospital on the Upper West Side, part of a system, we were twice forced to close our cath lab for months at a time because of staffing issues in those hospitals. In that first year after COVID, which all of us lived through and was true misery, you can understand it. A year later, we still went through that exercise because of staffing issues. These are really practical benefits to the hospital. Thank you very much.

All (Clapping)

Dr. Heslin Thank you.

Dr. Heslin I would just like to point out that Dr. Puma came back early from vacation to be here today. We are just greatly appreciative of him coming to give us some overview of the ambulatory surgical center world and also some of the data on ambulatory surgery and percutaneous cardiac intervention. If the committee has questions for Dr. Puma, it would be great to entertain them.

Dr. Heslin Mr. Lawrence.

Mr. Lawrence Thank you, Dr. Puma. Thank you for coming back from vacation. I hope it was in a place that you enjoy going to and enjoy staying at for very long periods of time. My question, listening to you, you're saying that the procedures, one, I guess, low margin for the hospitals at risk. What came to mind is that with the ASCs, essentially you have one door where those procedures could be done in another facility. What happens with those individuals who might be uninsured, might be on Medicaid, and the hospital Many hospitals, especially the safety net hospitals end up being the provider of last resort? They become overburdened, essentially you have ASC serving in this capacity, but they have no responsibility, no obligation to take patients who are either uninsured or underinsured.

Dr. Puma Well, Mr. Lawrence, that's a great question. I know this committee is going to figure out all those answers. I would just say, I live in New York City. I grew up in Brooklyn, in Central Brooklyn. It is underserved. 40% of New York City is either on Medicaid or a Medicaid replacement plan. I might be independent. I am a safety net doctor because of our offices are in communities with high levels of Medicaid. The insurance market is

unlikely to get better. Reimbursements go down. If you look at it from a physician standpoint business...we're the only business where we get paid less every year. Those are all legitimate issues. I'm glad to share, if I'm invited back another time data that I have that the reality of what's happening on the ground is that patients aren't getting treated. The most vulnerable patients are the ones getting treated the least. The amputation rates in Central Brooklyn, where Kings County, and I'm just using that as an example, where Kings County, for instance, and Downstate are. The amputations rates are three times higher for Black men than for white men with the same diagnosis by CMS data. The intervention rates, the treatment rates, prior to amputating are three time higher for white man than they are for Black men. I don't consider that a racial issue. I consider that a life and death issue. I don't consider that Medicaid issue. I think you heard my colleagues from Beth Israel say that at least in the small sample we have from 2020 to 2022 it's the ambulatory surgical centers, Sir, that have been caring for socially vulnerable patients, not the hospitals.

Mr. Lawrence Okay, that may be true.

Dr. Heslin I just want to make a quick response to that. The data there is for places that are very different than some of New York state. Just geographically, for example, in New Mexico, there is one surgical ASC. It's four hours to a hospital. That's a huge SVI area. That data skewing has to be looked at very carefully. I would be a little remiss to say that in New York State, we have four hours to any hospital or any site of care in New York State. The data that they presented is early on, but I'd also be careful about the interpretation of the SVI component of that data. They did put that disclosure in very strongly when I had my preliminary conversation with them.

Mr. Lawrence I guess just being a member of a committee, I mean, when we look at ASCs, they're always struggling to get to, and the question that always comes up is if charity care, and also a question of the percentage of Medicaid patients that they serve. I mean, those are always questions and issues. I guess my question is really whether we are...and I understand taking it out of the hospital, decentralizing. I'm just questioning whether that's going to put even greater burden on the already burdened safety net hospitals that serve the underserved communities of the state and the city.

Dr. Rugge Dr. Eisenstein.

Ms. Monroe Larry, go ahead.

Dr. Eisenstein I didn't know if you were going to answer.

Ms. Monroe Well, I was going to speak to that, but I'll come back to it.

Dr. Eisenstein However you want to go.

Dr. Eisenstein Thank you, Dr. Puma.

Dr. Eisenstein A couple of thoughts as we were listening. As a committee and then the Planning Council, we have to think about the big picture of healthcare, not only how this impacts cardiology and interventional cardiology in the patients. Something that I said earlier, Dr. Puma brought up again, which is the shift of nurses from the hospital where there's already a shortage to the more desirable specialty site. Right now, as per HANYS data, 75% of hospitals in New York State, 75% are either at a 0% margin or losing money.

A huge part of the losses are in labor. I know from my system that's the way it is. Because hospitals have to have nurses, even if they have to go out to high paid agencies and make sure that they bring them in. I am highly concerned about anything that pulls nurses away from the hospitals, most of which are safety net hospitals in New York State. That's something we have to think about even if we say this is a good thing for the cardiology site. Is it a good for healthcare in our state in general? Second quick thought, Dr. Puma brought up regulation in New York State versus other states. I'm a Brooklyn guy myself. We're not gonna be able to change that quite frankly. We got to go through these processes, but that is what it is. What I'm really concerned about, which I brought up last time when we first saw is, and I'm being open-minded here to say let's look going forward. We heard excellent presentations from Dr. Puma and from the Deaconess team, but I'm not sure any of it shifted my mindset on the safety data. What I mean is the Deaconess team as Dr. Heslin just brought up, studied a Medicare, meaning insured population in New Mexico, Louisiana, and Texas, which I really don't think considering the geography and the fact that they're insured is analogous to what we have here in New York. There was selection bias which they acknowledged. Their data is a great starting point. I thought, kudos to an intern for presenting to us. I mean, I really thought it was great. I'm not knocking it. I'm just saying to me that data didn't shift my mindset on do we have safety data yet that's sufficient. Maybe as we do this as a demonstration or whatever, we gather it. You know, the thing with cardiology, every time I was in grand rounds of cardiology and Dr. Puma has lived through this probably more than any of us. You hear about the great studies, Framingham and others, which is how we've understood cardiology based on literally hundreds of thousands of patients. That's how things become the standard of care. Even in Dr. Puma's presentation, part of it's because of the pandemic, but the best evidence we have on this is over a decade old. I would just emphasize, I think these were really important starting points, and I think we should look at it going forward, but I think that we have to be really cognizant of the gap in data and maybe work with the providers to get the data to make us more comfortable. Just my thoughts.

Ms. Monroe Just to expand a bit on what Mr. Lawrence said, I've been concerned for a long time that ASCs are not seeing a representative sample of their communities, which includes a higher rate of Medicaid than we see. I know there's just some recent data because Jeff Kraut gave it to me personally. I have it from the department. I just didn't think to relate it to this, which is that all the ASCs in New York and what percentage of Medicaid they serve, some are much higher than others. We may want to think about in a demonstration to reward those that have already done the outreach that we're looking for in the community with some kind of pilot program or whatever. I mean, I live in Buffalo. There is no room in one of our suburbs for any more ASCs. They are bumper to bumper in that well-endowed neighborhood. They are not seeing the population that you and I are talking about. I think we have to be really careful not to aggravate that problem and leave safety net hospitals, Niagara Falls Memorial Center for example with the low-pay, unpaid need for PCIs. Somehow we have to do a leveling thing as we do a demonstration or whatever to make sure that we're not, as I said, aggravating the problem.

Dr. Rugge Just as an editorial comment, I just have to reinforce that. Like every other part of the decision-making we make, the bigger question is, how do we protect the delivery system, so people are sure of getting care? But then also, how we protect the population, so we know that they have access to that same delivery system? There's no magic answer that we can come up with, but I think we have to address that in terms of a responsibility that all of us should be sharing. It certainly belongs to government.

Dr. Friedrich Dr. Puma, thank you again for the presentation.

Dr. Friedrich One question that this committee has to figure out as well is the question about freestanding ambulatory surgical center versus hospital affiliated. I just wonder if you have an opinion on that from your experience on that. Because that will be one of the major decisions how to allow in what process these centers, independent versus affiliation with the hospital or not. I'm just curious how you think about it.

Dr. Puma I appreciate the question. I just want to be clear neither myself nor the New York Ambulatory Cardiovascular Society is advocating for anything, whether independent or not. I think this process is what's important. Everyone's asking all the right questions. We're going to get all the data to try and figure it out for what's best for the residents of the state, which makes the answer to your question very challenging as well. I think it depends on how you look at it, Dr. Friedrich. One of the other challenges we have in the state is physician retention, and that was one of the points on my last slide that I didn't get to talk about. Physician retention. We have malpractice issue. I run a large practice. It's our largest expense right now. We don't have data. The initial data shows patients getting PCI in HOPDs have a higher mortality than ASCs have higher re-hospitalization rates. Those were statistically significant. They kind of buffered that over a little bit, which doesn't surprise you. They're hospital people. Now, is it because the hospital folks are the hospital docs, and they're kind of doing the same kind of cases or maybe a little bit higher risk? We don't have that data. My goal was to bring up, at least from my perspective, a number of issues. I feel like I failed in convincing Dr. Eisenstein about the safety... That was the thing I thought was going to be the least challenging issue because the safety has been so proven. I got a feeling we're going to come to the right answer. We're going start doing PCI at some point and the state's already robust data collection system for cardiac procedures is going to have a big role in continuing to collect data. That's what's likely.

Mr. Lawrence I guess another for you, Dr. Puma, since you're a cardiologist. Again, this is all sort of predicated on the fact that there's a business model that works. As a novice, I'm sitting here and I'm hearing. It's higher upfront initial costs because of all of the equipment that's needed. You're going to pay more for the staffing because of the technical skills that are required. Does this work in such a way that it can happen with individuals as opposed to an institution? What are the consequences of that?

Dr. Puma Yeah, that's a great question, and I think that some people have some financial models. I can certainly tell you all the large industry have financial models, but don't forget there's a large number of ASCs already. Even though per capita we're lowest in the country, we're such a big state, we still have a lot of ambulatory surgical centers. The upfit costs, right, especially if some of the larger ASCs may not be so great. I think all of these things are gonna be determined. I think many of us are gonna get information from our colleagues in other states. You can see from the data that the Beth Israel folks showed, which is one of the main society for cardiac angiographers and interventionists is at the forefront of this. In fact, their original position paper was in 2012 on this. There's a lot of collaboration going on and a lot of collegiality. I would say that you're probably right, or at least what you're alluding to, Mr. Lawrence, I don't think there's gonna be a rush for a gazillion ambulatory surgical centers to do PCI. I think it'll be a lot more measured. I don't think it's gonna like gastroenterology, let's say, where almost all colonoscopies are done in an outpatient center. In fact, I'm sure that's not gonna be the case... Because of patients with congestive heart failure, complex anatomy, patients that show up in the emergency room with heart attacks, which is the number one reason people get PCI, in fact. I think it's gonna be a balance, but I do think there's a large number of patients we could reach that aren't effectively getting therapy today, and that'll help our communities.

Dr. Eisenstein If you think you have a lot of ambulatory surgery centers, I'll put Long Island up against you any time. Quick thought. It's a question, Dr. Puma, that I'm going to ask you. I'm part of the Catholic Health System on Long Island. We have St. Francis Hospital with some of the leading interventional cardiologists who I'm sure you're familiar with. I met with the team in preparation for this because I want to make sense with what I speak about. A couple of them are adamantly opposed to this on safety grounds. That's where I'm getting my information. To be fair, Dr. Osinaga probably remembers when this came up to us the first time at the last meeting, I flat out asked. I said, I've done literature search. Literature looks kind of scarce on this. I think you agreed on that point. Where I'm coming from the safety point is I don't expect it to be like Framingham. I know we're not gonna have millions and millions. But to me, safety is the deal breaker. If I'm not comfortable that we're first doing no harm, then I have a problem. I'm open to the fact that it's probably okay. We don't practice medicine on it's probably okay, just need to see a little more. My question for you Dr. Puma is, and when this gets to the point of public comment, the doctors from St. Francis are planning on presenting their position on it. I don't want to speak for them. Is there a consensus among the interventional cardiologists that you know and that you've spoken to? How do they feel? I'm talking about in New York because it is such a different environment. The rules are so different. I think it's important to learn from what's happened elsewhere, but it's not always attributable or directly analogous. Even the Medicaid rules are different here. My question to you is, in trying to get me to be more open-minded about this... How do your colleagues in interventional cardiology feel? I only know the people I work with.

Dr. Puma I think hospital-based physicians have a hard time, like anyone, seeing things other than what they're in the midst of right now. Independent physicians would prefer not to have to go to the hospital. It's unpleasant. It's inefficient. Patients don't like it. At least in our society and in this state, everyone has from an interventional cardiology perspective, Dr. Eisenstein, this is the part where I feel like a failure today. We've moved on from the safety. We're not even thinking about the safety issue. We're just thinking about practical issues. In fact, most of us, what'll probably, and CMS, by the way, has moved on. PCI is in their rear-view mirror. All the EP codes are going up for a vote in two weeks, I believe, July 14th. It's not just gonna be PCI. It's gonna be ablations. It's going to be defibrillators. It's going to be paced. It's safe. It's not even an economic issue necessarily. The BI people put up the data. The difference in payment is not that great. If the hospital has an HOPD, they're getting paid more. It's a better cost model for the hospital in an HOPD. It's because the national safety data.

Dr. Eisenstein You didn't fail. You had fifteen minutes to address what I've been studying literally for three months. I don't want you to feel like you failed.

Dr. Puma I almost felt like he was spiking the ball there for a minute.

Dr. Heslin Mr. Robinson

Mr. Robinson Thank you.

Mr. Robinson I was compelled by the broader data that you talked about with the trends towards ambulatory care and ambulatory surgery, and the fact that cardiology seems to be sort of an outlier because of the emotional context associated with anything to do with heart disease, which is certainly very understandable. Our institution in Rochester is seeing somewhere north of 80% of our orthopedic surgery now in ambulatory settings,

including things that were unthinkable five, ten years ago, like joint replacements being done and people going home the same day. It's just remarkable. Ultimately, patient satisfaction, quality, and outcomes seem to actually be moving in a positive direction as a consequence of that. My guess is that even though we have to overcome some emotional baggage that we continue to handle, that this is probably the right way to go over time as well. I think we as a committee, and we think about what the recommendations are that we want to develop, there is the quality issue, as Dr. Eisenstein correctly points out that has got to be the priority. I do believe that question, at least in terms of the data seems to be answered. Some people take a little longer to get to acknowledging that. At the same time, the other things that Mr. Lawrence and others have been identifying really are critical. I think that we may need to sort of like, not bifurcate necessarily, but make a broader decision about what the right thing is for patients and where the best quality care can be driven and drive our decisions and our CON requirements in that direction concurrently. This is where stuff is a little bit out of our control as a council and a committee, the economic transition that takes place as a result of that is something that doesn't always get addressed at the same time. You kept these unintended consequences of doing the right thing. I think if we can push first the department and the state to think about what the real economic consequences are of rebalancing the system and then figuring out from a reimbursement standpoint and other ways how we can ensure the stability of safety net providers and how we can insure better or perhaps even improved access for underserved populations. Those things have to happen. We can't just make the isolated decision about what the right setting is for PCI or certain kinds of PCIs versus everything else. That wasn't a question, but I'd appreciate a reaction to that.

Dr. Puma Well, I think you articulated it quite well. I think that most of the physicians that are in our society and that I work with would actually agree. Most of the positions want to take care of patients. They want to improve the care of their communities and all the patients in their community. We understand the hospitals need to thrive. We want them to thrive, but that's the balancing act that we all live through every day now in healthcare, right? That's the challenge. I think you articulated it quite well, and I appreciate your comments.

Dr. Heslin While we're waiting, we had a little technical difficulty with our last group, so we're trying to get them the link. I want to point out that in your packet, you have the Society of Cardiovascular and Angiography Intervention Physician Statement on the performance of PCI and ambulatory surgery centers when they published this in 2020. When people are talking about SCAI, SCAI it's the Society of Cardiovascular and Angiography Intervention. That has got the list of the recommendations that are in it. That's the most recent thing that's been published on the recommendations. Of course, the Harvard's position paper from Beth Israel Deaconess, as we know, will be out in two weeks' time. Our technical difficulties seem to have become... Have seemed to have gone away because we have our external presenter on screen now.

Dr. Heslin I'd like to welcome Mr. Ted Johnson who is coming to us from Illinois. Actually, they have had an ambulatory surgery center from 2021 doing cardiovascular interventions. Mr. Johnson was an ultrasound imaging tech to start with. He joined the Quincy Medical Group in 2013 and has worked his way through that. He became the department Director of Cardiovascular Intervention in 2020 and built the first cath lab in an ASC in the state of Illinois. He has the firsthand experience of actually developing and building the first one within their state, they do have regulations that they function under. They performed over a thousand cardiac catheterizations in their ASC to date. Their cardiologists work both in their center, which is a multi-specialty center and the hospital, and they do a variety of

different services. Also joining us is Shauna Harrison, she's the Executive Director of Nursing Operations and as such she oversees the clinical delivery of care within the organization. She manages the care delivery teams. She manages quality division and the clinical effectiveness division as well across the suite of services that their Quincy Medical Group provides in their center. We welcome both of them to present to us today here.

Mr. Johnson Thank you.

Mr. Johnson Can you guys hear me okay?

Dr. Heslin Wonderful.

Dr. Heslin Thank you.

Mr. Johnson You gave us a little background. We had the privilege of being the first cardiac cath lab in an ASC setting in the state of Illinois, which as you can imagine were a lot of hoops to jump through. Just kind of give you a short timeline of how we presented. In 2020, CMS approved cardiac cath to be done in an outpatient setting. Our surgery center, which is a multi-specialty center, began construction in 2020. Our cath lab started about midway through that year as well. By, you know, Fall of 2021, our cath lab was finished in construction and we were able to do our first case. First case we did was actually a pacemaker generator exchange was done by Dr. Darien. The first cardiac cath was done less than a month later by Dr. Raffy was the... Well, Darien and then Dr. Raffy. For our team structure in our cath lab, I know that's some of the things that come up like who should be in there, who is required to be in there. In the state of Illinois, you have to be a registered rad tech, radiologic technician to be able to administer radiation, so run the CR and help the physician like a first assist. Our staffing model is that we have two RN circulators. They're not necessarily in the room both times, but we have backup. We really run a at minimum a three-man team. Our RN circulator is there to monitor the patient and give sedation. Our rad techs are the first assist and usually the person in the control room along with the physician.

Mr. Johnson Our next slide here that we have is basically what is in our cardiac suite equipment wise. I heard you guys talk about the SCAI document earlier. The SCAI Document, along with the American College of Cardiology have guidelines as to what equipment you need necessary within your cath lab to be able to function independently. We do have the Phillips Azurion as our C-arm, the Intel iView for hemodynamics management, our charting system. We use a power injector. We chose the power injector instead of the manual injection just because that's what our local hospital does as well. It's easy to use for our physicians to jump back and forth between. There's really not a learning curve. Our ASC cath lab is pretty much set up almost identical to the hospital cath lab. The physician's ease of use in transferring from one to the other is very easy for them to manage. We do have IFR and IVAS for more difficult cases or anything that we would need to differentiate our plaque from soft plaque in order to decide whether that case should be done in our surgery center or whether it should be deferred to the hospital if PCI is necessary. One unique function about our room versus like a regular cath or if you're doing just an independent cath suite since ours is multi-specialty we do have a getting a K Magnus table, which has an interchangeable top. It has a cath lab tabletop or you can change it out for a general OR tabletop. When our cath lab is not in use for cardiac procedures, it is able to convert the entire room into a general OR suite. We do not lose patient time or room usage. We can maximize the room usage. Our scheduling, as we only have two cardiologists right now that operate in the cath lab, they operate two to three

days a week. Morning block time, we can do a maximum of five heart caths a day out there. Our surgery is open from 6:00am to 6:00pm. All patients must be discharged by 6:00pm. In order for that to make that happen, we want to make sure we have them done in the lab in order if they need a, say, a four-hour recovery time, we can quickly establish that and don't have any issues with holding staff over or any patient delays, anything like that. We can do five left heart caths is what our max is. A lot of times we mix in exams. We may only have two or three left heart caths, a gen change. They may have a couple loop recorders to put in, things like that. The room is not always just dedicated to heart caths or many other cardiac procedures. We can it in ASC as well. We maximize the room usage as much as possible. Like I said, last patient is in PACU by 3:30pm is in the latest. I would say typically they're in there by 1:30. 3:30pm is our guideline, but generally they're there by about 1:30pm is the last time we're out of the lab. Recovery time, again, depending on the closure site. We do about 90% of our access as a right radial approach, which you will find is typical in a lot of hospitals now as well. Much faster recovery time, patients do much better afterwards. If we have to go groin we do, but most of our planned cases are right radial approach. Our current procedures we perform in our lab are right and left diagnostic cardiac catheterizations. We do perform staged PCIs, peripheral procedures as far as angioplasties, denting, atherectomies, and venous seals. We do renal interventions as well, pacemaker generator exchanges, loop recorders, insertions, and removals. I just want to kind of cap on our volumes. Volumes are a question that we've gotten from IDPH as well as what volumes should we regulate? How many should you have to do? We stay pretty busy in our lab. I kind of totaled it up. I didn't have like specific numbers on percentages from the hospital have what have come here and what have gone there. The hospital has about six cardiologists of their own, the local hospital does, and they don't do any procedures at our lab. I don't really have their numbers as far as total volume for the area that has shifted. I can say that we have shifted about 50 percent of our outpatient eligible, so that are eligible by the strict criteria to come to an ASC. About 50% of our outpatient caths we've been able to shift over to the ASC setting. That is a great benefit to our patients. We can get them in faster. It also opens up time slots at the hospital for more critical care patients. It allows our providers to, and us as QMG, to provide lower cost of care for community and our patients. Since we've started, it's been about three years now. We've performed 743 left heart caths with 140 PCI and 50 cabbage referrals, and the cabbage referrals go back to our local hospital. Any difficult PCIs, anything with hardened plaque or multi-vessel disease, even if it's not a cabbage, if it does not qualify or meet the guidelines for a PCI at an ASC, those patients are referred back to local hospital as well. Right heart caths, not near as common, but we've done 11. Pacemaker, generic changes 51, peripherals, renal, loop recorders, we do quite a few, and the venous soap procedures as well, which is a pretty quick procedure. I think you can see there's a variety of cardiac procedures we can perform in this lab and very safe and effectively in this outpatient setting.

Dr. Heslin Thank you.

Dr. Heslin Can you comment on a couple things? The first is can you comment on your safety outcomes since that's been a question that's been recurrent here and complications? Can you comment on how you manage the relationship with the hospital and the benefit or harms that you might have seen through putting this together with the hospital as your local hospital?

Mr. Johnson Our outcomes are very similar. Knock on wood while we're here, we have not had any severe outcomes to anything. Most of our hospital transfers have been either, I think we've had a couple hematomas, which are to be expected. It's going to happen.

We've had a few hospital transfers. Most of our hospital transfers are due to findings. We're referring over for someone who needs a cabbage or who needs more extensive workup that we're not able to do in an ASC and we'll refer over.

Ms. Harrison We have the exact data that I pulled for 2025.

Ms. Harrison Good afternoon. Thanks for having us. Some of the cardiac path complications that we look at is significant, no reflow during a PCI, which we've had zero of this year. We look at Type B, F, dissection and target vessel. We've had zero of those complications this year. A thrombus during PCI, we had zero this year. Transient vessel closure during PCIs, zero issues. Vascular access complication, zero. Cardiac or non-cardiac instability during PC I, we've had zero. To Ted's point, we have had a total of three cath lab hospital transfers year to date. They just needed further intervention from a hospital setting. As we look at our data even though we are a multi-specialty surgery center, we are looking at a less than one percent transfer rate to the hospital. Out of those 700 in some cases less than 10 have been... Less than 10 transfers have occurred from our Cardiac Center to the hospital. I would also add that when we were standing up, the cardiac cath, we engaged our ambulance teams, had them come out, take a look at our space, we did mock codes. Our physicians not only serve our surgery center, but also work at the hospital. When we're talking about coordinating efforts, they're the same doctors. They can admit to themselves at this hospital and continue to do whatever they need in that setting. I can tell you, although QMG and the hospital may be competitors in this phase, the physicians are the same physicians that service both. we don't look at payer. The surgery center accepts all payers that QMG accepts. We really just look at patient criteria. Does this patient meet the criteria for the surgery center? Are they safe to be done in the surgery center? If the answer is yes, which to Ted's point is over 50% of our patient population, then we perform it in the surgery center and have less than a 1% transfer rate. If the patient doesn't meet our criteria because of comorbidities or, you know, BMI or any of the other things, then we perform it at the hospital. I think we're uniquely set up to be able to be the decision makers on the right location to take the patient because our physician can go to both spots. Does that make sense?

Dr. Heslin It does. Thank you.

Dr. Heslin Can either of you comment about the relationship with the hospital, because obviously you're a freestanding center run by a medical group, and there's always those tensions. I'm just curious to hear about that.

Ms. Harrison They were not thrilled that we were going to be opening our own surgery center, especially were not thrilled that we are having a cardiac cath lab. They did oppose our opening through the CON process in the state of Illinois. The CON board did approve the project, which is why we're here. I would say it was tough when we started it. Once we proved our outcomes, then I would tell you that it hasn't really been an issue, partly because our physicians practice in both spaces. I'll let you kind of speak to your ideas and thoughts on that as well.

Mr. Johnson At first, I think there was just a tension of competition like there would be with any competition opening up. We have been able to collaboratively work with the hospital. We don't have any issues if we do need to send a patient over there. The communication has been great between facilities. I think being a smaller community as well, we constantly... We know the people who work there. They know us. It's not like there's a feud or anything between the personnel. We're happy to help each other and

share patient...whatever needs to be done, we get it done. I think it's just a, it is a professional environment. It's basically what I can say. You know, best friends, probably not, but it's a professional working environment.

Ms. Harrison I mean, it's very clear that we, you know, we are generating revenue on cardiac caps in our freestanding ASC. I'm sure that's revenue that they would love to have back in the hospital. I think that that's financial impact...it has a negative impact on them financially. At the same time, we've had as good of outcomes, if not better, and our patients are happier with a decrease in costs and not having to go to the hospital but being able to go through a free standing. For us, I would say we see the ways and they have found ways to generate revenue in other areas.

Dr. Heslin I'll follow up.

Dr. Heslin Have you provided benefit to the hospital because you've sent them more cabbages and things like that? You are doing more, are you finding more, and are you actually being a financial driver for them? Just curious.

Mr. Johnson I think we're able to get the patients in in a timelier manner. I think that is our job in the community and our promise to our patients is to deliver the most effective care we can for them. Our ability to treat patients in a timely manner is producing more timely revenue to the hospital. Would the patients have gone elsewhere if they couldn't have been seen here? Would they have taken their business to Springfield or St. Louis or somewhere else if they couldn't be seen in a timelier manner? Even though I don't have the direct numbers, I can say that we are access to care is better, which allows these patients to be seen faster and treated.

Dr. Heslin Ms. Farrell, you have a question.

Ms. Farrell Yes.

Ms. Farrell Do you accept all insurance coverage or are there any carriers that you do not accept?

Ms. Harrison All these things are what we accept as QMG as a whole, we accept at our surgery center; so, Medicare, Medicaid, commercial payers, we're accepting at our surgeries center. We do not have any carve-outs for our surgery center as it relates to payers.

Ms. Farrell If patients do not have insurance, how do you handle that?

Ms. Harrison Yeah, then they would be self-pay.

Ms. Farrell Is there a sliding fee scale?

Ms. Harrison I do not believe there's a sliding fee scale. They may choose to go to the hospital setting, where they can qualify for financial assistance.

Dr. Heslin Mr. Lawrence.

Mr. Lawrence Yeah, just to elaborate on that... What is the payer mix?

Mr. Lawrence Payer mix in terms of insurance, Medicaid, employer-based insurance, Medicare.

Ms. Harrison I would say about 60% is commercial. You know, I would another 20% is Medicare. Less than 10% is Medicaid in our market. I would say the other is a mix.

Dr. Heslin Any other questions for the group from Illinois?

Dr. Heslin Ms. Monroe.

Ms. Monroe Do you have plans for a second site or a third site? I know Quincy slightly and there's a lot of rural area around you.

Mr. Johnson I apologize. I couldn't hear the question.

Ms. Monroe Do you have any plans for expansion? There's a lot of rural area around Quincy. Do you feel that there's a need for perhaps a decentralized site? What do you see for the future?

Ms. Harrison I'll touch on that a little bit and then Ted could provide his thoughts as well. You know, we're really lucky at Quincy Medical Group to have primary care in those rural locations. We have where all of our primary care offices are designated as rural health clinic centers. We have multiple in rural Illinois, rural Iowa, and then also rural Missouri. We've had primary care hubs in those rural communities, and those patients are used to traveling to Quincy. We have primary care hubs, and then they refer to our two cardiologists. If we had more cardiology, possibly, you know... Our cardiologists are already providing services at Hannibal Regional Hospital, also at Blessing, and then perform some outreach. We don't have any plans in the future to add any additional suites, either in Quincy or rural. Part of that is the cost in being able to, one, we have to go back through the CON process in the state of Illinois. Two, then we'd have to build, convert and staff. We don't have plans to do any of that in five years and hope to continue to provide outreach to those rural communities and then continue to see them in our Quincy based office. I know Ted and his team also provide a lot of cardiac ancillary services, you know, whether that's echoes and a whole bunch of other things that we do right there in the rules, just not cardiac.

Mr. Johnson I would piggyback, as far as the rural areas, our providers go to six different outreach locations once a month to see those patients at the outreach locations, so they don't necessarily have to come here to Quincy. We provide remote monitoring services such as halter monitors and event monitors at those locations as far in, if the locations do not have echocardiogram services, like ultrasound imaging services, we actually contract with a third party to provide images, echo services in that area, so those patients are provided that care without having to drive over an hour to Quincy. Yes, we are reaching out to those areas, even though we don't have a surgery center there, we are providing some cardiac services for those communities.

Dr. Heslin Any other questions?

Dr. Heslin Well, thank you very much. We very much from New York appreciate that you guys are an hour different and that we had some logistical issues getting you the link. Thank you so much for presenting your data. Congratulations on being the first center in Illinois. We look forward to continued partnership and success. Thank you.

Mr. Johnson Thank you. Thanks for having us on today.

Dr. Heslin We have a few minutes left. I want to give a teaser of some data that we're able to pull. People have asked, do we have any data for cardiac catheterization in the diagnostic realm? We went back and we looked at SPARCS data which as people know is a reporting system that we have at the Department of Health for hospitals. They report claims data to us. We searched against the codes for cardiac catheterization, diagnostic caths. This has got all diagnostic cath including pediatrics in it. It does not include the percutaneous cardiac intervention. This is from 2023. The data looks different than the 2024 data that Dr. Osinaga gave us earlier and the 2018 data that she had. Again, apologize for the different years. There were 82,000 caths done in New York State for diagnostic purposes in the year 2023. What we did was we broke them down by the different regions in New York State to take a look at what it might look like from an economic development zone regional point of view. This is not in your packet. We'll send it to you.

Dr. Heslin Is it in the packet? I don't remember.

Dr. Heslin What did then was we then did a comparison of the number of caths that were done in total against per region as a percentage, and then we tried to match that against the percentage of population.

Dr. Heslin Go to the next slide, please.

Dr. Heslin What you're looking at here is the number hospitals in each region in column one, the diagnostic caths as a total number of caths in column two, the percentage of diagnostic caths were done as a comparison to the total caths by region in column three, column four is the total population of the state and broken down by region, and then in column five is the percentage of population. Again, a disclaimer, this is not age-adjusted. This is every all comers. This has nothing to do with comorbidities or anything else, so a very unscientific way to look at this. As we look, we look around and say, okay, are there areas of New York State that might not have enough cath labs? Are we doing a lot somewhere else? Again, I would submit that when you look, Long Island jumps out at us because they do 24% of the diagnostic caths in New York State and have about 15% of population. I'll also point out that every hospital except for three on Long Island has a cath lab. That's different compared to the rest of the state. So, for example, New York City has sixty hospitals but only twenty-nine of them have cath labs. As you look, you can say maybe they're doing too many, or maybe they're doing just the right amount because they're actually providing access to the patients. As you look, you can say, well, are there areas of the state that might not have enough cath labs in them? North Country has one right now, and that's at CVPH in Plattsburgh. The committee will remember that they just approved a second one in Watertown in the last meeting. 25% of the land mass in New York State is in the Adirondack North Country Region. We have one cath lab in that area. You might argue that they're doing half the number of caths as a percentage of the population. It is the oldest population in New York State at this point in time on a per capita basis. Maybe we're underserved there.

Dr. Rugge The proposition is very spread out. Having two lab, half labs, I think will fill the bill.

Dr. Heslin This is just a teaser of some data that we're able to get out of the system to say there might be areas of the state that we might need to have a way to think about this in terms of demonstration or geography or access for purposes of need as we sort through the other areas.

Dr. Heslin We have about three minutes left before people have to leave for their trains. We're not gonna get to the next steps discussion very much, aside from the fact that if you look at the list under future discussions, Cardiac Advisory Committee discussion, development framework, should it be hospital-based, should it single-special, should be multi-specialty, should it for-profit, should not-for-profit? Should it be demonstration versus full state? What will be the criteria for demonstration? What should be the Medicaid criteria? As thoughts as to some of the areas that have to be addressed going through. These are all things that were brought up today through the natural discussion of the meeting, and I think that those are going to be some of the topics we have to start to think about focusing on as we go forward with this type of meeting. We will probably have in our next meeting a fairly large component to the meeting that will be dedicated to external group speak. We'll invite the different societies, we'll invite hospitals, we will invite other groups, whether they're both from the state or outside the state to come to give information. We will probably do a smaller educational section based upon some of the commentary that we got today. We may invite the Harvard group back once their studies are published to be able to provide us with an update of information, since they may have more information for us. That's where we're at this point in time.

Ms. Monroe I would like to suggest that folks in the room send us written comments of what you, if you want, as you're thinking about this of what topics we need to be looking at as we move forward. We certainly have talked about them, but I think a note from each of you that says, let's look at this and let's at that will keep us grounded.

Dr. Heslin Absolutely.

Dr. Rugge Also, in future meetings, there will be opportunity for public comment. This is intended only to be educational, so I didn't allow enough time for that, but it will come.

Dr. Heslin Yes, we'll have sessions essentially dedicated to external public comment for that specific purpose.

Dr. Heslin Any closing remarks from anybody that hasn't said anything all day long? I'm looking around the room and seeing several people that usually have good thoughts silence.

Dr. Heslin I welcome closing thoughts from Mr. Perry, because he's sitting over there with that look like he wants to say something.

All (Laughing)

Mr. Perry No, not at all. I thought it was a good session, very informative. I look forward to providing additional comment back to our committee chairs for future consideration. Thank you.

Dr. Heslin Oh, I have one final thing. I would like to formally introduce Abby, who was married a week ago, a week and a half ago. She is now Mrs. Harabarovitch. Abby, congratulations!

Dr. Rugge Well pronounced.

Dr. Heslin With that, we will close today.

Mr. Thomas I just want to say thank you for the first half, all day. It was great to have a full discussion of the regulatory approval process, because you all are grounded in the science and the safety, but also in the process. That was very helpful. My only other comment is having been through cycles in this world in my career, I'm not medical, but I've been around all the administrative stuff. I would echo what Peter said, which is care evolves. Who would have thought there would be a knee or a hip or whatever else in an ambulatory setting, significant urology procedures being done now. It's funny how healthcare professionals adapt. I think that given one other common gene for the team from Deaconess, they covered the impact on everyone except the health system. They covered the physicians, they covered the payer, they covered everybody except the health system. That stood out for me.

Dr. Heslin Maybe we'll ask them to add that to the manuscript.

Mr. Thomas Thank you. I was going to write that to you.

Dr. Heslin Thank you, everybody. Really appreciate it.

Dr. Heslin We are adjourned.