

NEW YORK STATE DEPARTMENT OF HEALTH
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
HEALTH PLANNING COMMITTEE
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ESP, CONCOURSE LEVEL, MEETING ROOM 6 ALBANY
TRANSCRIPT

Dr. Rugge:

... Surgical centers ASCs. And we eventually came up with a report which was carefully reviewed by all the necessary people in state government, and have that distributed to all of us some days ago. In this meeting, we'll briefly review that report and have a discussion about thoughts of committee members regarding it. The hope is that we can avoid making any substantial changes in the report because that would entail several more weeks of review before it could be presented to the council and could delay our work further. However, comments are very welcome, and they will be included in a meeting summary and then can be reiterated to the council itself for deeper consideration. If that works, that would be great. By way of just a brief overview, the introduction states we went through three phases, three stages, I'm sorry. Stage one was going to the literature and national reports and state authorities to learn about PCI in ASCs.

ASCs, yeah. Anyway, what we learned was that more than 30 states around the nation are already performing this work, some without any regulations at all, others with regulations that mimic what we tried to do in New York State and found that the outcomes were equivalent in both settings, ambulatory settings and hospital settings. Stage two was inviting authorities and societies to come to the committee and present their experience, their perspectives, and any recommendations they might have. In stage three, we used to dedicate ourselves to deliberations about how to conceive our report, how to develop recommendations that led to the writing of the report, and its submission for departmental review, and then distribution to all of us. Following today's meeting and obtaining comments and how to place them and where to place them, the hope is that we will be prepared to submit these to the council at the February 19 meeting for review approval and usefulness to all those people interested in applying for this new status. Anne Monroe has a brief summary of the recommendations we're making. And Anne, it's your turn.

Ms. Monroe:

Okay, John. Thank you. Hi, everybody. I'll quickly run through the recommendations that we have. And then we got four comments

from members that we want to bring to the group to look at how we might want to handle them. Thank you everybody for reading this and for your involvement in the process. We really focused on the recommendations on phase one, trying to be as specific as we could be, because what we want is demonstration of safety and efficacy. And so, we were as specific as we could be in phase one, but we have not tied the department's hands for future phases, but they should be based on the learnings. So that's certainly the specifics of phase one. The only place where we disagreed with each other was whether hospitals had to own 100% of the ASC. And it was a pretty close vote, six to four, there were 10 of us. So, we put both things in the recommendations so that the department and the cardiac advisory committee will understand that.

In phase one, we're limiting it to hospitals with at least ownership control, if not 100%, and those that have existing cardiac surgery programs. So, we're trying to start phase one very narrowly where we can, and those who are looking at this can see and measure and manage the process. We said they needed to be nonprofit, and since they're owned by hospitals in New York, there are nonprofit ASCs owned by them. We want a CON approval process developed for these, along with the health equity impact assessment. And I believe Sabina asked me if the EIA would be required for this, or we're asking that it be put on extra special. And I thought it would be required, but it's not for a new... Well, we need to get clarity on that, and then we'll come back to that point for discussion.

They have to include Medicaid and low-income people. They have to have what we called here a relevant consumer patient education program, and there was a request to be more specific about what we meant. So again, we'll come back to that. In future, for all phases, the ethical consideration should be included that come from the Society for Cardiovascular Angiography and Interventions. Staffing and credentialing need to be looked at as well as necessary equipment, and safety and emergency protocols. And then lastly, we understand that the Cardiac Advisory Committee to the department and the department will be the ones to manage this program, but we have put in these recommendations very specific direction that PHHPC needs to be kept advised of this process all along the way. So, in other words, we don't want it to go into a black hole and then it comes up with a CON request, that that would not be an appropriate involvement of PHHPC and with the work that we do.

And then we really hope that as the program evolves, that we can look at different geographic and demographic populations so that we begin to understand this on a broader basis, and hospitals that may have different kinds of operations, as well as non-hospitals who may want to get in this picture. So those last things are really, again, a reminder that we're not dictating future phases. So that's where we stand on the recommendations. Is anybody unclear or needs clarification about what's written in the recommendations before we get to what people have asked about?

Dr. Ruge: I would just like to say that from my perspective anyway, this exercise was a real exercise in planning, as PHHPC is entitled and actually authorized to do. And so even though it took some time, I think it may help to set precedence in terms of how going forward in an ever-changing healthcare system, we can be of relevance and of assistance to the department and to New York State in developing new initiatives and new programs. We have four comments that arrived, and I think going in sequence to address those might be good. And further comments are certainly welcome for everybody here at the table. The first comment came from-

Ms. Monroe: John, before you go into mentioning the comments, it's our understanding from the department that if we make, "Substantive changes," in our report, it will need to go back through the approval process at the department, on the second floor, and wherever else needs approval. So, we need to be clear whether we're making a wordsmith change or whether we're making a substantive change that would mean we couldn't adopt the program as it is. However, in the minutes of the meeting, we can make sure if there are things that come up that we're not putting in the report, but we want to discuss that those can be addressed. Sorry to interrupt you, John.

Dr. Ruge: Excellent, it's a nice repeat. That's good. Does this make sense to everyone? Is this clear? Peter Robinson, we have interesting comments.

Mr. Robinson: Well, first of all, I think I'm going to make this as a comment rather than a request to change the report. So, it's more that I'm putting this on record rather than that I'm asking you to do anything different than what you're doing. Just a broad concern, which I believe is addressed in phase one where we are limiting PCI ambulatory surgery facilities to essentially hospital based not for-profit institutions. And I'm very comfortable with that. The area that I'm not comfortable with is this open-ended piece of it which reflects the fact that in fact, PCI centers can go the same direction as ambulatory surgery centers. I think it's opening another door to the

corporate practice of medicine, something we at New York State have been pushing against, but actually not successfully. And I'll point to lessons that we should have learned even in the area, especially as an example in dialysis, and how our decision to essentially invite corporations in or for-profit entities into the world of dialysis dramatically changed the landscape in New York.

And I would argue that that has not produced higher quality care for patients, it may in fact have created more challenges for ensuring good quality care. And PCIs, even with a lower cost being available in ambulatory settings, is still going to be a very profitable enterprise for anybody getting into that business. And so, it will attract people who are looking to generate a profit. And I don't necessarily know that that's in the public interest down the road. So phase one, I'm comfortable with, but I would argue that we may want to rethink whether we want to open the door to for profit practices in the future, even if it requires that we take PCIs and not call them ambulatory surgery, but create a separate category for them so that we're not locked into the precedence of ambulatory surgery and what we're doing with those centers going forward. So again, these are comments. I'm not asking that the report recommendations be changed, but I am just wanting to put that on the record, thank you.

Dr. Ruge: Yes, thank you very much, Peter. [inaudible 02:30:33].

Dr. Heslin: I was just going to say, the department appreciates the position, and we will take that back as a very thoughtful comment. Thank you.

Mr. Robinson: Thank you, Dr. Heslin.

Dr. Ruge: And thanks to your eloquence, it's been recorded and will be placed in our meeting summary. Would anybody care to accept Peter's recommendation and argue about this? He said, "There may be some people arguing," but I was just wondering.

Ms. Monroe: To accept his recommendation to include that?

Dr. Ruge: No, to comment.

Ms. Monroe: Oh.

Dr. Ruge: Yes?

Dr. Eisenstein: Well, you said [inaudible 02:31:23].

Dr. Ruge: Okay.

Dr. Eisenstein: I just want to wholeheartedly agree with everything [inaudible 02:31:23].

Dr. Ruge: You're very welcome.

Dr. Eisenstein: My microphone was off. I want to wholeheartedly agree with everything Mr. Robinson said on the record.

Dr. Ruge: I think if others agree, it would be good to have that on record. I see a nodding head. I agree, Dr. Berliner. Anybody else want to volunteer?

Ms. Monroe: I don't know enough yet about phase one to know how I would feel about future phases, so I'm going to abstain on that.

Dr. Ruge: Any other comments?

Mr. Thomas: But again, John, Peter's comments are on the record.

Dr. Ruge: Yes.

Mr. Thomas: They've been accepted by the department as in the record, but not a formal change to the proposal.

Dr. Ruge: That's true. That's right. So, it's a concern regarding the proposal, not an amendment to it. Okay. Recommendations thought number two came from Larry Eisenstein.

Dr. Eisenstein: So, thank you. Is that better? All right.

Dr. Ruge: Yes.

Dr. Eisenstein: Now I can sing. So, I think my comment is not a full amendment because it addresses staffing, and staffing is addressed already. So, I think it's an addition rather than a complete redo. The document that we received talked about that we must review staffing, but one of the perspectives that was left out that came up from numerous people at numerous times during our meetings was the fact that staffing, particularly nursing of PCI programs, is highly specialized and highly sought after because the hours are typically better than you might get in the hospital. And so, the concern that I have, which I think at least needs to be added into that staffing component when we do an evaluation, is there's already a shortage in a lot of places, we've heard that numerous times today,

especially for a PCI ambulatory center that's near a safety net facility where there may be a bigger shortage.

I think we should look back and make sure that we're not exacerbating a shortage already by pulling people out of their safety net facilities and their other locations to ensure that we're protecting the most vulnerable and not creating something new that may, even if it does help in one location, causes harm to another. We certainly don't want to do harm.

Ms. Monroe: We saw that today with the Rochester discussion.

Dr. Eisenstein: Yes. But I don't think that's all new concept as we addressed safety in the document, staffing in the document.

Dr. Rugge: Once again, would anybody care to elaborate or applaud in some verbal way on Larry's comments?

Dr. Heslin: So, the department's perspective is that in phase one, they are hospital affiliated or owned facilities. So, they would be handling the staffing themselves, and this would not be an issue during phase one whatsoever, and that we hadn't prescribed further phases down the line in terms of that sort of decision making. The other piece of information we think is very important to transmit to the planning committee is that these will all be going through a certificate of need process, and you will, as the establishment and review committee, when that time comes, be able to determine if there is a need and/or if there is harm being performed by establishing one of these things. So, you have the ultimate authority as the Public Health and Health Planning Council establishment and review and full council to make a decision not to move an application forward. It's always been your right.

Ms. Monroe: Yeah, I'm thinking. I don't like the idea of having something not be dealt with until it comes to a CON, because as we saw today, there's a lot of investment in CONs, and there's a lot of time and energy put in. And when it comes to us, for us to do something because it hasn't been done earlier, to me, feels a little bit disingenuous. I think the piece about impact on the community from a staffing perspective is probably something that we could put in a priority of phase one. We list the various things that are data collection methods. And I'm proposing that we add a wide variety of indicators including da da da da and staffing impact. Those two words, I don't think that is substantive, but I need to ask Mart. Is that substantive? What?

Dr. Ruge: She wasn't clear. She just said ask it again.

Ms. Monroe: Oh. On page four, the first paragraph, we list the kind of data collection we should have. And based on Larry's point, I'm suggesting that we add significant components of access and staffing impact, those two words.

Dr. Heslin: So, while Mart is determining whether that's substantive or not, one of the concerns of the department would be is that there's no way to collect that data. That's an impossible collection of data because the staffing impact would have to be something that would have to have happened as opposed to a prediction of what could happen. And as you heard Dr. Fish say earlier today, we have always worried about the catastrophic event of setting up a center somewhere near a hospital, but we have actually never seen that happen in the 20 years that we've been doing this. So, it's very difficult to predict what a potential outcome is prior to that outcome occurring. So, analyzing the potential of a staffing impact is something that would be extremely difficult to do.

Ms. Monroe: I would like to clarify that that was not my intent to have it be a predictor. It's part of the questions that the evaluation would look at, and so it is an outcome. At the end of a year or however it is, what's been the impact on staffing? So, I don't see it as a predictor, but I'm not going to push it either.

Dr. Ruge: Just as a way of bringing up more dust. Any change we make to the report has to be typed up and the revised typewritten document needs to then be approved. We can't just do it verbally. So, it's a little more impediment. I am certainly hopeful that the comments and the suggestions and the agreement that we're putting together today will appear in the meeting summary, will reappear in the discussion about our report at the full council meeting, and will be taken under serious advisement by DOH. And Gene has indicated just that.

Dr. Heslin: So, may I make a suggestion?

Dr. Ruge: Yes.

Dr. Heslin: And if it's okay with Mart, what I would say is that, and where we say in this-

Ms. Monroe: What number are you on?

Dr. Heslin: I'm on number one under C, phase one, column one, where it says, "And significant components of access." I would just say at the end of that, including staffing, because access to staffing could be considered a component of access.

Dr. Ruggie: Including accessing?

Dr. Heslin: Including staffing. And so, it's not changing the tenor, it's clarifying that one of the issues that has to do with access is staffing. So that's a clarification. And if that meets your needs and Anne's needs, I think that that's not a material change.

Dr. Eisenstein: I think it's a good compromise.

Dr. Ruggie: And we can do this without having it all typed up and circulated around again?

Dr. Heslin: I am putting it in right this second for it to be printed 10 seconds from now when we're done doing all this so everybody can look at it.

Ms. Monroe: It does not have to be there. And you're all comfortable [inaudible 02:40:29].

Dr. Heslin: Yeah, let's just keep going. We're fine.

Dr. Ruggie: So, do we have a motion?

Ms. Monroe: Oh, I guess I'll make it.

Dr. Ruggie: Okay. Do we have a second, to add this consideration to the report?

Mr. Robinson: I think we all accept that.

Dr. Heslin: There are two other comments that need to be addressed. Let's just make the two other comments and then make a full motion for everything.

Ms. Monroe: Exactly.

Dr. Ruggie: Okay. Okay. Moving on to Dr. Soffel. Denise, you had a nice set of thoughts as well.

Dr. Soffel: Yeah, I just had, I think, a clarification. It was on the second page when we were talking when the report talks about patient

advocates stressing the importance of providing clear communication, blah, blah, blah, along with the need for certain support services in the home. I felt that the point of those comments by the advocates was that lack of certain services at home could be an access barrier for some patients. And we wanted to be very clear that lack of home support should not stand in the way of people being able to choose an ambulatory procedure should they prefer that. And that's all, it was really absolutely a point of clarification rather than a change.

Dr. Heslin: So, what you're talking about is as part of the Society of Cardiovascular and Geographic Intervention, one of their requirements was to have home support in place as a decision whether a person would have an inpatient procedure or an outpatient procedure. And in fact, that's one of the things that is looked at now. If somebody doesn't have home support, they have a procedure that's done in the hospital where they stay in the hospital as opposed to being discharged to home. And so, when we reference in this document that we are looking towards the Society of Cardiovascular Angiography Interventions, ethical considerations, that would be part of that consideration. We don't want someone to go home and have harm. And so that's a patient selection criteria that has to be thought through, that's made as a decision by the clinician as to the appropriate site of service.

Dr. Soffel: My point though is that when the advocates talked about this, they raised it as a concern because of its possible negative impact on access for certain kinds of patients. And that's not reflected in the comments here. That's all.

Dr. Heslin: Okay. Thank you.

Dr. Rugge: So, are you happy with this being spoken to here, put in our meeting report? Are you looking for a change?

Dr. Soffel: If you recall what I sent to you, John, earlier last week, was simply to add a few words that talked about the need for certain support in the home, or the lack of those support services not being an access barrier for certain patients. I'm sorry, I thought it was a very clear clarification point, and it's becoming much more muddled the more we talk about it.

John Rugge: We're just trying to make it fit in those amendments. Do you have that? Okay, Gene?

Dr. Heslin: I'm trying to see where Dr. Soffel is looking for that.

Ms. Monroe: Where are you referring to?

Dr. Rugge: Where are you referring?

Dr. Soffel: It's on page two, and it's in the paragraph that starts in stage two, the committee welcomed input and received presentations. And it's at the bottom of that paragraph, where it says, "Patient advocates stress the importance of providing clear communication, along with the need for certain support services in the home." And my point is simply that that was raised because of the potential access barrier that lack of home services might create for certain patients.

Dr. Rugge: So, do we need to change the report to make that clearer?

Ms. Monroe: Her comment is fine. Thank you.

Dr. Rugge: Okay. Is that okay with you, Denise? She's smiling, I guess that's good.

Dr. Soffel: I'm not understanding why we can't edit that sentence to make the-

Dr. Rugge: Do you have something to suggest?

Dr. Soffel: I sent it to you.

Dr. Rugge: You did?

PART 5 OF 6 ENDS [02:45:04]

Dr. Rugge: We did? On page two, it talks about patient advocates addressing the need for support services. I would add something to indicate that lack of support services at home may be an access barrier for some patients. We need to know how to put that thought into specific language in this report.

Hugh Thomas: That's not what they're saying. It's just a clarification.

Dr. Soffel: It's just a qualification, right? It's half a sentence.

Mr. Kraut: It's there, but you're just interpreting it.

Ms. Monroe: Well, why don't we see what... Go through all the comments and then see whether any of them cross the line into substantive, which we don't want to do.

Dr. Ruggie: I don't think this is substantive. This is clarifying and I think it's... So, Denise, while we're going on to the next comment, why don't you-

Dr. Soffel: Fine.

Dr. Ruggie: Write up the language you would like to see?

Speaker 15: She didn't send the comment [inaudible 02:45:55]. We sent it to Gene [inaudible 02:46:00].

Dr. Soffel: I sent it to Colleen as I was instructed and then I sent it to John and [inaudible 02:46:06].

Dr. Soffel: Okay, all right, thanks. That's fine because it's not substantive anyway.

Dr. Gene Heslin: It's not substantive. I think that what we can add is at the end of the statement that's there for ... In ambulatory settings, along with the need for certain support services in the home could be perceived as a barrier for certain patients' access.

Dr. Soffel: That's fine.

John Ruggie: That's good. Everyone in agreement with that. Let's go on to Dr. Friedrich. Marcus Friedrich has a thought as well.

Dr. Friedrich: Hi, everybody. I did not send the comment out to the whole committee.

John Ruggie: If you can just move closer. They're not going to hear you.

Ms. Monroe: I don't know that your mic is on.

Dr. Friedrich: It is on. It is on. I just have to go closer. So, my comment was about the passage, D3 in the recommendations. And it is not clear to me that while the Department of Health and the Cardiac Advisory Committee has the authority for monitoring in the successive phases, it is not clear to me who makes the decision to move from a potential phase one to the next phase down there. I just want to point out I'm a big fan of the Cardiac Advisory Committee, but the last report that they published on PCI is the report from 2019. That data is now almost seven years old. I am also cognizant of the fact that they are working on subsequent reports, but I don't want data issues hampering us to move into a subsequent phase.

But the real question is, who makes the decision then to move it from phase one to the next phase? Is that part of our agenda, like the PHHPC? Is it part of the department? And I'm thinking also, Dr. Heslin, about writing potential regulations around that. And you made that very clear in one of our meetings that the best regulations are always written in a way that you don't have to go back and change it. And so, what is then the next phase to make sure that we encompass that? Because it is not clear what is here.

Dr. Ruggie: It's a preliminary comment and then off to Dr. Heslin. I think what we've established by doing it is we have a collaborative relationship with DOH. And so, there's no one authority making it final without consideration and the opinions of others. And we have specifically asked for feedback and reports on a regular and periodic basis for changes. But the technical question about who's responsible can go right off here to the first deputy commissioner of health.

Dr. Heslin: Thank you. Ultimately, as it has always been, it's been a departmental decision, and it has always been through the department that those decisions have been made as we move these things forward. But we tend to do these things with a lot of public notice and a lot of conversation because we recognize that it is still the authority of the Public Health and Health Planning Council to approve these things. And so, it would be foolish of the department to go, "Hey, we've been doing this for X amount of time, and we just think we should do this because we are not the authority that does the establishment. So, we need to make sure that the people that are going to be doing that establishment are comfortable with the fact that we have brought this issue forward to say that we're going to open this up."

So, it would be a collaborative process. There's no specific time established on that because as you saw, we don't know how many of these centers are going to be established in phase one. If we have one center that's established in New York State in phase one, it's going to be awful hard to make decisions. If we have 20 centers established in phase one, we'll have a lot more data to be able to do. And there'll also be national data as this continues to move forward. So ultimately it's a departmental decision, but we have our checks and balances and PHHPC is one of them.

Dr. Ruggie: As everybody can see, Hugh Thomas needs to depart but thank you very much for all the contributions you've made. You've been a real activist. Nobody else is allowed to leave. That, I think, carries us through ... Oh, Marcus. -

Ms. Monroe: What is... What are you proposing, Marcus? Are you suggesting that we change some wording in the report or that we keep it in the notes from the meeting that would accompany the report to the department? I just want to be clear about what you're looking for.

Dr. Friedrich: Again, it's probably to clarify the language that is in the proposal in D3 and because I feel not very clear who the authority then is going forward.

Ms. Monroe: What do you suggest it to say?

Dr. Friedrich: Again, I wanted not to wordsmith. I wanted to put it up for a discussion and now with the response from Gene-

Ms. Monroe: Are you saying it's well the authority for approving and monitoring? Is that where you're looking? It falls to the department.

Dr. Friedrich: Or a simple sentence that the Department of Health will then decide to move on from phase one. Or will decide to move on from phase one to a subsequent phase. I think that it would be very clear then that that is then the process. And it doesn't have to go back to the PHHPC, but... Or I'm not looking for an explanation about the whole process there, but just that by fulfilling this here and to put it in writing that the department then will decide to move on from phase one if the conditions are met.

John Rugge: It should be located in E rather than D3.

Dr. Gene Heslin: So, I think we should just make a number three on E. The Department of Health is responsible for the advancing through different phases.

John Rugge: I think that's good.

Dr. Gene Heslin: Okay, tell me what to write, Mart [inaudible 02:53:43].

Ms. Monroe: I'm just saying because... You're saying that you're [inaudible 02:53:48].

John Rugge: Can you use the mic please so that we can hear you?

Ms. Monroe: Mart, we can't hear you at all.

John Rugge: They can't hear you.

Ms. Monroe: Can you speak to the mic please?

Ms. Ngwashi: Can you hear me now?

John Ruge: Yes.

Ms. Ngwashi: Okay. So, I'm just saying because you're saying that it's going to be collaborative in D3, you can just use that same language for E3 to state how the evolution will be derived from phase one to phase two.

Dr. Gene Heslin: So, the Department of Health in collaboration with the Cardiac Advisory Committee will make the decisions on...

Ms. Ngwashi: Phase transition.

Dr. Heslin: Phase transition.

Dr. Soffel: I'm sorry. I am hearing it slightly differently. What I thought Marcus said is while there is collaboration in these conversations that the decision to move beyond phase one into phase two is the Department of Health's decision. And I would put that as D4 rather than putting it in E, because E is then about what we want to think about as we move forward. But I thought that Marcus' point was that the decision to move past phase one into phase two is a decision that is owned fully by the Department of Health in consultation, in collaboration, in conversation, but it is their decision to make.

Ms. Monroe: That could be D4.

Dr. Soffel: D4, that's where I would put it.

Ms. Ngwashi: E is about the phases of it and recommendations that should be considered. So E is working on [inaudible 02:55:19] too. I don't mean to make this crazy, but I think we need to do that.

John Ruge: But D says for all phases of cardiac catheterization. So, it seems that it should be there. It's not that big a deal would be in the ... But this is what talks about phases.

Dr. Soffel: Maybe it goes under C, specifics of phase one. It's the last item in part C, which says the decision to move beyond phase one is at the sole discretion of the Department of Health.

Ms. Monroe: Maybe it should be the last sentence of A. We're going to begin this process and the department is responsible.

Ms. Ngwashi: It actually should then go in B, because B says-

Dr. Soffel: Okay, we now have one suggestion for each-

Ms. Ngwashi: [inaudible 02:56:11].

Ms. Monroe: Do you want to pull your suggestion back?

Ms. Ngwashi: And put it as the last sentence for B and then there you go.

Dr. Soffel: That's fine.

Dr. Gene Heslin: Okay, so we're now going up to B.

Dr. Gene Heslin: So, what B now says is this process should be rolled out in phases and future phases to be guided by lessons learned of earlier phases of Department of Health in collaboration with the Cardiac Advisory Committee will make the decision regarding phase progression.

Ms. Monroe: That's fine.

John Ruge: So, we have two amendments currently. Are there any other?

Ms. Monroe: Sabina had a comment that she had... Oh, I didn't know you were saying.

John Ruge: Just looking for everybody, any comments or any additional motions that they would like to see? But Sabina, go ahead.

Dr. Lim: I don't want to ... Oh, sorry, everyone's name tags are falling down. My question to Anne, and what she had alluded to before, I was just wondering whether the inclusion of the HEIA as part of the CON process that was listed.

Dr. Soffel: I actually looked it up after you raised it, and the answer is that all Article 28 facilities, including ambulatory surgery centers, must include the HEIA. So, the answer is yes.

Dr. Lim: Right, and so that's why just is it asked for the statute, and I don't want to be overthinking because if it was otherwise, we would be potentially setting a precedent for introducing new reasons for the HEIA. So as long as it's part of the statutorily required, that was it. Thank you.

Dr. Ruge: Good. Larry?

Dr. Heslin: The only other change... The only other change there was one spelling error. We said health instead of health and I corrected that.

Dr. Rugge: Larry.

Dr. Eisenstein I had one more word that... And this is C7 and belongs in C7, but the sentence reads, "Any site selected under phase one should have a relevant consumer patient education program." In these documents, I just don't like subjective wording. And I think relevant is subjective because I don't know what relevant... I think we should just take the word relevant out and say, "Should have a consumer patient education program." And even the back part of the sentence, it says, "Including patient choice when available." That's very open-ended. I don't think we need to change it, but patient choice, there might be two facilities or 10. I'm not sure-

Dr. Soffel: No, it's inpatient versus outpatient.

Dr. Eisenstein: I understood, still. So, depending on where you are inpatient or outpatient, the choices may be limited or... Part of this is about access. So, if you're doing this because there isn't another choice, if you're creating access... I don't know what I think. More important, the word relevant, I didn't like because each of us would define relevant education differently. So, I think because that's subjective, that word should come out, just my opinion.

Dr. Gene Heslin: The department accepts that thoughtful, relevant words be removed.

Dr. Rugge: If everybody else does on the committee, any objections to Larry's input? No? Okay.

Dr. Heslin: Call of question, please.

Dr. Rugge: Yes. So, we have one motion with two amendments or three amendments now to the report. You want to list those and read them one more time?

Dr. Heslin: So, the three amendments to the report was we added a small sentence to the section under on page two, under section labeled stage two to say at the end of the sentence saying, "Certain support services in the home could be perceived as a barrier to patients' access." That was one. The second one was the relevant word that we just changed. And the third one was under section B, we added to the sentence, "This process should roll out in phases with future phases being guided by lessons learned of earlier phases, the

Department of Health in collaboration with the Cardiac Advisory Committee will make the decision regarding phase progression." And there was one spelling error that was corrected.

Dr. Ruge: And did your comments just include the and staffing addition?

Dr. Heslin: And staffing. That was the fourth change.

Dr. Ruge: Yes.

Dr. Heslin: Correct, including staffing.

Dr. Ruge: I'm sure everybody has-

Dr. Heslin: At the end of section C, subsection one, final two words, and significance components of access, including staffing.

Dr. Ruge: I suspect that... Everybody is nodding. Any further discussion needed? Is there a motion? We have a motion. Do we have a second? We have a second. Dr. Eisenstein and Dr. Berliner, any further comments?

Dr. Heslin: So, let me be clear. This is a motion that is being brought forth to make this recommendation to the full council for adoption to submit this to the Department of Health in the design of the regulations to support ASCs doing cardiac catheterization, both diagnostic and percutaneous cardiac intervention, correct?

Dr. Ruge: Well, I was thinking that we first make these amendments to our report and then have a motion to say this revised report will go to the council.

Mr. Kraut: Do it all one.

Dr. Heslin: We can do it all in one.

Dr. Ruge: Okay, we'll do it in one. We'll make it very efficient. Save it by shoulder. All in favor?

Ms. Monroe: Aye.

Dr. Ruge: Any opposition? Any abstentions? Perfect, this committee has been very productive, very helpful.

Mr. Kraut: So just to be clear, what we're going to do at the full council meeting, you'll instruct Colleen to... This will go out beforehand.

Ms. Monroe: Yes.

Mr. Kraut: I think your note was particularly helpful to remind everybody to actually read it before they walk into the room and that I think that you'll be... And I would suggest in your transmittal, you'll say you'll be asked to vote on this to forward it to the department for development of regulations. And so, we have you, we're going to make sure you're on the agenda, you're not rushed, can do a report because members who might not have had the opportunity to participate might have perceptions or ... You're going to have to educate them a little. That's all. Okay, perfect. Good job. Congratulations.

Dr. Ruggie: Is there any new work to do?

Ms. Monroe: I just have a question about ... Do we have to print out a copy of the final, final and adopt that? Do we all need a copy of that right now?

Mr. Kraut: I don't know if you need it now. I think ... No. We should get it to you right away.

Ms. Monroe: Oh, no, no, I know, but I thought there was a need to ... Oh, sorry. What?

Dr. Ruggie: These are so small, Mark says it's okay to do it this way.

Ms. Monroe: Oh, it's okay to do it this way. Good, all right. I have an item that Mark and I and John and Jean talked about. You'll remember in the meeting today, there was a discussion. We put a condition on the Rochester proposal about coming back in three years and that the department would like us from the planning committee to make a recommendation to the department and PHHPC that that be done universally rather than CON by CON. Did I get that right?

Dr. Heslin: So, what the department would like is that we feel that the planning committee is the appropriate place to have these type of discussions when we want to make a change to how the public health council would like the department to function. And so, what we're looking for is for the planning committee to take up this as an agenda item, which would be that the council would like to have data following up on these types of applications to make sure that what is being planned for and being testified to is actually being met. And so, rather than doing this on an individual basis for each application as it's come up multiple times, what we're looking for is for the planning committee to take this up, to discuss it. And if everybody wants to discuss it today and come up with a

recommendation, we're happy to accept that recommendation to be able to bring that to the full council at the next meeting to be able to move that forward. So that's what the department would like. And Mr. Crowell.

Ms. Monroe: But it's not connected to the stuff we've been working on, PCI and PSC.

Mr. Kraut: Right, right. But I would just add, if you're going to do that, just be mindful of the workload that it creates for the department. Therefore, I wouldn't make it an obligation of the department. I'd make it an obligation of the applicant to provide a report in a format prescribed by the department. Because you have to ... It's an enormous amount of work for an applicant and for the department to do it for multiple applicants, they don't have that. I do not believe you have the staff to do it in the way you're expecting the information to come back. What we have to have is a process that validates the data provided is in fact, and you might ask if you're doing that, that there's a corporate officer of the entity filing the report, it's attesting to its veracity. That's usual... That makes everybody slow down when they're submitting stuff. So, I would just suggest ... But that's not for today, but I think it's-

Ms. Monroe: I thought it was for today.

Mr. Kraut: Well, I don't know because you're going to ... I don't know where you want to discuss this.

Ms. Monroe: I'm sorry. I believe we were asked if we could pass that today, but I'm not putting that on the committee if we're not ready.

Dr. Heslin: I would prefer that there'd be a more formal discussion. I think it's a good idea to bring it up. I think it's simple in concept that may be complex in actually accomplishing, so I'd rather bring it back for us to be able to give some of where we see the risks and where we see the opportunities.

Ms. Monroe: Okay.

Mr. Robinson: Gene, this is part of a larger discussion for the committee to discuss the roles and functions of PHHPC over these next several months and to be sure we have an updated conceptual overview of the functions of the council and how we go about it.

Ms. Monroe: Okay, I move that we adjourn.

Mr. Robinson: Just one other point. Dr. Heslin, the other issue that came up during the committee meeting today, you'll recall that we required the Roswell Park application to reflect charity care obligations. As I recall, the only place where we formally went through a process where that requirement was in place was the ad hoc committee for ambulatory surgery. I don't think we've actually looked at that as a requirement for applications outside of that in a formal sense. I think we do want it, but I just point out that we are extending that parameter into the discussion of other applications other than freestanding ambulatory surgery centers. And so, I'm not saying it's a bad thing, I'm just saying that's been very ad hoc.

Dr. Heslin: So, with the completion of the PCI in ambulatory surgery center discussion, we have been contemplating what could be different topics that planning committee should take up. And there's a potpourri of different topics that have been suggested as to what could be. One of them was that. One of them is this particular issue.

Mr. Robinson: Sure.

Dr. Heslin: The third one was the new type of service that is being offered as a recommendation to start to think through implications. So, we as the department are taking back a lot of different ideas to see what the next appropriate topics for the planning committee could be to take up. And it may be worthwhile taking up some of these smaller topical areas to move things forward. One of the things we are considering is how and what happens with the Public Health and Health Planning Council and how it functions and some of its needs to be able to make it function more efficiently in conjunction with the department. And so, we're in discussions and thinking about that through. So more to come as to what the next steps could be for the planning committee.

Dr. Ruge: I think we could be confident the next meeting will not be before Monday. Larry?

Dr. Eisenstein: If I can recommend... Sorry. We saw a CON today where we were asked to evaluate what basically has traditionally been alternative medicine. And even on the vendor's website, they list their product as alternative medicine. And so, I abstain, which is not my style. I usually say yay or nay. And I think the reason I abstained is because I want to give myself the ability to go through all of the literature that they testified that they presented to give them a fair shot. But honestly, it would be so much better if something tries to

go from alternative to license by the PHHPC and the state, if this committee had the opportunity to talk about that.

- Mr. Kraut: That's exactly what we agreed to today, that they shouldn't bring those projects to us without going through the planning committee where you could do it in a more thoughtful way and frankly invite public input. Okay.
- Dr. Eisenstein: And that, honestly, just so there's no surprises, that's how I'm planning to vote when that goes to full council.
- Ms. Monroe: With abstention?
- Dr. Eisenstein: No.
- Ms. Ngwashi: We don't need to know what you're...
- Dr. Gene Heslin: We do not need-
- Dr. Eisenstein: I'm going to give them a fair chance.
- Ms. Monroe: I thought you were-
- Mr. Kraut: The project is not in front of you. We don't discuss it now.
- Dr. Ruge: Chris, Jean and Jeff, have we given you the background information or discussion that you need for us to...
- Mr. Kraut: We're fine. We're ready to go as long as you're ready to present.
- Dr. Ruge: So, is there a motion to adjourn?
- Mr. Kraut: Peter.
- Ms. Kraut: Nice job.
- Ms. Monroe: All right. Thanks guys. We're, I think, going to be a really interesting committee.
- Dr. Ruge: Yeah.

PART 6 OF 6 ENDS [03:12:36]