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TRANSCRIPT

Ms. Monroe Good morning, everyone. We'd like to get started. I know many of you have a busy day ahead, and we appreciate your coming early and on time. We've been up here discussing how much time to give people. We'd like to start out by giving you five minutes. If you're here with someone else from your organization, we appreciate the organization split the time. We'll also allow our members of the committee to ask a clarifying question if there's something confusing or unclear, but we're not going to go into a dialog, or we'll be here all day. Not that what you have to say isn't important. It's just that we want to make sure we get the gist of it. Those of you who have submitted written letters, we appreciate that as well, because that's been a place for you to expand on the ideas that I know you want to share with us. There's some standard language that I need to go through. By the way, I'm Ann Monroe and I'm the Vice Chair of the Planning Committee. Dr. Rugge, who is Chair is unavailable today. The rest of the committee will take close attention and make sure that we inform him of your comments when he returns. It's being webcasted. This meeting is subject to the Open Meetings Act. Don't say anything you don't want to see come back to you at some point in time. You can access these webcasts through the Department of Health or through Colleen Leonard, who's the staff to the Public Health and Health Planning Committee. There is synchronized captioning for people who are not necessarily in the room, but who are watching on webcasting. Don't talk over each other. Try and be as clear in your comments as you can. When you speak, the first time you speak give your name and your affiliation. If you're a member of the committee, indicate that with your name. The microphones here are, as they call them, hot mics. Asides or comments that you might want to make to your colleagues is really discouraged, as you can certainly understand. If you're a member of the audience or wish to speak, there's a form that needs to be filled out, and I assume you have done that. If not, please make sure you do that. I think that's the introductions. I'd like the committee members to just go around and introduce themselves to you, and then we'll begin with public comment. As I said, we're going to provide five minutes and time for clarifying questions. We will begin today after the committee introduces themselves with the clinicians who are in the room who have surgeries and other procedures, maybe even cardiac cats scheduled for the rest of the day.

Ms. Monroe Let's just start here.

Dr. Wilcox Good morning. Wendy Wilcox, member of the committee.

Dr. Soffel Denise Soffel, also a committee member and one of the consumer representatives to the Public Health and Health Planning Council.

Mr. Thomas Hugh Thomas, a member of the Public Health and Health Planning Council.

Dr. Lim Sabina Lim, member of the council.

Dr. Eisenstein Dr. Larry Eisenstein, member of the council.

Mr. Perry Stanford Perry, member of the council.

Ms. Monroe I'd like to just say that given what my colleagues have said, please speak into the mic when you have your opportunity. It's really important that we be able to capture everything and that the people here in the room can hear the important things you have to say.

Ms. Monroe With that, let me begin with Richard, and I want to do this right, Shlofmitz? Is that correct? If you'd like to take a seat at the table, these are the cameras. You don't want to get too close. Please, as I said, speak into the mic.

Dr. Shlofmitz Thank you.

Dr. Shlofmitz My name is Richard Shlofmitz. I'm a Cardiologist at St. Francis Hospital Catholic Health System and appreciate the opportunity to speak today. You're going to hear from many different people on both sides of the argument, a lot of it related to financial situations. What I'm going to focus on is safety. I think, you know, since I've been watching the Governor in office and legislators, their focus has been safety of every New Yorker, not just in healthcare, in every aspect of life. As a Physician, I'm concerned about safety. That's my number one goal. I've done many procedures in over forty years. I know when I do an angioplasty, as simple as it may seem, there are potential inherent risks on every patient that comes on my table. As simple and straight forward, when I do an angioplasty and inject contrast in someone's artery, and if I try to open up a vessel with angioplasty and stents, complications could arise with that procedure. Unfortunately, I can tell you a procedure that I did two weeks ago on a very special man that was a straightforward angioplasty, and the wire actually perforated the artery, which is a complication in any angioplasty. The patient went to the holding room where they recover and was clinically stable. Our amazing nurses picked up that his pressure was dropping brought him back to the cath lab, where we did an emergency echocardiogram looking at the heart, and so there was fluid around the heart from that perforation. In order to save that person's life, it required an incredible team working together. I needed one of my associates sticking a needle in the chest, draining the fluid. I sealed the hole of the artery. Someone else was putting a left ventricular support device called impeller in to maintain the flow. I had nurses rotating doing CPR until we get cardiac activity back. I had an anesthesiologist intubate the patient. The patient require transfusions. Had to go to ICU, needed an emergency surgery on the leg from the impeller device. This went on for two weeks. The patient's finally fine on the floor. If that occurred outside a hospital setting, there's zero chance that patient would have lived. Now, that's just one real life example that I have. Every single day when I'm doing cases, I have the potential of having a complication. I take it seriously. In my hospital, I feel confident that if anything can be done to save a patient, it can be done in a hospital. In New York, Tri-State, in the city, Long Island, there are so many hospitals that do what we do. I don't see where the safety value is for a patient to go next door to my hospital where they're potentially at risk. It just doesn't make sense. I don't think you would want you or your family to have your angiogram in a place that, God forbid, there was an emergency, couldn't be taken care of as competently as it was in a hospital. Finally, because I'm going to give a couple of minutes to my associate from Mississippi who takes a lot longer to speak. We have the best nurses in the world. There's a nursing shortage. What's the chance that the nurses are going to stay at a hospital setting if a private facility says, I'm going to let you work night to five days a week, no nights a week and say I'm going to double your salary. There's going to be a drain on the best nurse in our hospital. If you cripple the hospitals, it's going to cripple the healthcare system. Thank you.

Ms. Monroe Is there a clarifying question?

Mr. Perry Yes, I have one. Stanford Perry, a member of the committee. What percentage of your interventions would you say result in problematic circumstances?

Dr. Shlofmitz The standpoint for my hospitals, right, we call that MACE, major adverse cardiac events, and that could be something as simple as a hematoma of blood in the groin versus perforating someone's heart or retro perineal bleed. The number is 4 percent, 4 percent.

Ms. Monroe Thank you very much, Doctor, for joining us this morning.

Ms. Monroe We have Arthur Klein.

Ms. Monroe Will somebody flag us when he comes back? We'll put him in the queue.

Ms. Monroe Justin Ratcliffe. Oh, how convenient that you're then the next one.

Dr. Ratcliffe Hello. I'm Justin Ratcliffe. I'm an interventional Cardiologist. I work for Sorin Medical. Thank you all for having me. I've been practicing for the last eleven years now, and the two points that kind of I want to make here is number one, access. We have a busy practice, and a lot of people are here from the practice. We're in all communities throughout New York. we kind of here from the ground level patient complaints and how hard it is to kind of get access, get their cardiac procedures in a timely manner. I have privileges in six different hospitals across New York City just to kind of adequately take care of my patients who need cardiac health. I'm here, my team is here. They hear it every day from patients who need procedures. Why can't I get this sooner? Just from an access perspective, it's really difficult to kind of take care of patients, especially in these highly populated underserved communities, and get them timely, adequate care, just like cardiac catheterizations. The second thing is safety. We do cardiac catheterizations. I mean, the complication rates, I think are way less than 4 percent. I think in targeted populations or specific kind of cases, right? You can select a subset of population that has a very low complication rate. It doesn't matter what hospital you're in, because the hospitals will vary with the type of resources kind of that they have that we're able to treat kind of the low complication rates that are here. Technology has really advanced. We can select patients who are high risk for complications. We can have those be done in hospital settings. We know which patients should be done in ambulatory surgical centers, which patients to be done at hospital settings, so I think we're moving into this new realm or new era where we can highly select the patients and do things in a safe, effective manner while increasing access.

Ms. Monroe Thank you.

Ms. Monroe I’m not familiar with Sorin Medical. Is that an ambulatory surgery center? Where do you do your cardiac cats?

Dr. Ratcliffe Mount Sinai, Columbia, NYU, and NYP Westchester, literally five or six different hospitals because every hospital gives me a cap on how many patients I can do per week. During those times where I do the catheterizations, there's a lot of emergent cases that come in through the ER, which obviously should be done in hospitals, but the elective patients typically wait all day and sometimes stay overnight because we have to

do the procedure later or they get admitted to the hospital. We have we have the procedure the next day. There's just from a from an access standpoint it's just very disruptive.

Ms. Monroe Larry, quickly.

Dr. Eisenstein Yes, two quick questions for you. You mentioned that there's a lack of access. I know a lot of cardiac catheterization labs, particularly in the city and around the tri-state area, maybe different in other parts of New York State. If you have any data that you could share with us, not now, but afterwards, because I am not aware of there being an access problem for cardiac catheters certainly in the New York City area, perhaps there's focused areas. You know, as a committee, we should respond to data. If you can provide that to back up your comments that there's an access shortage, that would be helpful. The other thing is, can you clarify the comment that you said about we could be selective about who we take? One of the concerns is the opportunity to cherry pick patients. If you're going to become selective, it also can become selective for those who can afford to come to you versus not. As a committee, making sure that everybody has equal opportunity, health equity is important. I was concerned about the comments that were selective about who would come to us that's the opposite of creating access in my mind.

Dr. Eisenstein Thank you for clarifying.

Ms. Monroe Thank you.

Ms. Monroe Excuse me, we missed Arthur Klein. Is he back?

Ms. Monroe We'll move on.

Ms. Monroe Newell Robinson.

Dr. Robinson Newell Robinson. I'm Chairman of the Cardiovascular Service Line Catholic Health Services. I'm a Cardiac Surgeon at St. Francis Hospital for the last four decades. I actually have been before this committee before to gain approval for underserved parts of Long Island to gain an approval for open heart surgery at Good Samaritan Hospital. I'm familiar with this process. My principal goal in presenting is to support what Dr. Shlofmitz said in terms of patient safety. I've observed the growth of. I'll speak up. For me the New York State database since I was one of the original members to be presented with a database has been very helpful. There are many centers on Long Island, Suffolk and Nassau County that are centers of excellence, many represented in this room. If you look at your own statistics, the high performers are statistically better; St. Francis Hospital, NYP Cornell, Mount Sinai, Lennox Hill, NYU, and Brooklyn Mamanides. My point to add is that what does the science tell us in terms of the kind of care you need to provide support for a PCI program? You need a high volume of procedures. You need advanced technology with imaging like shockwave imaging, with imaging that provides immediate feedback as to the effectiveness of your therapy. You need access to mechanical support Impella and ECMO. Now, I understand that the goal would be to preselect patients. Your own database shows that what are the odds ratios associated with a high-risk procedure. One is obesity, another is ejection fraction, others include renal failure, and a number of other factors that may not be accounted for in the average citizen of Suffolk County or Nassau County. So, pre-screening is something that could be done. I assume that ASCs will be treating only elective patients, but what happens when a patient comes to a center of excellence is

there is a large team of people providing these services. As it turns out on a weekly basis, I mean our cardiac surgical service will have as many as six to eight patients who are kept in the hospital for open heart surgery out of the mix of patients that are being presented to the cath lab. I just look at this from the perspective of cost effectiveness for the health care dollar. You could end up in an ASC and then you might find that you find things that were not accounted for in the preoperative or preprocedural evaluation that need to be addressed. There's duplication of services. There are many very capable centers of excellence in at least in our demographic area and the New York Metropolitan area you are within ten to fifteen minutes by ambulance of one of these centers is hard to understand why a free-standing ASC is necessary to provide this care.

Dr. Soffel I have one quick question. When you say Center of Excellence, is that a state designation or is that term of art?

Dr. Robinson No, in terms of a Center of Excellence, the definition is not state defined. It's defined by the scientific evidence supporting that. Now, the state does define in the database those centers that are statistically better than other centers. I listed those centers in the preamble. St. Francis Hospital being one of those places. That the mortality rate, for example, in a center of excellence with high performance rating, the mortality rate across the board would be like 0.6%. When you get down into the middle group of facilities, the mortality for a PCI might be as high as 3% or 4%.

Dr. Soffel Just to be clear, you are not suggesting that there is a formal designation of Center of Excellence. You are using this as a term of art that we clearly know which are the better performers.

Dr. Robinson There is a formal definition scientifically in there.

Dr. Soffel Designation.

Dr. Robinson Not a designation.

Dr. Soffel That was my question. Thank you so much.

Ms. Monroe Thank you very much, Dr. Robinson.

Ms. Monroe We'll go back one more time to Arthur Klein.

Ms. Monroe Well, perhaps you'd like to submit a letter.

Ms. Monroe Moving on down, we have Jeffrey Flynn.

Mr. Flynn Good morning. My name is Jeffrey Flynn. I'm the President of the New York State Association of Ambulatory Surgery Centers. Our membership represents a majority of surgery centers in the state of New York with 142 members across the board. We are in favor as an organization in taking the CMS codes that are currently approved with cardiac into the ambulatory surgery center setting. A number of things have been said, obviously, today about it, and one of the things that's key in every aspect in Ambulatory Surgery Center, patient selection is the paramount situation, and that's what we take into every procedure that we do in every center that we currently do today. We do have issues of access care. In rural parts of the state and also in the urban parts, there are certain issues of access of care for patients. This develops more access of care for patient. What we've

done, and we've actually gone to other state associations, and we have submitted data to the committee already specifically regarding studies in the three states that primarily started doing PCI and the ASC setting. Their studies have shown that hospitals were not hurt in that situation. What it actually showed is that lower acuity procedures were gravitated to the ambulatory surgery center setting, but that the cath labs in those hospitals actually started doing more higher acuity procedures and that grows up. It was an issue of access in the first three states that actually have done it. Recently, we've also submitted information of the state's similar to our state in the sense of Michigan and Illinois of what they've both set up that having PCI in the ASC setting. Both states have now officially adopted that and move forward with it. We also work with a number of national organizations that have centers in the states. What we did is we reached out to those states to where they had surgery centers that are actually producing this information. We're actually going to submit the studies of the complication rates, hospitalization rates, mortality rates for that. We just received the information yesterday, but that will be submitted by the end of today to the committee to go forward. We feel ourselves as an organization is we're providing quality care and access of care to the 20 million New Yorkers. We work closely with the Department of Health and obviously with the Governor's Office too to provide that information for them to go forward with it. Thank you for the opportunity to speak with you.

Ms. Monroe We look forward to that information.

Ms. Monroe Dr. Lim.

Dr. Lim Hi. Quick question. You referenced you'll be submitting data, which is very helpful. In terms of, could you also submit data if available for the other states that did roll out PCIs and ASCs? Was there a, quote, improvement in access, whatever that's defined, and access for whom? Which does it include, for example, Medicaid beneficiaries, Medicare beneficiaries? That level of detail would be very helpful, I think to also get.

Mr. Flynn Actually, that is in the CASA study itself was the actual breakdown of the information, so we'll be more than happy to produce that. The other information of real data from the information we'll submitting today was we took centers across the country and just deep dived to the data of what the quality points are in the Quality Assurance Committee meetings specifically, and we've listed it down specifically by the CPT code so that you'll actually see complication rates and everything specifically by the codes themselves.

Ms. Monroe Anyone else?

Dr. Wilcox Wendy Wilcox, member of the committee. Does your data include racial and ethnic data?

Mr. Flynn Yes, it does.

Ms. Monroe Well, it sounds like it'll be a rich set of data for us to review. Thank you very much.

Mr. Flynn Thank you for the opportunity.

Ms. Monroe I apologize to Dr. Jeffrey Kuvin. Is that the name? You're coming with Cynthia Khan.

Dr. Kuvin Good morning. My name is Jeffrey Kuvin. I'm the Executive Director of Cardiology at Northwell Health, Professor of Medicine at the Zucker School of Medicine. I'm a past trustee of the American College of Cardiology. As you know, Northwell Health is the largest provider of cardiovascular care in the region. We take care of about one third of all of New Yorkers who seek cardiac care. We employ over 300 cardiologists. We actually have 39 cardiac catheterization laboratories in 16 locations. We perform 13,000 PCI procedures, and our quality is at the top of the nation. We recognize this decision as to whether or not to allow diagnostic cath in PCI in New York is one that should not be made in haste, and the questions posed by this committee mirror those exact questions that we asked ourselves when we came here to develop a satellite cath lab at Northwell Greenwich Village Hospital. I'm proud to say that that opened up last month and is doing very, very well, largely in part because of its connection with Lenox Hill Hospital and the broader Northwell Cardiology and Cardiac Service line. This linkage is crucial in terms of quality, staff training, and the ability to leverage an existing system with protocols and procedures. Northwell, I'm proud to say is the only system in the state with this type of experience to date. Delivery of cardiovascular care is undergoing rapid transformation across the United States. Many states, as you've heard, are moving to selected cases being performed in ASCs. The volume of US Cardiovascular Services in ASC's is projected to grow 15% over the next few years. The rise in cardiovascular procedures performed in the ASCs has highlighted the importance for appropriate case selection, as we have heard today, given that these sites don't have the same level of support offered at hospitals. There are published guidelines that focus on risk assessment and provide clinicians' use for guidance. As New York is considering allowing for some cath PCI to be performed in the ambulatory setting, we believe at Northwell that it's imperative that the sites be affiliated with existing programs at hospitals. This will allow easy flow of information and personnel, proper oversight of case selection quality, seamless care should patients need acceleration of care, and importantly, no financial conflicts of interest. The hospital-affiliated model allows for the choice of site of service based on clinical considerations only and allows hospital-affiliated staff members to maintain adequate volume as more cases migrate to ASCs. This will ensure competence at both the hospital as well as the ASC. There is significant geographic variation in ASCs across the United States. The entry of ASCs into a market, especially when near a hospital, does reduce hospital outpatient volume by a few percentage points. This may be particularly relevant for rural and safety net hospitals. CMS began reimbursing PCIs and ASCs in 2020, projecting $20 million cost savings if 5 percent of PCIs migrate. Of concern is that the migration to ASCs will dilute volume for staff members, negatively impact competence, and disconnect patients from well-established care and quality oversight. In addition, competition for a limited skill pool may increase labor costs, as you have already heard. If ASCs are rolled out in New York, it makes the most sense to focus on a single specialty ASC, which allows for streamlined focused care with staff comfortable with all procedures utilizing common equipment. While multi-specialty ASCs might, in some instances, be more cost-effective, the lack of a single focus could often lead to dilution of talent and lack familiarity with cardiovascular patients. Single Specialty ASCs. Might continue to grow, for example, in cardiology to include coronary, peripheral, and even electrophysiologic procedures. Our position at Northwell strongly supports ASCs being not for profit. This aligns best with the patient-centered care and avoids any conflict-of-interest risk. We strongly oppose any financial incentives that would drive patients to an ASC over a hospital. In our opinion, this is fundamental to proper case selection and patient safety. We feel that a demonstration project in New York is reasonable, as this would be a substantial change from the present practice. We believe this should be limited to a few sites with direct oversight regarding case selection, quality, decision-making, and outcomes. While

there is widespread participation of hospitals in procedural registries such as the NCDR led by the American College of Cardiology, similar patient registries do not exist for ASCs as of yet. Published outcomes for ASCs are sparse and restricted to small multi-center databases. In summary, at Northwell, we're supportive of a pilot project that would trial cardiac catheterization PCI at ambulatory specialty centers if and only if, first of all, there's strong coordination with well-established hospital programs. Number two, case selection is well documented and adjudicated. Number three, there is a focus on quality outcomes with public reporting. Number four, all bias and conflict of interest are addressed. Thank you very much.

Ms. Monroe Comments, questions?

Ms. Monroe Well, that was very thorough and did address the questions we raised. Thank you.

Ms. Monroe I missed that there were two other representatives of Sorin Medical here.

Dr. Nouri I'm Dr. Shayan Nabavi Nouri from Sorin Medical, interventional Cardiologist.

Ms. Navarro Carmen Navarro, Practice Manager.

Ms. Salazar Lexis Salazar, PPC team of the cath lab for Sorin Medical.

Dr. Nouri Just want to start with a couple stand-alone points. One I want to echo, and one of my colleagues, Dr. Ratcliffe made earlier about access. I practice primarily in Northern Manhattan, the Washington Heights, Inwood area. Patients that require cardiac catheterization are often having to travel many, many miles away for their procedures. One of the members of the committee brought up, there's so many hospitals in the city. He's right. You can't throw up a rock without hitting a hospital in the city. Just because there's a hospital across the street doesn't mean the patient has access to it, especially as insurance coverage carries, changes between hospitals. Patients are often having to travel across boroughs for elective outpatient procedures. The other standalone point I'd like to make is that I think that the hospitals are there to best serve acutely ill patients and includes the acute procedures as well as high-risk procedures, which we have very well-validated and rigorous methods to select, people have sort of talked about. For the elective outpatient cases, low-risk patients who you've adequately screened, not just from a patient profile perspective, but also from a procedural anatomic perspective, I think the data's borne out that you can do it very safely in outpatient setting. I know one of the earlier comments was about a very sad, very difficult case, and those anecdotal cases definitely stick with us, but I think that the data will show that overall PCI can be done very safely in the ASC setting.

Ms. Monroe Ms. Navarro.

Ms. Navarro As a practice manager, I hear a lot of complaints from the patients.

Ms. Monroe Please speak closer to the mic.

Ms. Navarro As a practice manager, I hear a lot of complaints from the patients as I talk with them a lot. I hear their troubles with having to travel long distance for extended periods just to get the care they need, which leads to worsening conditions and unnecessary suffering from them. Sometimes for patients it's difficult due to insurances,

the insurances are not taken to a close by hospital and might need to travel elsewhere. I just wanted to make my issue about what I hear from the patient.

Ms. Salazar As a PCC team leader of the Cath lab, my biggest challenges currently right now that I face is time slots, the access. I work with over four hospitals weekly. Most of the times, if I only have seven cases, I probably have another twelve waiting and they sometimes have to wait almost two, three weeks and they're in a panic. I have this amazing system at 120 Wall Street, this heart scan, and they see this vivid picture of this red line. It's telling you have blockages, but now you have to wait three weeks out because I don't have no space for you. If I don't have no place for you, I just don't. I can't help you right now. And then even that, sometimes patients are coming in and insurances are not being taken. I'm scrambling in that aspect. I can't assist you at Mount Sinai because they don't accept United Healthcare. I have to send you across to Westchester. Why do I have gone all the way across to Westchester? Unfortunately, that's the only place I can send you and that's only place that my doctors can help you at currently. I do this five days a week. I give patients my cell phone number. I have two children at home. I get calls at 5:30 in the morning. It's just beyond me at this point now, like not having enough manpower or just having enough space to help these people. My Mother's an open-heart surgery patient. I wear this with me heavily. Thank you.

Ms. Monroe Thank you all.

Ms. Monroe Questions or comments?

Ms. Monroe I guess we had heard earlier, Dr. Eisenstein asked a question about a lack of, that it, he didn't think there were a lack, of cardiac cath labs, places to get that work done. You would say you're having trouble getting your patients into services, and Dr. Ratcliffe said he had a cap on the number of patients that each hospital, he could work on in each hospital. Is that what you're running up against, that there's no more space at this one or that one, or is it a lack of people to do the work?

Ms. Salazar There's no space. At Columbia, I have one room. One room only holds seven cases. God forbid the room breaks down, that pushes me over and now I have to scramble those patients over. That pushes another set of patients over. It's definitely not. It's just not enough space.

Ms. Monroe Thank you very much. We appreciate you all coming in.

Ms. Monroe Patrick McNulty, Albany Medical Health System.

Dr. McNulty Good morning. My name is Patrick McNulty. I'm an Intervental Cardiology student at the Albany Health System.

Dr. McNulty My name is Pat McNulty. I'm an interventional Cardiologist at the Albany Med Health System. The Albany Medical System is a four-hospital system centered on the state Capitol. It includes the only academic medical center in Northeast New York State, Albany Medical Center Hospital, and the only medical school in Northeast New York State, Albany Medicine College. It's the only locally governed and locally led health system in the Northeastern part of the state. We have four hospitals that span a geography from Hudson, New York, up to about Lake George, so a pretty large geography. We take care of urban inner-city patients in the City of Albany. We also take care many suburban towns. We blend into rural areas at the Northern and Southern regions of our system. We have

three hospitals that have cardiac cath labs, and among those hospitals, we do about 3,000 percutaneous interventional procedures per year, including about 1,200 PCIs at three hospitals and about 800 structural heart procedures. Just to cut to the chase, my own hunch, based on what I read from the thirty-four states that have done demonstration projects or accredited ASC, cardiac cath and PCI is that it's likely that these procedures can be done with adequate safety, quality, and financial sustainability in ambulatory surgery centers. The problem we have is that there's no evidentiary basis to support that right now. For that reason, I can't presently look my patients in the eye and tell them that it's safe, effective, and cost-effective to have a PCI procedure done in an ambulatory surgery center in New York State rather than my hospital outpatient department. Now, just to save time, I'm just going to respond to the specific questions that the committee asked. We did submit a detailed letter with more detailed responses. Should the state accredit freestanding versus hospital-affiliated ASCs if it does accredit those? For more than thirty-five years, New York State has pioneered and been both a national and an international leader in the use of data collection and public reporting for quality outcomes in PCI and cath to drive quality improvement. The state is famous for this with thousands of publications. We are a national leader. Mississippi, not to disparage anybody has reported the early outcomes of their experiment in doing PCI in ASCs. We are not Mississippi. We are the national leader and need to remain that in quality, safety, and appropriate use of cardiac procedures. We believe that only hospital-affiliated, not-for-profit ambulatory surgery centers should be the initial trial spots for moving cardiac procedures, including cardiac catheter and PCI, from hospitals into ambulatory center if that's done. The financial impact and community impact. There's no data so far to guide us on any this. The states that have approved ASC, PCI, and cardiac cath do not publish generally. They generally have fairly lax regulatory laws. Many of those states did not have CON laws. The robust quality involvement has existed in New York State between the Department of Health, the Cardiac Advisory Committee, and hospital quality departments is simply not there to support the feasibility, safety, or quality of this proposal in the states that are currently experimenting with it. We need to reinvent this in New York State, in my opinion. Should New York State credit for-profit or not-for-profit ASCs if it does, there's no experience in the state performing or regulating PCI procedures outside of not- for- profit hospitals. We believe that migrating simultaneously from hospitals to ambulatory surgery centers and from the not-For-profit environment to for profit environment would be excessively risky and unnecessarily forward. We believe this should instead be done in a step-wide fashion. Demonstration projects, yes, we believe that the only responsible way if the committee decides to accredit ambulatory surgery centers in New York State to perform cardiac procedures would be to do this as demonstration projects. Remember that not only do we have no data to support that what we're proposing is safe, the evidentiary basis for doing PCI in any hospitals without cardiac surgery is very thin. It consists of only two randomized clinical trials published in 2012 and 2013. There have been no randomized clinical trials that have compared same-day discharge to overnight stay in a hospital, even though we think that's safe. There have no randomized trials that have compared ambulatory surgery center, cath and PCI, or patient implant versus hospital-based, even though there's some questions there. Not clear whether this is even financially advantageous. Data presented in May, a very exciting cardiac angiography and intervention meeting, suggest that there may be hidden excessive costs. Additional costs associated with migrating these procedures to ASC. In summary, at this time, we believe it would be only responsible to accredit Surgery Center to perform cardiac catheter PCI in stepwise fashion, starting with carefully conducted demonstration projects and not-for-profit hospital-associated ASCs affiliated with large academic medical centers. In addition, those places need to develop and validate new ways that we don't have now for assessing quality and safety in low-risk patients. Mortality is no longer the benchmark for this. Thank you.

Ms. Monroe Dr. Soffel.

Dr. Soffel Hi. We just heard some fairly compelling testimony about the challenges of access to services. How does that look in Albany?

Dr. McNulty There are two issues there. One is a financial issue. Our hospital and probably supplies the largest hospitals would be financially advantaged by being able to decant low-risk, low-reimbursement cardiac procedures, like diagnosing cath PCI to an ASC. It would allow us to cut our current long wait times for more remunerative structural heart procedures, and that would improve patient access. At the same time, the number of PCIs performed in the United States has been dropping, as most of you know. The number PCIs and cabbages performed in New York State versus Ontario, for instance, is higher. I think that this is one of the many questions that we don't have answers to, and one of many reasons why a demonstration project to this, I think will be the first why step to take.

Ms. Monroe Thank you.

Ms. Monroe Anyone else?

Ms. Monroe Yes, Dr. Lim.

Dr. Lim You referenced hospital affiliated or hospital associated. Could you expand a little bit more detail if you can about what you mean by that? What I took from the representatives from Northwell is that what they meant by that in short was some degree of operational integration. It isn't just like a referral type of relationship. It's something much more integrated in clinical protocols and overall processes. Is that along the lines of what you're talking about?

Dr. McNulty I think we would agree, in principle, with most of what the Northwell representative proposed. I think the most important thing is to keep ambulatory surgery centers, if they're doing cardiac procedures, within the robust quality and safety environment the Department of Health has developed with hospital quality departments, so that's key.

Dr. Lim Dr. Lim, did that explain it?

Dr. Heslin I just want to thank Dr. McNulty because he's the first one that has actually mentioned diagnostic as a separate category from PCI. I'm stimulating people to think about that a little bit, only in the sense that that was one of the questions we had posed. As I'm going through the questions that we had posted, having answers is always helpful.

Ms. Monroe Did you have a question for me before we go on?

Ms. Monroe Next on the list is Joseph Puma, New York Ambulatory CV Society.

Dr. Puma Thank you.

Dr. Puma My name is Dr. Joseph Puma. I'm the President of the New York Ambulatory Cardiovascular Society. Ms. Monroe, Dr. Heslin and the rest of the committee, it's nice to see you again. I thank you for the opportunity to provide testimony. The society has

provided a letter to the committee. I won't read the letter. I will, I think, take a minute to summarize a little bit what the process in New York State is and highlight a few facts. Number one, this is part of the committee that approves Certificate of Need for ambulatory surgical centers in the state. I think it's important for everyone to recognize that this committee has the force of law. There is already a robust regulatory environment for ambulatory surgical centers, including at least some affiliation, not well-defined with a local hospital in the event of complications. If we look over the last forty to fifty years, we see that there has been a significant arc in in terms of advancements in techniques, advancements in physician capabilities, provide care across multiple specialties in ambulatory surgical centers. I think New York's own data, this committee's own data, demonstrates that we have fifty years of safety, regardless of whether the ambulatory surgical centers are physician-owned, single specialty, multi-specialty, hospital outpatient departments. In addition, New York State was a national leader and the first to put a regulatory environment in place for quality of care, for coronary intervention, and now for diagnostic catheterization. There is no state more well-suited to monitor safety as we already have a framework. My colleagues have already made points regarding access and safety. I do want to highlight one thing regarding safety. Cardiac catheterization and angioplasty has been performed in the United States. The first one performed at Lenox Hill Hospital here in New York City in 1987, I believe. We have multiple societies, the Society of Cardiac Angiographers and Interventionalists. We have the American College of Cardiology, as well as the American Heart Association, who have combined consensus statements on the requirements for staffing, facility, equipment, for catheterization labs that are followed nationally, both in hospitals as well as ambulatory surgical centers. There is already a robust framework nationally for safety. The last point I will make regarding safety. It's rewarding to hear all the hospital representatives opine on the safety of procedures done in hospitals. They will recognize that their hospitals all own multiple ambulatory surgical centers far beyond the number of hospital facilities that they own. The purpose of the majority of those centers has been to move lower risk patients, clinically lower risk patients, not better insurance patients, but clinically lower-risk patients to an ambulatory setting so that the hospital, which does have more facilities and services, can provide care to higher risk patients. Last, I would say, all of the representatives who have come up here, bar a few, have been physicians or surgeons. Quality and safety is in the hands of physicians and surgeons by dictates from the Department of Health, not from hospitals. I think we already have, and I believe this committee reviewed the recent article published out of Harvard looking at the first 400,000, comparison of the 400,000 ambulatory surgical center PCI procedures that were done. The mortality rate, whether it was hospital or---

Dr. Heslin 30 seconds.

Dr. Puma Or private ambulatory surgical center was less than 1%. In fact, the mortality rate was statistically significantly higher when the procedures were done in hospital outpatient departments as opposed to private. I thank you for your time. I appreciate your consideration, most importantly to patient safety and the health of all New Yorkers.

Ms. Monroe Thank you very much.

Ms. Monroe Any questions or clarifying?

Ms. Monroe We'll be looking at all the material that you've provided.

Ms. Monroe I have trouble with this, but it's Steven Geyer.

Mr. Geyer My name is Stephen Geyer, Senior Vice President from Corazon. We are a national consulting and recruitment and accreditation firm. I thank you for the opportunity to speak this morning. Dr. Puma just referred to the 2023 SCI expert consensus statement for PCI without surgical backup. Has approved Corazon's accreditation services. What we're seeing in states that are moving into this regulatory language is the use of accreditation in service-specific accreditation for these services. Due to the importance of case selection and adherence to clinical practice guidelines in cardiac services in general, and particularly in the ASC setting, Corazon recommends that the state requires service-specific accreditation for these programs from an existing recognized body such as Corazon to monitor quality outcomes and compliance with guidelines and regulations regardless of affiliation type or financial status. The accreditation should be in addition to whole house accreditation for required ASCs in general. Speaking to some of the questions that were raised by the committee, Corazon believes ASCs should be allowed to offer cardiac service regardless of hospital affiliation status. Both hospital affiliated and freestanding services can provide these services. To allow only hospital or only freestanding centers to initiate services would limit patient access to care without notable improvement to the care provided, which is also supported by this guide document. Speaking to some of the benefits, the financial benefit and cost savings shifting lower acuity cases from the hospital to ASC setting can create hospital capacity for more complex and higher revenue-generating cases, while requiring fewer and less costly resources for that less acute care. This results in overall cost savings for both health care systems and patients, with ASCs offering lower out-of-pocket expenses and receiving lower reimbursement for most services. Speaking to community service and patient convenience. ASCs improve patient convenience by providing care closer to home, reducing travel and navigating challenges, and enhancing access in underserved areas, which should be primary consideration in policy recommendations. ASCs also offer new access points for care beyond those existing in hospitals, freestanding emergency departments, urgent care centers, and physician offices. Speaking to demonstration projects, cardiac services should not be a demonstration project because sufficient clinical evidence already exists that proves diagnostic catheterization and PCI procedures are safe in the ASC setting, and the CMS has approved these procedures since 2020. Furthermore, 50% of states currently allow PCI procedures to be performed in an ASC based setting and Corazon's research of state health care regulations including Pennsylvania, Michigan, South Carolina, and with more states changing regulations each year, such as Illinois changing they're in 2025 to allow PCI in the ASC with ASC accreditation. New York initiating this discussion currently, as you are. Regarding community benefit, Medicaid and self-pay benchmarks are not unique to cardiac procedures in the ASC setting and should be considered within the broader context of the ASC regulations instead.

Ms. Monroe Thank you.

Ms. Monroe Any questions or comments?

Ms. Monroe Dr. Eisenstein.

Dr. Eisenstein Thank you for your testimony.

Dr. Eisenstein This is not the first time this committee's met to talk about this topic. What I've been consistent about and has been referred to by some of the speakers before you is the lack of evidence-based safety data. I'm not opposed to this conceptually, but we

practice medicine based on evidence-base practice. In your statement, you said it's been proven safe. I'll ask you, like I've asked other speakers earlier, send us that data so that we can make an educated decision. I will tell you when, at the last meeting, when I asked New York State Department of Health if that data exists, they agreed with the position that there isn't evidence-based. Dr. Puma said there's going to be data coming or somebody for later today. I look forward to seeing it. We just as a committee have to know that what we're doing safe, and the demonstration project to prove that safety, great, but you in your testimony said that data exists. I'd like to see it.

Mr. Geyer Well, just as Corazon saw as the demonstrations began with PCI without on-site surgical backup proved that those settings were safe. The important thing is to provide safety and guidelines in these settings that are similar to those facilities that were new in the administration project. We've learned how to do that over these years and to provide similar guidelines and guardrails are the way to do because that data already exists. There has to be parallels. Accreditation is one way to that. Certainly, looking at that data is the most important thing and Dr. Puma is correct, and we'll look into that data to provide as well.

Ms. Monroe Dr. Hesselund.

Dr. Heslin Thank you.

Dr. Heslin Corazon's involved with accrediting these centers, correct?

Mr. Geyer Correct, in multiple states.

Dr. Heslin Do you have an estimate of how many centers you're currently working with?

Mr. Geyer No, but I can provide that.

Dr. Heslin Can you also provide the safety data from all those centers so that the committee could take a look at that? Because if you have the quality, the safety, and the accreditation and seem to be on the pulse of what's happening nationally, it would be worthwhile having that data. You know, to be clear, there is a database that's being established by the American College of Cardiology, but when I went to access that database was not yet fully vibrant. It was built but did not have information in it. That was six weeks ago. Your information might be the first set of information that could be coalesced. It might be a worthwhile paper that Corazon could write, but we welcome that data.

Mr. Geyer Thank you. I appreciate that.

Ms. Monroe All right, well, thank you very much.

Mr. Geyer Thank you.

Ms. Monroe Lois Utley.

Ms. Utley Good morning. I'm Lois Utley. I'm here representing Community Voices for Health System Accountability. It's a statewide network of advocates for equitable and affordable access to hospital and health facilities for all New Yorkers. We wanted to begin by thanking the community for inviting public comments on the subject and notifying us

well in advance so that we could schedule to be here. We encourage the council to do this more often. We did have some questions about whether there is existing data that the department or other entities have about whether, there is, in fact, a shortage of cardiac cath lab capacity. I heard the testimony, the earlier testimony, that was quite compelling, but I haven't heard any data about it. We suggest that the ASC cath services should be added where there is clear need for more capacity, not simply because there are providers eager to enter the market. We discussed the questions that you helpfully provided. If the department decides to go forward with some type of a program, we suggest that it be a demonstration project, the most prudent way to test the provision of services in question in an ambulatory setting and then make any necessary policy and clinical adjustments based on the results. I would suggest a five-year trial period with a limited number of participating facilities. If possible, the demonstration should test the feasibility and impact of such a program in rural, suburban, and urban areas. We suggest that the state require yearly reports on the number and demographics of patients served, clinical outcomes, payer mix, and importantly levels of service to Medicaid insured and uninsured patients. We also encourage the state to track and compare the cost of providing these services in an ambulatory setting as opposed to a hospital setting. You know, if existing capacity is overbooked...we clearly need more. Overall health system costs in New York might rise if multiple new facilities are built and divert patients from existing capacity that then goes underutilized. We strongly believe that a hospital affiliation should be required in order to better ensure the prompt transfer of a patient, if need be, to a hospital setting in the event of complications. We strongly believe that the ambulatory centers should be nonprofit, as are the private hospital systems throughout our state. For-profit centers could be more likely tempted to cut corners or bend guidelines in order to further the bottom line. We want to emphasize that we think the state should set strong guidelines for expected service to Medicaid-insured and uninsured patients and hold accountable those facilities that fail to meet those standards. We recommend benchmarks based on the average percentage of Medicaid insured and uninsured patients within each facility's primary service area. We urge the department to aggressively monitor the performance of these facilities. Your committee did not ask any questions about how patients should be informed about and directed to ASC centers, but we think this is important. Will there be a process that informs patients about why they're being suggested to go to an ambulatory center versus a hospital setting? Will they be made to understand, help to understand why they are considered high risk or low risk? What's the reason for sending them to that patient center? We have concerns that there might be a referral process that favors commercially insured patients. We want to make sure that there is not a referral a process that discriminates against publicly insured or uninsured patients. Thank you.

Ms. Monroe Thank you.

Ms. Monroe Any comments or questions?

Ms. Monroe Well, thank you for taking this request seriously and really spending time with your group to come back to us with.

Ms. Utley Again, we really appreciate your initiative in setting up this hearing. We would like to see more like this opportunities for ordinary consumers like myself to comment.

Ms. Monroe Point well taken.

Dr. Soffel I'd like to just make a comment for our consideration, which is who makes the decision about whether a patient receives PCI at an inpatient versus an outpatient setting?

Does the patient have any opportunity to weigh their own personal preferences in that decision-making process? I have no idea what the answer is, but let's put comments raised for me, the question of is there any patient choice in the decision, and I just don't know.

Ms. Monroe Well, let's park that for our next discussion, and we can always reach out and get, because it may vary from system to system. It may vary from system to system, and we'll learn more about that in our next discussion. Thank you.

Ms. Monroe Erin DuPree, is that correct?

Dr. DuPree Good morning. Good morning, Vice Chairman and members of this committee. My name is Dr. Erin DuPree. I'm the Senior Vice President and Physician Executive for Quality and Clinical Initiatives at Greater New York Hospital Association. Greater New York proudly represents hospitals throughout New York State both non-profit and public, as well as hospitals in New Jersey, Connecticut, and Rhode Island. Thank you for this opportunity to provide comments on this topic. My understanding of care delivery comes from my clinical training and practice as a physician, my experience as Chief Medical Officer at a large academic medical center in New York City, and the Joint Commission Center for Transforming Healthcare, and my quality and clinical initiative responsibilities at Greater New York.

Ms. Monroe Would you put the mic a little closer to your face?

Dr. DuPree Greater New York's position is that this proposition is a solution in search of a problem. Relocating cardiac catheterization cases from hospitals to ASCs could create excess capacity in the healthcare system and significantly weaken hospitals. Moreover, we believe that ASCs don't necessarily serve unmet community needs. Across the country, 99% of ASCs are for profit. Hospitals actually provide those services, such as trauma and emergency care, that the community needs. ASCs are often less likely to participate in Medicaid or provide uncompensated care. All we're asking is that the Health Planning Committee should factor in the impact on hospitals when considering the issue of cardiac catheterization in ASCs. The following outlines the concerns. This is reiterated in the letter that we have sent. But just to say, at a minimum, just further analysis should be undertaken. I think it's been pointed out multiple times. Where's the data? We want to see the data. Where is the problem? Is there an access problem here? Let's look at it, let's understand it, get to the root cause of it, and then develop a solution. We're kind of going down this path. Where are we starting from? From an improvement background, you got to define the problem. What is the aim? What are we trying to achieve here? Certainly, we all want equitable. We want to take care of the vulnerable patients here. If that's it, where's the access problem? Without clearly stated goals, there's a high potential for unintended consequences. That's all. We just need to not go into this in haste. So, from a clinical quality perspective, you know, for-profit motive can often lead to an increase in the overall number of procedures performed, including those that may not be medically necessary. Studies have found that the opening of an ASC is associated with a greater increase in outpatient volume than can be explained by the shift from hospitals alone. Again, many have talked about the patient procedure selection. Often, for-profit ASCs have an incentive to select those healthy or low-risk patients, and that cherry picking can artificially inflate outcome metrics. Again, the devil's in the details, right? You got to get into the reporting that this state has established with the Cardiac Advisory Committee for hospitals is critical. One of the things pointed out in the July 1st meeting on this topic was data presented on complications in hospital outpatient departments versus ASCs. Compared to a 4.7%

repeat PCI rate in hospital-outpatient facilities, ASCs had a 10% rate. What is going on there? Has an analysis been done? Is there a quality concern? Ultimately, could that bring additional costs that haven't been measured into the overall system? Most importantly, the caring for the underserved and underused, many uninsured. Many hospitals in New York State serve large members of Medicaid and uninsured individuals. The regulations are very clear that it requires a determination of need when considering how the proposed ASC would enhance access and promote availability of patient services. Now, the testimony is great, but where is the data? Where is the problem? It's very important to do that. We know that hospitals provide the full array of services that their communities need, such as emergency department, trauma services, behavioral health, and more, many of which cause significant financial losses. By contrast, ASCs don't provide those critically important but unprofitable services. Also, the quality reporting has been pointed out here is very key, and if this is done in any type of demonstration or more fully, they should be required to participate in the New York State Cardiac Reporting System. I'm going to jump to the economic implications. With the passage of HR1, the big, beautiful bill, there will be an estimated 1.5 million more uninsured in New York. New York State also anticipates significant budget shortfalls totaling $8 billion total, which will impact 7% of hospital operating revenues. Any migration of profitable hospital services such as cardiac caths to ASCs must take into consideration the impacts of HR1. Understanding the context that's going to unfold over the coming years is extremely important in addition to the quality. Again, the workforce considerations is the next topic. These procedures require highly skilled and expert personnel that are already in short supply at our hospitals and could also leave to go to these other facilities. That needs to be analyzed also, right? More information, more data. I understand that my time is up. I think the main point here is not to exacerbate disparities and to slow down. Understand what the problem is, what are we trying to solve, and where is the data. Thank you so much.

Ms. Monroe Thank you.

Ms. Monroe Dr. Eisenstein, Dr. Lim, did you have a question?

Dr. Eisenstein Thank you for that testimony.

Dr. Eisenstein One of the things that I think comes out of this is really important. Whatever the perspective is, we have a lot of prestigious doctors here and it's really helpful to hear from them on all sides. I want to thank them for taking time out of their crazy busy schedule to be here because we can debate it all we want, but hearing from the actual boots on the ground, the expert in the field is very valuable. Dr. Heslin and for the state and Ann, as we discuss this going forward, interventional cardiologists don't fall off a tree. There's not an unlimited supply of them. I think a point that was brought up that we should hear as we go forward in discussing this is, if we are moving interventional cardiologists out of one setting into another setting regardless of what it is, is there capacity for that? You can build facilities. You can build an airplane, but if you don't have a pilot, it doesn't go anywhere. We also want to make sure that if people migrate, interventional cardiologists migrate, that we leave a safe situation behind in the hospitals who are going to be the safety net caring for people who come in. Just data on that as we discuss this going forward, what is the capacity of interventional cardiology would be, I think, an important part of our discussion.

Ms. Monroe Great point.

Dr. Lim Thank you, Dr. Dupree.

Dr. Lim I just have a clarifying question. You had referenced that you are actually part of the leadership of the Joint Commission. Could you speak to, I'm not quite as familiar for the benefit of the committee, the basic how are ambulatory surgical centers currently accredited? What are the different accreditation organizations as a Joint Commission? Do accreditation for ASCs? If there's some background that you can give us, I'll be great.

Dr. DuPree I'm happy to provide fuller that was not the focus of my talk today. In basic, the Joint Commission is the nation's largest accreditor for hospitals. Importantly, as many people don't know, actually accredits many other healthcare settings, including ambulatory surgical centers.

Ms. Monroe We'll look for a little more information on that.

Dr. DuPree I'd be happy to provide more on ASCs and the Joint Commission.

Ms. Monroe Anyone else?

Ms. Monroe Thank you very much.

Ms. Monroe We're moving to Jeffrey, someone from Catholic Health, Long Island. I'm sorry, Jeffrey, I don't know how to read your last name.

Ms. Monroe Moses!

Ms. Monroe Well, I should have known that.

Dr. Kuvin Well, thank you for allowing us.

Ms. Monroe Would you make sure your mic is on? Green light.

Dr. Moses Is this working now?

Dr. Moses Thank you for this opportunity. It's been a lot discussed, and I won't replicate a lot of the testimony that you've seen. I'm the Chairman of Cardiology at the St. Francis Heart Center of Good Samaritan, but I've also helped build the programs at Lenox Hill and Columbia. I've been involved in over 30,000 interventional procedures. One thing I can say is when I think about this. Is what benefit does this accrue the patient? It's what I would call the Mother test. I can tell you, even taking the lowest risk patients, these cardiac complications from PCI, which can be sudden, unanticipated, and immediately lethal. I think when I was thinking about the testimony today, I was thinking about a patient I did about two years ago. Where I finished the angioplasty, everything was fine. He certainly would have qualified for an ambulatory care facility. At the end of it, he decided to scratch his nose. Unfortunately, he had a catheter in his wrist. When he scratched his nose, he went into refractory ventricular fibrillation, which could not respond to medication or cardioversion. Fortunately, we were in the hospital. We had the anesthesiologist there. We had nurses there giving medications. We brought in the ECMO. We brought the Impella. I was able to support him while we cannulated the vest. I figured out that it was the mammary that had been dissected. We opened it up. He was saved. If this had happened in the ambulatory facility, I don't care if the hospital was across the street, he would have died. I just don't know how many of those, when you speak of safety. How many of those are tolerable, to what benefit? That's just a question I think for myself when I'm talking to

an individual patient. As far as capacity goes, I mean, I've been involved in building cath labs literally since the 80's. I know that there's been an arms race of cath labs, certainly in the Metropolitan area, and we've also lowered the minimum requirements. You could have the data, or leave it to the greater hospital people, but I cannot imagine that there's overutilization of these. There's got to be excess capacity here. Another aspect, though, when you talk about selection, as a clinical researcher, these low-risk patients are valuable to us, obviously, to treat, but those are the very populations that we conduct clinical research on. If that is pulled out of the medical centers, especially the university centers that conduct most of the research, I think it will really hurt the population that we're that's available because these clinical studies generally want very low-risk patients without any other noise in the system from morbidities, and siphoning them off to ambulatory facilities I think will also hurt that whole enterprise and the advancement of our field.

Ms. Monroe Could you say that one more time?

Dr. Moses Low risk patients are generally the prime targets for many clinical trials because they reduce the noise in the system in terms of complications because with other comorbidities, they can interfere with the purity of the data. That's a very important population. In the United States, we always have major challenges in recruiting for these trials anyway, but that's a key part in advancing our field and improving techniques and technology. I fear that siphoning them off, especially from the medical centers that do that...the bulk of these research, and there are many of them in New York, certainly, that it would really limit access to those patients by the researchers and I think detrimental to the advancement of our field.

Ms. Monroe Questions? Comments?

Ms. Monroe Well, thank you very much, Dr. Moses, correct?

Ms. Monroe Allison Goldberg.

Ms. Goldberg Thank you.

Ms. Goldberg Good morning. My name is Allison Goldberg. I'm a Health Policy Analyst at the Community Service Society of New York. As a general matter, CSS supports permitting ASCs to provide the services in question but offers specific suggestions in an effort to promote healthcare affordability for the consumers who would be using ASCs. CSS believes the ASCs should be hospital-affiliated but suggests that they adopt site-neutral policies for paying for these services, such as capping payments at 150% of the Medicare non-hospital rate. CSS also suggests that the ASC should not be permitted to charge facility fees and that they should be required to provide financial assistance to eligible patients using the state's uniform hospital financial assistance application form and following the affiliate hospital's income guidelines. With regards to payer mix benchmarks, CSS suggests that the state set guidelines for expected service to Medicaid insured and uninsured patients based on the average percentages of uninsured and Medicaid ensure patients in each facility's primary service area as defined by the Department of Health criteria. Setting these region-specific benchmarks would ensure that each ASC's payer mix is representative of the patient population within its community. Additionally, ASCs that provide services to greater percentages of uninsured and Medicaid insured patients than required by the guidelines should maintain or increase these percentages over time. The state should hold accountable facilities that fail to meet any of these standards. CSS appreciates the opportunity to offer comments on this matter. We provide these

suggestions with the goal of maximizing patients' access to high quality and affordable healthcare.

Ms. Monroe Thank you.

Ms. Monroe I have a question. Talk a bit more about the facility fee. It's not a concept I'm that familiar with. You say they should not be able to charge a facility fee?

Ms. Goldberg Generally, we are suggesting site neutral payment policies where the higher prices that would be paid in a hospital setting are not paid in these outpatient settings just because of the hospital affiliation. We provide more detail in the written comments we submitted.

Ms. Monroe That would be good.

Ms. Monroe Anything else?

Ms. Monroe All right, we have one last speaker. Dr. Ali F. Aboufares.

Dr. Aboufares Good morning, members of the committee.

Ms. Monroe You need to take the mic closer and make sure the green light is on.

Dr. Aboufares Good morning, members of the committee. My name is Dr. Ali F. Aboufares. I'm an Interventional Cardiologist and the Secretary of the New York State Ambulatory Cardiovascular Society. I'm also the Medical Director of an ambulatory surgery center in Manhattan, New York, where we already perform advanced vascular and endovascular procedures. I appreciate the opportunity to speak in strong support of allowing cardiac catheterization and PCI in the ASCs. Across the country, more than half of the United States already permit these procedures in ASCs, twenty-six states. In our neighboring state of Pennsylvania, they have been performed for years with excellent outcomes, reduced costs, and high patient satisfaction. New York should not remain an outlier. These procedures are safe and standardized. Robust protocols and low complication rates. When performed by experienced board-certified interventionalists in accredited facilities, outcomes are equivalent to the outcomes we see in hospitals. Quality should be monitored, though, through metrics such as thirty-day complications, readmissions, and patient satisfaction. I'm sure we all heard about the access and the equity, so I'm not going to be redundant about this point. From a system perspective, ASCs lower cost compared to hospitals. I heard all the pushback from the hospitals. They do. They lower the cost. This cost can be used somewhere else. It can benefit Medicare, benefit patients too. Savings can be reinvested in preventative cardiovascular medicine. We don't have to do PCI all the time. The issue of the for-profit versus non-profit debate has already been settled in our state. It has been settled. Both models exist, and both models deliver high-quality care. New York should allow both hospital-affiliated and freestanding ASCs. As you know, when we open an ASC, we have to get a Certificate of Need, and this Certificate of Need has to be associated with the hospital system that is within thirty minutes of the ASC. There are strict safety standards that we can go by for the facility and for the operator. From an operator's standpoint, like me, you can say this is not for all comers. This is for experienced interventionalists. This is, for example, for the board-certified interventionalist whose X number of years out of fellowship, let's say five years. I've been nineteen years out. With low complications rate, below the national average, for example, in your New York State PCI registry, you can say, look, if you meet this criteria

one, two, three, and you're experienced, you as an operator, we can allow you to do that. I myself teach the procedure at Columbia University and at Lenox Hill Hospital. We have fellows. We teach fellows. I'm a teacher just like some of the doctors behind me. Some of the doctors behind me are hospital employed. I'm not a hospital employee. In short, cardiac cath and PCI and ASCs, I believe, would expand access, as we discussed, and I think Mr. Flynn will share the data with you. I think it reduces costs because we proved this in other specialties, not just in intervention and cardiology. I think safety has been proven. Who cares about an anecdote of a patient who had a complication? We're talking about 400,000 patients done in an ASC setting.

Dr. Heslin Thirty seconds.

Dr. Aboufares 400,00 patients done in an ASC settings, we have data on that. Data speaks. New York now has an opportunity to join the majority of states delivering these services successfully. I urge you to move this initiative forward. Thank you very much.

Ms. Monroe Thank you, doctor.

Ms. Monroe Any thoughts or any questions or comments?

Ms. Monroe Thank you.

Ms. Monroe If you could leave your comments with us, your written comments and that would be great.

Ms. Monroe Is there anyone else who wanted to speak that we don't have on our list? Anyone else in the room?

Ms. Monroe Yes, Sir.

Mr. Bell Yeah, I just arrived. I signed in.

Ms. Monroe Well, would you like to join us here at the table?

Mr. Bell Yes, please.

Ms. Monroe Introduce yourself and Please make sure the mic is on with the green light.

Mr. Bell Can you hear me?

Dr. Heslin May I remind you, you have five minutes.

Mr. Bell Thank you.

Mr. Bell My name is Leon Bell. I'm the Public Policy Director with the New York State Nurses Association.

Ms. Monroe New York State?

Mr. Bell New York State Nurses Association.

Ms. Monroe Nurses Association. Thank you.

Mr. Bell NYSNA represents more than 42,000 nurses across the state for collective bargaining. We're also an advocate for universal high-quality health care coverage, eliminating health care equity issues from our health care system, and protecting the practice standards and working conditions of nurses and other health care workers. NYSNA poses the proposals being pushed by the State Department of Health to change current state policy and regulatory standards and allow private for-profit entities to provide PCI and diagnostic catheterization services and freestanding ASCs. Our concerns include the following. One, the impact on quality of care and patient safety will be negatively affected. The underlying premise of these policy changes is that shifting PCI in diagnostic cathetization to for-profit ASC settings is safe and will not affect quality of care. This assumption is not supported at this point by the existing data. The paucity of relevant patient safety and quality care data has been acknowledged to some extent within the discussions in the April and July meetings of the committee. New York has detailed quality of care measures, but that's not the case in other states. I think one of the things that we should be looking at is comparing how the hospital-based system in New York compares to some of these states, primarily Southern states that have allowed wide penetration of freestanding ACs into the business and how those metrics state to state compare. We're concerned that this proposal will further undermine the financial stability of hospitals in general. You know, it will basically encourage shifting the PCI work to the freestanding ASCs, which are cheaper. It's clear that the motivation promoting this policy change is to reduce state expenditures by shifting PCI to ASC providers, but we have to also look at how that's going to affect general hospital revenues. These are well-reimbursed procedures, and if more of them are done in for-profit ASCs that's going to leave less money for the hospitals to subsidize their less profitable services that we don't see a rush of private ASC seeking to get into. For example, psychiatric, pediatric, ER, and trauma services, and other services that don't pay as well. We would expect that those services will suffer if hospitals lose income on the coronary side. We're concerned that this proposal will increase the role of for-profit providers in our healthcare system. I'm not going to get into detail on that, but as opposed to expanding the role of for-profit providers, we think it's antithetical to the provision of high-quality care to all patients across the state. We're concerned that the proposal will increase inequality in racial and class inequities in our healthcare system, again, based on the fact that, A, there's a well-documented trend or tendency for for-profit entities to try to avoid taking on low-income patients or uninsured patient populations. Shifting these revenues or these procedures to the private sector will increase that tendency. We think there are workforce implications regarding this proposal. Shifting PCI to freestanding ASCs will disrupt and undermine hospital RN workforces as ASCs increase their market share and take on more of these profitable coronary care services. Hospitals will be directly forced to reduce their own coronary workforce and will be facing competition from ASCs to hire nurses and other staff. In addition, there will be indirect effects as the loss of these profitable services will leave less money within the hospital budgets to provide less profitable services, and that will lead to indirect layoffs or reductions in staff outside of the coronary care sector. We also note that hospitals have high union density while private ASCs are largely non-union, and that shifting PCI services from hospitals to ASCs will negatively affect pay benefits and working conditions. Also, the staffing law, recently enacted staffing law doesn't apply to ASCs, which would lead to worse staffing conditions and no role for nurses. Finally, we are concerned that this will include and expand the role and power of corporations and financial interests in the healthcare system. Increasing financialization will lead to the extraction of money revenues in the form of profit, not to reinvest in healthcare, but to line the pockets of private investors. For that reason, as well, we stand opposed to this. I'll just wrap up. We urge the committee to vote no on this proposal or in the alternative to slow the proposal down,

because we don't really see what the big rush is at this point in terms of moving forward at the pace that the DOA seems to want to move forward at.

Ms. Monroe Thank you.

Ms. Monroe You were the last speaker, but I want to comment on some of the things that you said. Just to assure you, we are not at the point of making a recommendation. This is the Planning Committee that is looking at everything ranging from doing nothing to some very wide range shift. We appreciate your perspective on for-profit ASCs, which is only one possible outcome of our work. We welcome the Nurses Association comments. On the other range of activities, should they be hospital-affiliated? Should they non-profit? Should we do a demonstration project? Perhaps, you could give us some comments in writing about your sense of those options as well as the far-reaching one that you clearly oppose. We're in the analytical stage and the evaluation stage. And at some point, the committee will make a recommendation to the council about where the council should come down on this issue. At that point, it may or may not look like what you described. Please stay in touch with the process along the way and we'd love your feedback on the various steps.

Mr. Bell Yes, if you're open to it, we could forward more detailed sort of analysis of some of the issues that we raised. We understand that this is early in the process, although I'm also getting the sense that there is a sense of urgency coming from above on the committee to move this quickly. That's kind of perplexing to us, because we're not really sure where the crisis is that needs to be addressed so urgently that it sort of upended what the committee has been working on over the last couple years and made this suddenly a top priority issue that needs to be moved quickly, which, again, we don't really understand where that's coming from because it doesn't really.

Ms. Monroe Well, we have our work to do and that is on this topic at this time.

Mr. Bell Yes.

Ms. Monroe Thank you for your comments.

Ms. Monroe Any other questions or comments?

Ms. Monroe Well, I think that's everyone in the room.

Ms. Monroe This has been very invaluable in many ways. There are strong feelings and very valid perspectives on all sides of this issue. A common thread that we heard was we need more data. We need more data to make a truly well-informed decision. Some of that data we've learned may be out there. We just didn't know about it. We welcome that. We have another meeting next month. We'd like to be able to incorporate everything we've heard today, the letters that have been written and the data that we can receive between now and then to help formulate our thinking as we move forward. We have made a commitment to the Public Health Council that by the end of the year, we will have some sort of recommendation to them. You will see us moving rather quickly between now and the end the year. All options are open at this point. We have not on the committee made any... We may have our own opinions about where this should come down. As a group, we have not collectively formed a perspective on this, and that's what we'll be doing over the next month to do. As I said, your comments, your letters, the data you can provide both today and with any at any other time between now and the time we have to make a

decision, it will be welcomed, it will review, it'll be incorporated into our recommendation. This has been very valuable to us and very helpful. On behalf of the committee, I want to thank everyone who came forward today out of your busy schedule to make sure we knew both the seriousness of this decision that we were making and the different perspectives on how it might move forward. On that, unless I have other comments from committee members, I will adjourn the meeting.

Ms. Monroe Thank you very much.