

STATE OF NEW YORK  
STATE EMERGENCY MEDICAL ADVISORY COMMITTEE

Committee Meeting

DATE: May 25, 2010  
TIME: 1:34 p.m. to 4:45 p.m.  
LOCATION: Crowne Plaza  
State & Lodge Streets  
Albany, New York 12207

- 1 SEMAC, 5-25-2010
- 2 APPEARANCES:
- 3 Arthur Cooper
- 4 Lee Burns
- 5 Mark Henry, M.D.
- 6 Lewis Marshall, M.D.
- 7 Bradley Kaufman, M.D.
- 8 Sharon Chiumento
- 9 Joseph Takats, III, D.O.
- 10 Israel Miranda
- 11 Craig Cooley, M.D.
- 12 Carl Goodman, M.D.
- 13 Robert Delagi
- 14 John Detraglia, M.D.
- 15 Michael Waters, M.D.
- 16 Donald Faeth
- 17 Mark Zeek
- 18 Jack Davidoff, M.D.
- 19 Daniel Olsson, D.O.
- 20 John Morley, M.D.
- 21 Greg Young, M.D.
- 22 John Broderick, M.D.
- 23 Michael Dailey, M.D.
- 24 Jeremy Cushman, M.D.
- 25 August Leinhardt, M.D.
- 26 Timothy Haydock, M.D.
- 27 Michael Mastrianni, Jr.
- 28 Andrew Johnson
- 29 John Freese, M.D.
- 30 Joshua Kugler, M.D.
- 31 Lisa McMurdo
- 32 Donna Gerard

- 1 SEMAC, 5-25-2010
- 2 (The meeting commenced at 1:34
- 3 p.m.)
- 4 DR. HENRY: We'll call the
- 5 meeting to order and thank you for coming. Can we
- 6 have a roll call vote -- I mean a roll call of
- 7 attendance please.
- 8 MS. GERARD: Dr. Broderick?
- 9 DR. BRODERICK: Here.
- 10 MS. GERARD: Dr. Cooley?
- 11 DR. COOLEY: Here.
- 12 MS. GERARD: Dr. Cooper?
- 13 DR. COOPER: Here.
- 14 MS. GERARD: Dr. Cushman?
- 15 DR. CUSHMAN: Here.
- 16 MS. GERARD: Dr. Dailey?
- 17 DR. DAILEY: Here.
- 18 MS. GERARD: Dr. Davidoff?
- 19 DR. DAVIDOFF: Here.
- 20 MS. GERARD: Dr. Delaney-Roland?
- 21 (No audible response)
- 22 MS. GERARD: Dr. DeTraglia?
- 23 DR. DETRAGLIA: Here.
- 24 MS. GERARD: Dr. Goodman

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- 2 DR. GOODMAN: Present.
- 3 MS. GERARD: Dr. Haydock?
- 4 DR. HAYDOCK: Here.
- 5 MS. GERARD: Dr. Henry?
- 6 DR. HENRY: Here.
- 7 MS. GERARD: Dr. Huffner?
- 8 (No audible response)
- 9 MS. GERARD: Dr. Kaufman?
- 10 DR. KAUFMAN: Here.
- 11 MS. GERARD: Dr. Kugler?
- 12 DR. KUGLER: Here.
- 13 MS. GERARD: Dr. Leinhardt?
- 14 DR. LEINHART: Here.
- 15 MS. GERARD: Dr. Marshall?
- 16 DR. MARSHALL: Here.
- 17 MS. GERARD: Dr. Martin?
- 18 (No audible response)
- 19 MS. GERARD: Dr. Olsson?
- 20 DR. OLSSON: Here.
- 21 MS. GERARD: Dr. Takats?
- 22 DR. TAKATS: Here.
- 23 MS. GERARD: Dr. Waters?
- 24 DR. WATERS: Here.

- 1 SEMAC, 5-25-2010
- 2 MS. GERARD: Nonvoting members:
- 3 Sharon Chiumento?
- 4 MS. CHIUMENTO: Here.
- 5 MS. GERARD: Michael Mastrianni?
- 6 (No audible response)
- 7 MS. GERARD: Daniel Blum?
- 8 MR. BLUM: Here.
- 9 MS. GERARD: Donald Faeth?
- 10 MR. FAETH: Here.
- 11 MS. GERARD: Tim Czapranski?
- 12 (No audible response)
- 13 MS. GERARD: Robert Delagi?
- 14 MR. DELAGI: Here.
- 15 MS. GERARD: Israel Miranda?
- 16 (No audible response)
- 17 MS. GERARD: Mark Zeek?
- 18 Roll call complete.
- 19 DR. HENRY: All right. Thank
- 20 you.
- 21 So, chairman's report. Since the
- 22 last meeting I've had the ability to go to the STAC
- 23 meeting, and that was just last week, and there's
- 24 an action item that I'm going to bring forward from

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2 that to -- for us to work on here.

3 And that has to do with the

4 implementation of the trauma triage protocols that

5 we approved back in September of 2007. I found the

6 minutes from our meeting and SEMSCO meeting, and

7 Dr. Trish O'Neill, who was our representative from

8 the State Trauma Advisory Committee was present at

9 both the meetings and brought the deliberations of

10 STAC, and we have discussions then, and we voted

11 for those protocols and the state council had a

12 roll call vote in September 2007. It's on page

13 ninety if you want to look at it, on those -- on

14 that very issue.

15 So, if you recall then, we took

16 the page out of the Committee of Trauma from the

17 American College of Surgeons, 2006 Green Book, on

18 Standards for Trauma Centers where they had

19 published the recommendations from the C.D.C.'s

20 Expert Panel on Trauma Triage. They had adopted

21 them, and many other organizations have adopted

22 since -- National Association of E.M.S. Physicians,

23 ASEP, multiple others.

24 We decided to include, or retain,

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2 pulse as a physiology criteria, because in analysis

3 of our data, that Ed Hannon had done, it was an

4 independent predictor for serious operations and

5 morbidity, separate from other physiologic

6 criteria. So, that was the big difference, we

7 include -- we kept pulse. It replaced both adult

8 and pediatric trauma schemes because it

9 incorporated both children and adults in one

10 scheme.

11 The decision point after finding

12 a physiology high-risk criteria or anatomic

13 high-risk criteria, was to take to the highest

14 level center in the region. We had asked the

15 regions to discuss what that might mean on a

16 regional basis. And those discussions took place,

17 but we never implemented, fully, the protocols

18 after we asked people to discuss what did that

19 sentence mean.

20 So, at the STAC meeting,

21 resolution was made and voted on that we ask the

22 Bureau to publish the protocol we approved back in

23 2007 on the Web page. We implement the protocol

24 for when medics are advised to take to the highest

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2 level center in their region, to go to the closest

3 approved trauma center, unless directed otherwise

4 by their REMAC, and that we encourage the use of

5 Center for Disease Control educational materials

6 for our E.M.T.s, our paramedics, our physicians,

7 our nurses, which are available and would be

8 supportive of the document, and this with a

9 reminder again that we still retain pulse as a

10 criteria.

11 So, that's the motion that I

12 bring forward from STAC to the SEMAC for, you know,

13 discussion and vote.

14 Let me reiterate it: That we ask

15 the Bureau of E.M.S. to publish that document on

16 the Web page; that we implement the protocol

17 statewide; that providers are told to take the

18 trauma patient to the closest trauma center in

19 their region, unless directed otherwise by their

20 REMAC; and that we encourage use of C.D.C.

21 materials in the education effort.

22 So, to the best of my ability,

23 that's what we voted on at STAC a week ago. So, is

24 there a second to that?

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2 FROM THE FLOOR: Second.

3 DR. HENRY: Okay. Any

4 discussion?

5 (No audible response)

6 DR. HENRY: I know Dr. Cooper was

7 there. I don't know if he's here now, but -- oh,

8 he's here, good.

9 So, that was -- that's the sense

10 of the STAC, and hearing no discussion.

11 DR. COOPER: I support the motion

12 as you've stated it.

13 DR. HENRY: Okay. All right.

14 So, we need a roll call on this -- to implement

15 this, or are we good with aye and nay?

16 FROM THE FLOOR: Actually do a

17 roll call.

18 DR. HENRY: Okay. Can we have a

19 roll call vote?

20 MS. GERARD: Dr. Krupp (phonetic

21 spelling)?

22 DR. KRUPP: Yes.

23 MS. GERARD: Dr. Broderick?

24 DR. BRODERICK: Yes.

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- 2 MS. GERARD: Dr. Cooley?
- 3 DR. COOLEY: Yes.
- 4 MS. GERARD: Dr. Cooper?
- 5 DR. COOPER: Yes.
- 6 MS. GERARD: Dr. Cushman?
- 7 DR. CUSHMAN: Yes.
- 8 MS. GERARD: Dr. Dailey
- 9 DR. DAILEY: I abstain.
- 10 MS. GERARD: Dr. Davidoff?
- 11 DR. DAVIDOFF: Yes.
- 12 MS. GERARD: Dr. DeTraglia?
- 13 DR. DETRAGLIA: Yes.
- 14 MS. GERARD: Dr. Goodman?
- 15 DR. GOODMAN: Yes.
- 16 MS. GERARD: Dr. Haydock?
- 17 DR. HAYDOCK: Yes.
- 18 MS. GERARD: Dr. Henry?
- 19 DR. HENRY: Yes.
- 20 MS. GERARD: Dr. Kaufman?
- 21 DR. KAUFMAN: Yes.
- 22 MS. GERARD: Dr. Kugler?
- 23 DR. KUGLER: Yes.
- 24 MS. GERARD: Dr. Leinhardt?

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- 2 So, that's my report for the --
- 3 since the interim of the meeting. I guess we could
- 4 go to the Bureau's report before we go to
- 5 Committee.
- 6 Oh, wait -- wait, let me ask you.
- 7 Are there any -- regarding the minutes from the
- 8 last meeting, are there any amendments or additions
- 9 or any other items that anyone would wish to
- 10 correct?
- 11 (No audible response)
- 12 DR. HENRY: All right. So
- 13 hearing none, I'll take a motion to accept the
- 14 minutes as published.
- 15 (No audible response)
- 16 DR. HENRY: So moved.
- 17 A second?
- 18 FROM THE FLOOR: Yes.
- 19 DR. HENRY: All in favor, aye.
- 20 FROM THE FLOOR: Aye.
- 21 DR. HENRY: Opposed.
- 22 (No audible response)
- 23 DR. HENRY: Abstentions.
- 24 (No audible response)

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- 2 DR. LEINHART: Yes.
- 3 MS. GERARD: Dr. Marshall?
- 4 DR. MARSHALL: Yes.
- 5 MS. GERARD: Dr. Olsson?
- 6 DR. OLSSON: Yes.
- 7 MS. GERARD: Dr. Takats?
- 8 DR. TAKATS: Yes.
- 9 MS. GERARD: Dr. Waters
- 10 DR. WATERS: Yes.
- 11 (The motion carried.)
- 12 MS. GERARD: Roll call complete.
- 13 DR. HENRY: Okay. Thank you.
- 14 So, for the rest of my report, I
- 15 would just say that Dr. Kaufman shared details on
- 16 the protocol in hypothermia we discussed last
- 17 meeting from the fire department, I'm very grateful
- 18 for the communications. And I had forwarded a
- 19 letter to the commissioner with some details about
- 20 that -- our deliberations and whether, in essence,
- 21 it should be considered standard of care. And we
- 22 had a conference call with the Department and
- 23 representatives from FDNY. And I'll let Lee talk
- 24 about that later in her report.

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- 2 (The motion carried.)
- 3 DR. HENRY: Thank you.
- 4 MS. BURNS: This -- to start off,
- 5 at -- at some point in the not-too-distant future,
- 6 between two and two-thirty, one of our attorneys
- 7 from the Division of Legal Affairs is going to come
- 8 and present to you an update on the Family Medical
- 9 Health Care Decisions Act, I'm -- I'm missing an
- 10 initial in there.
- 11 This is -- actually, we had
- 12 talked about probably doing it at both SEMSCO and
- 13 SEMAC, but I think we're going to start here. The
- 14 reason is that as practitioners, this Act will
- 15 effect you and that information that Jonathan
- 16 Karmel will present will be important both to -- to
- 17 all of us as prehospital care providers, but also
- 18 as U.S. hospital practitioners. Also, he's going
- 19 to talk about MOLST, and on the work group is Tim
- 20 Czapranski, so he also is a resource to us.
- 21 So, that's -- that will happen in
- 22 the next little while. To give you an -- I talked
- 23 about this briefly at Medical Standards and it will
- 24 be briefly here too, a blood update.

Page 14 SEMAC, 5-25-2010 We reached out to the blood and tissue program to find out where the amendments to Part 53 are, that would include advanced life support providers in transporting blood and blood products. And they advised me that they had passed through the Blood and Tissue Council, that is good and that the Division of Legal Affairs had done what they do to them. And next -- or now, they are in the Governor's Office of Regulatory Reform. So, they're following them there. From there they get published in the state register for a sixty-day comment period. And then once the comments are addressed, they get forwarded to the commissioner for approval and promulgation. So, we're moving. It's -- we've moving. There's not much news to report to you as far as the budget is concerned because there's not much news to report. A couple weeks ago we were dealing with the possibility of furloughing state staff. With that said, you do need to know that with the exception of three people in our office,

Page 15 SEMAC, 5-25-2010 all of us are state staff, and would be affected by a furlough. And when asked I turned to my boss -- but when asked what sorts of things we would be doing to maintain the Bureau during a furloughing period, after she told me no to taking Friday off or closing the Bureau for Friday, our primary mission, should we be furloughed, frankly is to answer the telephones and to do what is our statutory responsibility purely. So, should we be forced to furlough, and I'll tell you that it is a very -- it will be devastating for our staff, we will revert back to our very basicest -- basicest functions. So, that is not a good thing. We had -- on May 13th, we participated in a stakeholders meeting for pediatric -- regionalization is not the word, centralization is not the word -- but -- FROM THE FLOOR: Standardization. MS. BURNS: -- standardization, and it was an incredibly -- it was a great meeting. Dr. Morley was -- was the master of ceremonies pretty much, and -- and kept people

Page 18 SEMAC, 5-25-2010 October on your schedule. It will be in New York City, just in case you might have forgotten that. So, please register. I'm told to tell you, I register. If you're traveling and you want to stay in the City, make reservations very soon because about eighty percent of our hotel block has been booked. So, if -- if those numbers translate or I should say, you know, be afraid of Donna pretty much, but when those numbers translate to registrations, it will be a very big event. So, please, please, please. We -- this is -- this is my nagging part. We've introduced to the -- we started with the STAC almost accidentally introducing our project management tool, and we talked about it at Medical Standards earlier, and we will work with the committees on a more face-to-face basis, but we -- Andy developed what initially looks like a rather threatening form collection, on -- for a project management tool. But when you actually take a look at it, it's -- it has a number of -- of intentions. Some are veiled

Page 19 SEMAC, 5-25-2010 and some are not. The not veiled are that we need to be able to produce for the Department and -- and the public and interested parties, a way to -- to prove that you are a productive advisory council, and the project management schema keeps you on track. And so, we are -- we -- it will all be electronic, so while you are thinking up new and exciting projects, you're going to be tracking them using a project management tool. And the veiled part is that we'll be sharing them with you when we're -- when you're done developing them, and we'll be sharing with -- them with you at your next meeting to keep you on track, and to remind you of where you were. The intention is that because you have so few meetings, we want you to be able to connect the dots, and rather than rework everything you did at the last meeting -- that's counterproductive and you don't have time for that -- the project management tools will help keep everything focused and moving forward. And in the end -- and this is what

Page 22 SEMAC, 5-25-2010 back saying, "no, we don't deal with pediatric trauma," we would be in trouble. So, far though, we've gotten fifteen responses, so we're a little over half, and all of them have said they are pediatric trauma capable. We initially thought they were the "Upsate" hospitals, but we decided they were actually the "out-of-New York City" hospitals, because it -- some of you are actually not Upstate. So, once -- once we get a full response, and we expect to, we will be sharing with all the RTACs and the REMACs and the SEMSCO and SEMAC, so you'll have an idea. And the last thing is really important actually. This week the National E.M.S. for Children conference is going on, and it -- it's interconnected with all kinds of things, but they -- the National E.M.S. for Children group association which is very large, voted to bestow the honor of lifetime achievement award for pediatric care, both hospital and prehospital to our own Dr. Cooper. So, you are the first to hear this publicly, because they have -- they said we

Page 23 SEMAC, 5-25-2010 could tell you. This is a huge honor. I don't know where he wandered off to, but he does know. FROM THE FLOOR: Yes. FROM THE FLOOR: He knows. MS. BURNS: But this is a huge honor, so when he walks in the room, please -- FROM THE FLOOR: He's outside the door. MS. BURNS: He's probably on the phone. One thing to note, and I -- I did -- I did write to my bosses, that this -- this honor is generally bestowed posthumously, and because Dr. Cooper has his own unique qualities, he had the nerve to get it while he was still alive. So, this is -- it's being given to him on Thursday in Washington. So, again, if we can drag him in here. That's the end of my report. Dr. Henry. DR. HENRY: Well, congratulations to him, and we'll give them to him when he appears. Give him a round of applause.

Page 26 SEMAC, 5-25-2010 second motion that's being brought forward was a discussion of the equipment list from the E.M.S.C. program. In 2005, national equipment for ambulances was approved by the Federal Emergency Medical Services for Children and the American College of Surgeons Committee on Trauma and ACEP and N.A.E.M.S.P. That list was brought forward to Medical Standards. The list included pediatric equipment specific for -- for B.L.S. -- we're talking about a B.L.S. ambulance - suction catheters, oxygen delivery, bag valve mask, mask for -- for children, airways -- different airway sizes specific to children, pulse oximeter with pediatric probes, A.E.D. paddles for children, immobilization devices for children including cervical collars and lower extremity traction devices, O.B. kits, and a length/weight-based tape or appropriate reference material for pediatric sizing and drug dosing. Some discussion on some additional items that members thought should be included, and some discussion on some of the items that could be fulfilled by having a -- instead of a

Page 27 SEMAC, 5-25-2010 rigid cervical collar for each size, having an adjustable collar. But you would still -- an ambulance would still be required to have three. So, the motion was to approve the E.M.S.C. equipment list as it was brought forward for pediatric equipment for ambulances, not -- not for first response vehicles or other response vehicles at this time, but that will be part of ongoing discussion. So, that came forward, and it was approved without additions. DR. HENRY: Is there any discussion on this motion? (No audible response) DR. HENRY: All right. Hearing none, we'll take a vote then. MS. GERARD: Dr. Broderick? DR. BRODERICK: Yes. MS. GERARD: Dr. Cooley? DR. COOLEY: Yes. MS. GERARD: Dr. Cooper? (No audible response) MS. GERARD: Dr. Cushman? DR. CUSHMAN: Yes.

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2 MS. GERARD: Dr. Dailey? 2 repeat dose of furosemide was removed from the
3 DR. DAILEY: Yes. 3 protocol. The rest of the protocol remains the
4 MS. GERARD: Dr. Davidoff? 4 same.
5 DR. DAVIDOFF: Yes. 5 The third protocol that was
6 MS. GERARD: Dr. DeTraglia? 6 brought forward, were addition of changes in their
7 DR. DETRAGLIA: Yes. 7 interfacility transfer protocol, and -- in that
8 MS. GERARD: Dr. Goodman? 8 they made a list of I.V. drips and listed
9 DR. GOODMAN: Yes. 9 E.M.T.C.C. protocol drugs that could be utilized
10 MS. GERARD: Dr. Haydock? 10 during an interfacility transport. They also
11 Thank you Yes. 11 listed medications and treatment that could be
12 MS. GERARD: Dr. Henry? 12 administered by an E.M.T.-P. One of those drugs as
13 DR. HENRY: Yes. 13 a drip was listed as propofol. That was withdrawn,
14 MS. GERARD: Dr. Kaufman? 14 as administration of propofol in an ambulance
15 DR. KAUFMAN: Yes. 15 prehospital, requires a presence of a licensed
16 MS. GERARD: Dr. Kugler? 16 independent practitioner in New York State. So,
17 DR. KUGLER: Yes. 17 the propofol was removed from their protocol as it
18 MS. GERARD: Dr. Leinhart? 18 was brought forward.
19 DR. LEINHART: Yes. 19 There was discussion on use of
20 MS. GERARD: Dr. Marshall? 20 facility -- the transferring facility's I.V. pumps
21 DR. LEINHART: Yes. 21 and education and training of the prehospital
22 MS. GERARD: Dr. Olsson? 22 providers in their use, and that seems to have been
23 DR. OLSSON: Yes. 23 addressed by the region, and those come forward --
24 MS. GERARD: Dr. Takats? 24 I think that was the only change. And those --

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2 DR. TAKATS: Yes. 2 those three come forward as a seconded motion.
3 MS. GERARD: Dr. Waters 3 DR. HENRY: Any discussion on
4 DR. WATERS: Yes. 4 that?
5 (The motion carried.) 5 Yes. Dr. Goodman.
6 MS. GERARD: Roll call complete. 6 DR. GOODMAN: Just a point for
7 DR. HENRY: Thank you. 7 education is that we added to our -- just a note,
8 It passes. 8 in our protocol in the Suffolk Region, with regards
9 DR. MARSHALL: The next protocol 9 to CPAP, that patients who are preoperatively on
10 that's brought forward is from the Central New York 10 CPAP that recently undergone bariatric surgery can
11 Regional Emergency Medical Services Council. They 11 be continued on CPAP, but if a patient has never
12 made changes to three of their existing protocols, 12 seen CPAP before, and is within six weeks
13 so the approvals were for the changes in the 13 postoperatively bariatric -- you know, bariatric
14 protocols. 14 surgery or some type of -- any type of esophageal
15 The first one was for the acute 15 surgery, there's a risk of having a blow-out. So,
16 respiratory distress protocol in which a CPAP was 16 I would just recommend to the region that as part
17 added to the adult acute respiratory distress 17 of their education, that that be a relative
18 protocol, including online medical control to 18 contraindication.
19 notify the receiving hospital. 19 DR. HENRY: Thank you.
20 The second change was similar in 20 Dr. Dailey.
21 the pulmonary edema adult protocol, adding CPAP 21 DR. DAILEY: I'm just wondering
22 again with provider contact of online medical 22 if I can get a little clarification. I realize
23 control to notify the receiving hospital. In 23 there's been a lot of conversation about his
24 addition, in the pulmonary edema protocol, the 24 off-line, and now Dr. Marshall has said it -- said

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2 it very clearly on the record. Propofol, for 2 nurses outside of the I.C.U. setting, with
3 providers in New York State, the C.M.S. regulations 3 unintubated patients, the State Education
4 that have gotten many organizations concerned, were 4 Department has indicated they cannot.
5 driven by titrated boluses of propofol for 5 Now, I just provide that by way
6 sedation, not drips of propofol on pumps for 6 of background that -- what somebody else is doing.
7 patients that are intubated. 7 I don't know of any regulation or
8 Have we written regulation in New 8 law in New York State that identifies who can use
9 York State that goes farther than -- than C.M.S., 9 propofol or not, but there are restriction on
10 or is this recommendation from New York -- New York 10 certain licensees that exist.
11 State? What -- what are we looking at here? 11 DR. HENRY: Okay. Thank you.
12 Because this is going to effect a 12 Because it was the C.M.S. issue
13 lot of patients that are being transported between 13 that led to removal of propofol from an existing
14 institutions intubated, and it's going to be a very 14 protocol; correct --
15 significant advisory from the Department of Health 15 DR. MARSHALL: Correct.
16 to all hospitals and all ambulance agencies in New 16 So, yes, Dr. Davidoff?
17 York State. 17 DR. DAVIDOFF: So, with the
18 DR. HENRY: Well, I would welcome 18 clarification that we've just received, where did
19 clarification on that, too. It's the first I've 19 we come up with saying that personnel in ambulances
20 heard it today. I don't know if Dr. Morley or 20 cannot use propofol, because I missed that?
21 others -- I don't want to put -- meant to put anyone 21 DR. HENRY: I think it was
22 on the spot, but do you know if that's a particular 22 interpretation of, you know, remarks about the
23 rule in New York that you need to be -- have the 23 C.M.S. ruling, if you will.
24 independent practitioner to administer propofol in 24

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2 an ambulance or to continue a drip? 2 DR. DAVIDOFF: C.M.S. has no say
3 DR. MORLEY: I -- I think you've 3 in what we do in the back of an ambulance. We've
4 got a couple different questions that are there and 4 been using propofol safely for a significant number
5 some of which I can make some comments on, and -- 5 of years. Propofol is not a controlled substance.
6 DR. HENRY: Sure. 6 We could probably list a few other reasons why, at
7 DR. MORLEY: -- this is obviously 7 this time, saying that we can't use propofol in the
8 complex. 8 back of an ambulance in certain patients is
9 There's been a great deal of 9 probably not appropriate.
10 discussion between State Education and the 10 DR. HENRY: Well, the framework
11 Department of Health regarding propofol, and then 11 again, this was interfacility transfers; correct?
12 the recent C.M.S. announcement, on top of that, 12 DR. DAVIDOFF: Right.
13 that they're looking to see it limited in -- in 13 DR. HENRY: So, these are
14 scope and use. It just complicates matters. 14 patients who are taken from one level of care to
15 In the hospital and -- and the 15 another, some of whom are intubated, and I would
16 nursing departments -- or excuse me, the -- the 16 assume that's when the propofol is being used, to
17 Division of State Education, the Nursing -- State 17 maintain the ability to keep them intubated.
18 Nursing Board has indicated that it can be used 18 DR. MORLEY: That's our intent,
19 only by those trained in airway experience, or as 19 yes. This is not something the field provider
20 Mike Dailey was just describing, in the setting of 20 would start, but would, like all the other
21 a continuous infusion in the intubated patients. 21 medications, they're -- they are prescribed by the
22 So, they clearly identify a separation in -- in how 22 physician at the transferring referral center, and
23 it's used. 23 they're carried on and maintained during the trip.
24 As to items used by registered 24 DR. HENRY: Okay. So, one -- if

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2 one wishes one could discuss amendments to this 2 I think this would seriously
3 motion. But this is the motion we had coming out 3 impact the -- the quality of care in interfacility
4 of our Committee and this is what stands before us 4 transports in certain areas of New York State.
5 now is a motion from our Committee. 5 DR. HENRY: Dr. Young.
6 DR. MORLEY: Well, certainly I'm 6 DR. YOUNG: I would question --
7 happy putting the propofol in as we wrote it, but 7 when we talk about having used propofol for years,
8 it was this group that felt it shouldn't be. So, 8 exactly what time -- sort of time frame we're
9 I'd -- I'd like to see it back, but -- 9 talking about; and my other question is what
10 DR. MARSHALL: I think that the 10 training do the individuals have that are actually
11 discussion -- some of the discussion this morning 11 using this as far as the E.M.T.s?
12 was -- was more along the lines of that if you were 12 I mean still being a director of
13 going to continue a drip in the back of an 13 a paramedic C.C. -- or paramedic intermediate and
14 ambulance, interfacility transport, that a licensed 14 basic training program, it's not in the curriculum.
15 independent practitioner had to be on board. It 15 We don't have O.R. time anymore, unless you're --
16 wasn't that you can't use it, but you just had to 16 it's hard to get our staff in. I mean I -- I
17 have a licensed provider. That was the discussion 17 manage the other Mercy Flight to the west, and we
18 that we ended up with this morning, so you know, 18 have a tough time getting our staff in hospitals
19 more clarification would be welcome. 19 for clinicals. In fact, we can't unless it's part
20 MR. MORLEY: I'd like to add that 20 of their recent education program. So, we -- they
21 we've moved, over the past fifteen years, towards 21 don't have the O.R. time. They don't really have
22 sort of reducing the use of licensed practitioners 22 the in-hospital familiarity they used to any more,
23 in the back of the ambulance. We've trained our 23 other than when they recert.
24 paramedics to critical care levels, so that they 24 So, I would -- my concern would

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2 don't need to have a licensed provider in the 2 be on the other side is while we have used agents
3 vehicle with them. They do have medical control in 3 from time to time, what -- what is the training
4 using these advanced drugs, and now we're seeming 4 that they actually have ongoing training with the
5 to be moving backwards again. 5 drug, and we see hospital patients now being
6 Many of our paramedics have been 6 transferred on multiple, multiple infusions, not
7 successfully and safely using propofol drips to 7 just one or two drugs they have to keep track of,
8 sedate patients who are intubated for many years. 8 they're multiple. Sometimes with multiple pumps.
9 They have continued drips that were started in 9 And which we heard today was some -- in some cases
10 hospitals, and they have started drips on patients 10 just-in-time training on the actual pumps. So, I
11 who were failing to be sedated with other 11 think we're putting our providers in a situation
12 medications. If we take the propofol away, we have 12 that they shouldn't be.
13 very little left. 13 Hospitals have issues with
14 We were able to add fentanyl! 14 staffing, but to expect our providers necessarily
15 recently, but we're limited to carrying two hundred 15 to take the brunt of that, and just run with the --
16 micrograms, which, on a long-distance transport, is 16 the -- the individuals they have without
17 nowhere near enough. We're trying to get away from 17 expecting -- or hoping for support in some of the
18 the benzodiazepines, and that would pretty much 18 real complex cases, I think puts us and our
19 leave us with benzos, although we rarely carry 19 transferring institutions in -- in jeopardy.
20 enough in the way of benzos to sedate these 20 DR. HENRY: Dr. Dailey, you had
21 patients on longer trips. So, we're effectively 21 a --
22 restricting the ability to transport very sick 22 DR. DAILEY: With all respect to
23 patients longer distances, as we've tried to be 23 Dr. Young, I think we -- well, I had a challenge.
24 able to do over the past few years. 24 I -- I think he raises a number of good questions

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2 that we've addressed here before and will continue 2 Levophed, you know, you can keep on rattling them
3 to address. In particular, ways that we have of 3 off. It doesn't answer for one drug, and why
4 getting our providers the training that we 4 propofol suddenly becomes the big, bad drug in the
5 desperately want to get them. However, as soon as 5 little white bottle.
6 we question all of the things that we do on 6 It killed Michael Jackson. I'm
7 interfacility transports, based on one drug that 7 sorry. But what killed Michael Jackson wasn't
8 happened to kill a popular entertainer, I think 8 propofol; it was a cardiologist administering a
9 we're making a drastic mistake. 9 drug inappropriately, not a drug being given after
10 You could very quickly raise the 10 education in the right environment.
11 same questions about dobutamine, Nipride. You 11 DR. YOUNG: I don't --
12 could easily say that a patient should never be 12 DR. MARSHALL: I'm sorry.
13 chemically paralyzed and then transferred. And 13 DR. YOUNG: If I might --
14 we've got a significant number of other vasoactive 14 DR. MARSHALL: We had -- just so
15 medications that we put into patients now. 15 I can bring it back a little bit. It was -- we
16 I think these medications need to 16 didn't discuss the evils of propofol, but whether
17 be given by pump. I think they need to be given by 17 or not a licensed, independent practitioner was
18 pumps that the providers transferring them know 18 needed on the ambulance, that -- that was the
19 well, either because they are their own pumps, or 19 issue. It wasn't whether propofol was good or bad,
20 because they've been well-trained by the hospitals 20 or you could use it or not use it under appropriate
21 with whom they have -- the transferring ambulance 21 circumstances, but whether or not you could use it
22 agency has a close relationship, and we need to 22 with a paramedic, or an advanced, you know,
23 make sure it's being done as safely, with as much 23 paramedic with additional training, or you had to
24 active quality assurance as possible. 24 have a licensed independent practitioner on the

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2 But to say that one drug that 2 bus.
3 happens to be white and a little bit slippery, all 3 So, that was really the
4 right, is the worst drug ever, and we shouldn't be 4 discussion. And I don't have the answer to that,
5 using in the back of an ambulance is a mistake. As 5 but if -- if we don't require a licensed
6 long as the patient is intubated, the patient's 6 independent practitioner actually on the bus during
7 intubation is appropriately monitored with wave 7 that interfacility transport, then propofol is
8 form capnography, the drug is being given by pump, 8 still an absolutely valuable drug under the
9 and there's good parameters written for the 9 appropriate circumstances.
10 management of that drug by the transferring 10 DR. HENRY: So, if that's the
11 physician, and the paramedic has been trained, I 11 correct understanding, let's proceed from there.
12 think that drug should be at the purview of the 12 If you don't need an independent licensed
13 transferring and receiving physician with just 13 practitioner in the back of an ambulance to
14 paramedic being able to transport. 14 maintain a drip, or to use to keep an intubated
15 DR. YOUNG: If -- if I may, just 15 patient in a good state.
16 a quick question. Mike, if you've got a patient 16 FROM THE FLOOR: What do you need
17 being transferred from an I.C.U. to an I.C.U., who 17 in the back of an ambulance?
18 is providing the direction on that transfer? 18 DR. HENRY: No, I'm saying if we
19 DR. DAILEY: Ultimately the 19 don't need an independent practitioner, that was
20 medical director of the transferring agency is 20 the assumption for the change in the protocol
21 going to assist the paramedic. 21 earlier today.
22 But -- but Greg, that's going to 22 DR. MARSHALL: Correct.
23 be a potential vec infusion, potential fentanyl 23 DR. HENRY: Right?
24 infusion, potential Versed infusion, potential 24 DR. BRODERICK: That's my

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2 understanding, yes.
3 DR. HENRY: Okay.
4 DR. BRODERICK: That it was that
5 you would need a -- an E.M.T. could not -- you'd
6 need a nurse, or an independent licensed -- well,
7 independent -- well, independent licensed
8 practical nurse basically in the back of the
9 bus, and that would -- speaking to Dr. Cooper's
10 comment earlier, as it relates to the Specialty
11 Care Transport TAG, I think if we start to be, you
12 know, tailor one drug that we can use and one that
13 we can't, that -- that decreases the amount of work
14 that the S.C.T. tag could do, because this is
15 something that needs to be discussed again, and --
16 and this -- this drug -- this particular
17 discussion, brings that up very, very well as to
18 what we can use.
19 And there's many neurosurgeons
20 that I know that intubated in particular want
21 propofol. This is a huge help for them, and I
22 would make an argument that propofol is the better
23 drug, in the event that the airway is lost, if you
24 have a long-ended benzodiazepine or a paralytic on

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2 board, you're in a hell of a lot more trouble than
3 if you can take the propofol off immediately and
4 possibly get that patient through that period of
5 time.
6 DR. HENRY: So if I may, before I
7 think you, Dr. Cooper, focused the discussion.
8 There was a motion to strike the last clause here
9 of this motion; right? With the removal of
10 propofol by Dr. Olsson.
11 DR. COOPER: I don't think that's
12 what it comes down to, yes. If we don't need a
13 licensed, then we'd like to have it. If we need a
14 licensed provider, then we don't.
15 DR. HENRY: So, the motion is to
16 amend this record by restricting -- I mean removing
17 the phrase removal of propofol.
18 Is there a second to that motion?
19 (No audible response)
20 DR. HENRY: There is a second to
21 that motion.
22 So speaking to the motion at
23 hand, Dr. Cooper. Or -- no?
24 Okay. Yes, Dr. Morley.

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2 speak against it?
3 (No audible response)
4 DR. HENRY: Well, hearing none,
5 let's take a vote on the motion to amend, which
6 would be to remove -- to strike the words as with
7 the removal of propofol under the I.V. drip section
8 for paramedics.
9 All in favor of that? I think we
10 can take a show of hands. For -- please raise your
11 hands.
12 (No audible response)
13 DR. HENRY: Okay. Against?
14 (No audible response)
15 DR. HENRY: Abstentions?
16 (No audible response)
17 DR. HENRY: Okay. One
18 abstention.
19 (The motion carried.)
20 DR. HENRY: So, the motion is
21 amended.
22 All right. Now, let's speak --
23 discuss the motion at hand. Any discussion on the
24 amended motion?

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2 (No audible response)
3 DR. HENRY: All right. Do we
4 need a roll call on this, Director Burns?
5 MS. BURNS: For a protocol, we're
6 voting for a protocol.
7 DR. HENRY: All right. Okay.
8 Let's take -- yes, please. Discussion?
9 DR. KUGLER: For clarification,
10 what I had heard Dr. Olsson state is that
11 potentially the -- the -- the medic can start the
12 medication, the propofol in the back of the
13 ambulance, too, not necessarily just continue the
14 drip.
15 DR. MORLEY: These are all
16 interfacility. So, all the medications, including
17 propofol are started prior to arrival of E.M.S.
18 They're receiving the doctor's orders, and they're
19 maintaining the drip and watching the patient the
20 whole time.
21 DR. KUGLER: Okay. So, that --
22 that comment did not come forward as from --?
23 DR. HENRY: From Dr. Olsson. It
24 didn't come from Dr. Olsson.

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2 DR. MORLEY: The -- as it would
3 be to decrease it, if there was something that went
4 wrong.
5 DR. YOUNG: So --
6 DR. MORLEY: And that goes
7 back --
8 DR. YOUNG: -- so, it's more --
9 DR. MORLEY: -- to the agency
10 medical director.
11 DR. YOUNG: -- okay, so it's more
12 than simple maintenance. If the -- obviously if
13 they're on a drip, it can be adjusted up or down
14 then.
15 DR. MORLEY: That --
16 DR. YOUNG: That's the intent.
17 DR. MORLEY: -- that would be
18 correct. The only stipulation, again, is they
19 don't start it.
20 DR. HENRY: Okay. Yes.
21 DR. COOLEY: I was just going to
22 question the definition of "maintenance," doesn't
23 that involve adjustment? Otherwise, it's
24 "observation."

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2 I mean if you've got
3 parameters -- the maintaining the drip, that there
4 can be -- if part of the orders are to adjust the
5 drip accordingly, I don't -- that's not starting
6 the drip, that's still maintaining the drip, that's
7 just modifying the drip.
8 DR. YOUNG: I'm trying to get
9 that clarified.
10 DR. HENRY: Semantics.
11 DR. YOUNG: Well, it isn't
12 semantics.
13 FROM THE FLOOR: No.
14 DR. MARSHALL: On the
15 interfacility -- excuse me -- transfer document
16 that I presented as an informational item, you'll
17 see it says "medication continuous infusion," it
18 gives a fluid, the rate, the parameters, and then
19 any of the other parameters that the ordering
20 physician would include.
21 DR. HENRY: Any other discussion?
22 Okay. Yes, Dr. Morley.
23 DR. MORLEY: Is it -- sorry to
24 drag this on. But -- so then from the discussion

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2 DR. HENRY: Oh, Dr. Cooper.
3 MS. GERARD: That's correct?
4 DR. HENRY: All right. Thank
5 you.
6 DR. MARSHALL: Moving right
7 along. The next protocol that comes forward is
8 from Nassau REMAC, which is a change in their
9 pediatric altered mental status protocol. What
10 they did was that they added a note, perform a
11 glucometer test for blood sugar level, if it is
12 less than sixty, administer glucagon or dextrose as
13 indicated in step three, "which is glucagon, point
14 one milligram per kilo I.M. or if no I.V., "or step
15 five," which is dextrose "D-ten or D-twenty-five
16 I.V. and continue monitoring as needed after
17 administration." And that was the only change in
18 their existing protocol which just the addition of
19 that note.
20 DR. HENRY: Any discussion to
21 this motion?
22 Okay. Hearing none, we'll take a
23 vote.
24 MS. GERARD: Dr. Broderick?

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2 DR. BRODERICK: Yes.
3 MS. GERARD: Dr. Cooley?
4 DR. COOLEY: Yes.
5 MS. GERARD: Dr. Cooper?
6 DR. COOPER: Yes.
7 MS. GERARD: Dr. Cushman?
8 DR. CUSHMAN: Yes.
9 MS. GERARD: Dr. Dailey?
10 DR. DAILEY: Yes.
11 MS. GERARD: Dr. Davidoff?
12 DR. DAVIDOFF: Yes.
13 MS. GERARD: Dr. DeTraglia?
14 DR. DETRAGLIA: Yes.
15 MS. GERARD: Dr. Goodman?
16 DR. GOODMAN: Yes.
17 MS. GERARD: Dr. Haydock?
18 DR. HAYDOCK: Yes.
19 MS. GERARD: Dr. Henry?
20 DR. HENRY: Yes.
21 MS. GERARD: Dr. Kaufman?
22 DR. KAUFMAN: Yes.
23 MS. GERARD: Dr. Kugler?
24 DR. KUGLER: Yes.

Page 62 SEMAC, 5-25-2010 1 standard of care. 2 And I spoke with Dr. Morely about 3 it, and we ended up facilitating a very good 4 conference call to discuss the whole process and 5 what the fire department wanted to do. And the end 6 result was that - and correct me if I'm wrong Dr. 7 Morely - essentially that -- that the Department is 8 not comfortable with the interpretation that this 9 is a standard of care, and as such, we would -- we 10 would say that the regional protocol for doing this 11 in New York City really does need to be withdrawn, 12 and that -- that FDNY continue with this as a 13 demonstration project, and that the -- you know, at 14 the completion of it, or as it progresses, report 15 to this body the progress or the data that they're 16 collecting as a result of this. 17 Did I miss anything? 18 DR. KAUFMAN: I could comment. I 19 have Dr. Freese here as well if any questions come 20 up, but the -- what was presented at the last 21 meeting by Dr. Freese and Dr. Prezant was the plan 22 for what we call phase two of the hypothermia 23 project in New York City. The same plan that has

Page 63 SEMAC, 5-25-2010 1 been put forth at least a year and a half before, 2 that we've really been working towards as a 3 regional system of hypothermia care in New York 4 City. 5 Phase one, that's been in effect 6 and -- and very successful involved organizing 7 those hospitals that chose to participate and to 8 receive post-arrest patients. If you all remember 9 from the last meeting, I think that the -- the data 10 was presented, and I know we distributed the white 11 paper on the science behind the idea of prehospital 12 and intra-arrest initiation of therapeutic 13 hypothermia for these patients, and the -- and the 14 likely benefits, or -- or assumed benefits, or 15 hoped for benefits, from that procedure. 16 I think what this Committee 17 decided at that time was that this was an 18 appropriate level of care, and the science 19 supported that, as was put forth, and -- and that 20 was the vote that was here. 21 I think we certainly understand 22 the concerns. You know, the definition of 23 "standard of care" is -- is always tricky.

Page 66 SEMAC, 5-25-2010 1 experiment to provide a nonstandard of care in the 2 classic sense of the term standard of care to 3 cardiac arrest patients? 4 DR. FREESE: So, just to clarify, 5 the I.R.B. application which we forwarded to Dr. 6 Henry, and would share with anyone, specifically 7 stated that this was being pursued as a change 8 through REMAC and SEMAC, as a change in regional 9 protocol, and that this was not a nationwide or 10 otherwise accepted standard of care, but it would 11 be a change in the regional standard, or the 12 regional -- 13 DR. HENRY: What you're 14 providing. 15 DR. FREESE: Right. So, we did 16 not pursue this as a waiver of informed consent. 17 We did not pursue this as an experimental therapy. 18 We -- we pursued this I.R.B. application as a 19 change in therapy, and we did speak to them last 20 week and clarified that was their understanding as 21 well, that we were not looking for experimental 22 approval. 23 DR. MORELY: So, then what you're

Page 67 SEMAC, 5-25-2010 1 for the data collection and the data evaluation of 2 the project. So, I understand there was some -- 3 some misunderstanding, but I know that's what was 4 stated from Dr. Prezant and Dr. Freese at that 5 time. 6 DR. HENRY: Dr. Morely? 7 DR. MORELY: This -- this -- for 8 the record though, the commissioner hasn't reversed 9 anything, he's just asked additional questions for 10 clarification purposes, and it -- and it is still 11 being studied, but I expect that we'll be able to 12 respond in -- in just a matter of a few days. 13 But as you're discussing the -- 14 as you're presenting this now, a question came to 15 mind that you've presented this to the I.R.B., and 16 you -- they've approved it for data collection. 17 Has -- has the research board approved this for 18 treatment of a patient from whom you cannot obtain 19 consent? 20 A consent for a new and 21 experimental treatment, not experimental to cool a 22 person off post-resuscitation? And it is a minor 23 issue, but did the I.R.B. provide approval as an

Page 70 SEMAC, 5-25-2010 1 like that's what it is, an experimental therapy; am 2 I mistaken? 3 DR. FREESE: We were not looking 4 to do this as an experiment, we were looking to 5 change the regional protocol. Much has been done 6 in other states -- as we discussed on the 7 conference call, things that have been done in 8 other states and other cities. 9 In Seattle, if you remember back 10 to 1999, when they published the C.P.R. before 11 defibrillation, this is the same model they used. 12 They took the existing therapies which were not 13 providing any additional care. They changed their 14 regional protocol to do defibrillation after two 15 minutes of C.P.R., and then subsequently went back 16 and looked at that and published the data. We took 17 that same approach. Minimally invasive -- I'm 18 sorry. 19 Minimally interrupted C.P.R. 20 That was done in Arizona. They did the same thing 21 They changed the statewide protocol. They actually 22 went for I.R.B. after the fact. 23 But that's the model we followed.

Page 71 SEMAC, 5-25-2010 1 We wanted to change the regional care, and then 2 look at the impact of that care, as we do with 3 ResQPOD and everything else. 4 DR. MORELY: Okay. We -- we -- 5 we may -- you know, as I mentioned, we're -- we've 6 got the paperwork that you sent and are reviewing 7 it, and you know, we may have another question or 8 two about that. 9 DR. FREESE: Okay. 10 DR. HENRY: Dr. Cooper. 11 DR. COOPER: This issue, of 12 course, has been discussed extensively both at a 13 regional level and a state level, you know, and 14 we're sort of in a -- in a bit of a -- of a 15 quandary, because it's not yet, if you will, the 16 national standard of care, which implies that this 17 is the standard to which every single community 18 must aspire. Yet there is good strong scientific 19 evidence, you know, that it's beneficial. 20 In other words, some regions 21 throughout the nation have adopted it as their 22 standard of care, and we are seeking to do the 23 same. And that, as we do with every protocol,

Page 74 SEMAC, 5-25-2010 1 system to do this, and they are doing it today, 2 Wake Forest, North Carolina. Wake, as you know -- 3 or Wake County has been doing very novel things in 4 E.M.S. and pushing the hypothermia boundaries 5 further and further. And for anyone who would like 6 to speak to Brent Myers, the medical director, 7 we're happy to give you the contact information to 8 confirm that. 9 DR. HENRY: All right. 10 DR. KAUFMAN: I'd just -- just 11 like to mention, there -- there actually are 12 providers within the city, at both Columbia 13 Hospital that I know of, Elmhurst Hospital -- 14 FROM THE FLOOR: Beth Israel. 15 DR. KAUFMAN: -- Beth Israel. 16 where -- where they are indeed doing intra-arrest 17 hypothermia. So, this -- this is occurring in New 18 York City, not as an experiment, but as a level of 19 care. 20 DR. HENRY: Okay. Good. So, any 21 other discussion? 22 So, it's -- you know, it's -- 23 people are hopeful, as we try to push the

Page 75 SEMAC, 5-25-2010 1 frontiers, everyone's been working on cardiac 2 arrest for a long time and struggling to raise the 3 numbers of survivors. 4 DR. COOLEY: I -- I just have a 5 question for the Bureau, and you mentioned maybe 6 you were going to talk about demonstration projects 7 a little bit later today, but what is the Bureau or 8 the -- and the commissioner looking for, and I'm 9 more specifically with the post-ROSC cooling as a 10 demonstration project before they move forward. 11 Are we looking for ability of the providers to 12 perform that appropriately? 13 Are we looking for -- to -- I said 14 we looking like in research for outcomes? 15 I've -- I've asked this a couple 16 times, and I feel like I'm still -- I've never 17 gotten a clear answer, or I've misunderstood the 18 answers I've gotten, I guess. 19 MS. BURNS: Actually, not -- the 20 Bureau and the Department is not specifically 21 looking at -- at any -- at either of those things. 22 The purpose -- and we'll talk about it -- the 23 purpose of the demonstration project plan is

Page 78 SEMAC, 5-25-2010 demonstration project, but not using the standard of appropriate care for our E.M.S. systems? MS. BURNS: Or not. But the regulation requires that the commissioner approve the demonstration project, and this commissioner is interested in these things, and he is responsible and has the right and authority. So, that project -- that -- the process allows an organized way for him to review this, or his designee. DR. COOLEY: Thank you. DR. KAUFMAN: I'd like to clarify one more point, which I know has come up in the discussion, but I think it would be beneficial to -- to -- to bring it up to the full Committee. And -- and -- and we've discussed this quite a bit and certainly understand that there's a concern that a protocol change approved for one region would then allow that protocol to be utilized, or be brought forth as a protocol change by other regions, as -- as is typically the case if -- if one region is allowed to administer a medication after it goes through that approval, you would support other regions doing that. But I think it's

Page 79 SEMAC, 5-25-2010 important to note that the reason -- that -- that -- and certainly for this, giving cold saline, is not a complicated skill, but it does require a system in place; a system that goes from the prehospital environment through the hospital environment. So, unless the region has established that communication and -- and agreements, it's not successful for the prehospital administration of cold saline if the hospitals are not already on board to continue that process, as it would actually be a detriment to the patient to give the cold saline, allow the patient to rewarm, to then be subsequently cooled. So -- and that I know came up as a concern with the protocol that was approved for New York City. However, I think it's clear to all of us when we review any region's protocols as we have, that that it's certainly in the context of that region. So, it's -- there's certainly no automatic approvals of every region administering prehospital cold saline, simply because the New York City protocol was approved. While we would hope that all regions would work to establish that system,

Page 82 SEMAC, 5-25-2010 part of your consideration. They may not necessarily be pivotal to whether you do or do not do the project, but they have to be considered. DR. HENRY: Yes, Dr. Cooper. DR. COOPER: Yes. This discussion, I think, has served to illustrate, as Ms. Burns has indicated, some of the strengths but some of the limitations of the demonstration project process. I think Ms. Burns may have misspoken in one respect. I believe the demonstration project regs were put into place long before the late 1980s. I think they were put into place in the 1970s or perhaps at the latest the early '80s. Long -- long before there was any kind of robust capacity anywhere to be doing prehospital research. The playing field has changed dramatically since that time. And our systems for -- for conducting -- I'll use the word evaluation, to specifically avoid use of the term research for the moment -- our systems for conducting evaluation in the prehospital

Page 83 SEMAC, 5-25-2010 environment have not exactly kept pace with the times. I think Ms. Burns is exactly right that -- that we need to open up the entire issue of demonstration projects, prehospital research, and so on, for a full and frank discussion, so that whatever regulatory and/or statutory changes may be required to ensure that it's done safely and -- and effectively in the public interest, you know, are -- those mechanisms are -- are in place. With respect to the particular project at hand, you know, there -- there -- you know, I voted for the -- the -- the protocol in New York City. I voted for the protocol here at SEMAC because my reading of the literature is such that an intra-arrest approach, makes sense from the available scientific evidence. It doesn't make sense to warm a patient only to cool them again, and there -- and there's sufficient evidence in the literature that -- that therapeutic hypothermia may be effective. That it's something -- that it's something worth doing.

Page 86 SEMAC, 5-25-2010 same time, I would hate to see this project get held up in a -- in a morass of red tape, when there is at least a good chance that -- that it may help, and you know, understanding that there could be a chance that -- that -- that it might hurt. But I think that there's a -- there's a good chance that it may help, and I think we should proceed as, you know, extremely cautiously here. Dr. Morely and Dr. Henry, I'll leave it to you to work with the commissioner to decide the -- the legalities of it. DR. COOLEY: I would just quickly ask one last question then; at what point in this process do we see other regions being able to come forward with their own protocols, or would they all be demonstration projects as well? DR. HENRY: Which type of protocol are you talking about? DR. COOLEY: Well, let -- I'll -- I'll carve out the intra -- the post-ROSC hypothermia. If another region in the state want -- has worked with their hospitals and wants

Page 87 SEMAC, 5-25-2010 to come forward with that, can we do that? DR. HENRY: Well, that's being conducted now. FROM THE FLOOR: Aren't we doing 6 that? DR. HENRY: We had two reports earlier. DR. COOLEY: I -- I -- I get off, I'm already doing this. DR. HENRY: Oh. DR. COOLEY: But my point is -- because I'm still a little unclear about this idea of the time line when things stop becoming a demonstration project and start becoming an acceptable process to have a protocol change. MS. BURNS: It's interesting you should say that because a real weakness in the -- in the -- the real -- the fact -- fact that currently there is not a real delineated process, the time line is unclear. And what the demonstration project process does is, it establishes project time lines. Now, the -- the process doesn't

Page 90 SEMAC, 5-25-2010 science -- we probably have more science about this than we do a lot of things we do for cardiac arrest. A lot of things we do in general. So, I'm still -- I guess I'm -- maybe I'm naive or confused about the idea of what we're looking for to move past that point or will these just go to -- to a stop point, and then we'll -- are we going to pick an arbitrary time to do this? DR. HENRY: Well, I -- I don't think we had labeled the post-ROSC hypothermia prehospital a demonstration projects before today. They were -- DR. COOLEY: Ours are, yeah, yes. DR. HENRY: Okay. DR. COOLEY: Yeah. Both -- all the -- DR. HENRY: So, we're -- DR. COOLEY: We're considered -- DR. HENRY: -- and we're asking 20 for the data to come back from that; correct? 21 Just -- for the oversight. 22 DR. BRODERICK: But -- but Dr. 23 Henry, I think what Dr. Cooley is saying, more than 24

Page 91 SEMAC, 5-25-2010 anything else, is that while all we're really demonstrating is that we can carry cold saline and give it -- DR. HENRY: Right. DR. BRODERICK: -- because neither Dr. Cooley nor I are going to come up with a significant and robust enough body of data to be able to influence this body one way or the other into whether or not we should have -- whether or not we should make this a statewide implementation. We can look at what current literature shows, which is that therapeutic hypothermia is good. This body should, as I suggested during Medical Standards, tell every hospital in New York State that they should either be doing therapeutic hypothermia for their ROSC patients, or should be transferring those patients immediately to a hospital with the capacity to do that, because that is very clearly, from ILCOR, the standard of care for V-fib arrests, and can clearly be interpreted to the two-B level, at non-V-fib arrests. We haven't done that. We should. But I think at the end of the

Page 94 SEMAC, 5-25-2010 1 SEMAC, 5-25-2010 2 four thousand patients a day. They have that ability to collect data quickly. They're utilizing the e-P.C.R. system, so they -- they have a venue to -- to collect that data quickly. 6 I -- I -- there's been a lot of research, a lot of work that has gone into this. This body has already approved the -- the protocol, which the commissioner obviously has the ability to -- to deny, but at -- at this point in time, I think that there's a lot of support for the science behind it. I -- I -- I think they should be able to move forward with the demonstration project. I mean we're -- we're not going to meet again until October, you know. And I know no matter how hard you whip the snail it's still going to move at a snail's pace, but I think we really need to start moving, and -- and seeing whether or not this is actually something that might be beneficial to our patients. DR. HENRY: All right. Do you have any other discussion on this item? (No audible response)

Page 95 SEMAC, 5-25-2010 1 SEMAC, 5-25-2010 2 post-arrest interviews. DR. HENRY: So, Dr. Marshall, do you have further items in your report, then we'll have our address from our speaker? DR. COOPER: Is there an action that needs to be taken on this issue or was this merely for information? DR. HENRY: I think this is for information at this point. I mean as a body, I had, you know, informed the commissioner of the actions we took, and it was under an auspice of a -- of an I.R.B. and the type of auspices it was under. I just queried whether -- asked for advice. It was for information and advice whether it was appropriate in terms of calling it a standard of care as -- as we move forward. What the implications could be for a SEMAC body with an action. So, it was just -- it was -- it was advisory in asking for it. DR. COOPER: I just -- I just wanted to be clear that there was nothing you needed from us --? DR. HENRY: No, I don't believe so.

Page 98 SEMAC, 5-25-2010 1 SEMAC, 5-25-2010 2 on. We also had some discussion, a year or two ago, about online medical control, and who provides that. In the regulations it says that a physician, or somebody under a physician's direction, can provide online medical control. However, our policy statement, ninety-five or one, states that it must be a physician who provides online medical control. Recently the governor signed new legislation into law regarding the practice of a physician assistant, which for our purposes states that "a physician assistant may perform any function in conjunction with a medical service lawfully performed by the physician assistant in any healthcare setting." And that would apply to prehospital care and E.M.S. So, looking at that I -- over the -- the next summer, the next couple of months, would like to bring them back up to the forefront, so we can resolve the conflict between regulations and our policy, so we can take care of that. I did some looking around, and

Page 99 SEMAC, 5-25-2010 1 SEMAC, 5-25-2010 2 the only places I could find any mention of P.A.s doing online medical control were in New Hampshire and North Carolina. And they are both very rural states, and if you remember we had some presentations on surveys that were done, and our rural hospital systems don't have twenty-four-hour physician coverage, they have P.A.s and nurse practitioners in the emergency department and these are the people that are providing online medical control. The medical director is a physician, but the person on the end of the radio, or the end of the telephone might be a P.A. or a nurse practitioner, so over the summer we'll have some further discussions about that. There was a policy, for information purposes, brought by North Country in terms of Taser removal. So, we had some discussion about when it's appropriate to remove the Taser prongs from a patient, which patient should be transported to the hospital, and their policy which patients might require a twelve-lead E.K.G. based on the patients' condition prior to being tased, and some other issues.

Page 102 SEMAC, 5-25-2010 1 SEMAC, 5-25-2010 2 So, that was brought forward. We had some interesting discussion on that. It was suggested that the North Country consider making that a protocol, rather than a regional policy. There were also some discussion from other regions that the police department officers, sheriff's department, are trained to remove the prongs, and that E.M.S. does not do that, and if -- at least one region, E.M.S. responds, they will respond to take the patient to the hospital, or evaluate them medically, but not necessarily to remove the prongs. And that is my report. DR. HENRY: Thank you. We have a guest speaker. Dr. Cooper. FROM THE FLOOR: Traffic. DR. KAUFMAN: -- Traffic, close -- is proceeding forward, and in the future our Committee, probably at the next meeting, will empower a TAG to start working on version six of the paper New York P.C.R. form. We had an excellent discussion regarding STEMI center destinations, with the goal

Page 103 SEMAC, 5-25-2010 1 SEMAC, 5-25-2010 2 of identifying Q.I. data points for the regions within the state to use when evaluating STEMI cases, as well as the hospital outcomes of those patients that are transported to a STEMI center. We were -- it was -- it was interesting to us to learn that the STEMI center designations have been approved statewide in the recent revisions of the 405 regs, and that E.M.S. agencies are able to directly transport STEMI patients to those P.C.I.-capable hospitals. I'm sure we'll have more clarification of this, and our Committee actually asked for more clarification, because we didn't think this was clear to E.M.S. throughout the state that this process was complete and available for all E.M.S. agencies throughout the state to do these transports. So, that was an interesting bit of knowledge that we discussed. The Committee is -- was distributed copies of the incident reports that the Bureau has received from throughout the state, and we'll be reviewing those and providing feedback to the Bureau, and to the SEMAC and SEMSCO.

Page 106 SEMAC, 5-25-2010 1 SEMAC, 5-25-2010 2 And finally, we had a productive discussion regarding patient care restrictions that take place around the state. So, it's clearly been identified that often there are cases where a provider is found to be deficient in a skill or they particular educational piece of knowledge that they should have, and an agency or a medical director may choose to temporarily stop that provider from working on the ambulance until he or she has a chance to be remediated and reeducated in that area. And we felt that this was viewed as an important safety component for the public, to prevent providers who may be lacking in an area, from working on an ambulance until that reeducation is achieved. However, it's clear that sometimes those providers, once restricted from an ambulance agency, may simply go on to work on a different ambulance agency within the same region, or an ambulance agency within another region. And certainly that's a concern to the Committee because if they're identified -- if they have to care for a similar patient, they may similarly not provide

Page 107 SEMAC, 5-25-2010 1 SEMAC, 5-25-2010 2 appropriate care. Realizing that when these restrictions are placed, there also should be some protections for the provider, so that should that restriction be placed, and then the medical director or agency decides not to lift the restriction, the provider may need some ability, some recourse or due process. We really view this process as an educational/quality assurance process, and not a disciplinary process. And we'll continue to discuss maybe some guidelines for the regions or for the State Bureau to put forward as guidelines in this regard. If anybody has any thoughts or comments, the Committee -- Bob DeLagi and myself, would love to hear your input, so we could continue to put together this document. And those were the major points of discussion at our Committee today. Thank you. DR. HENRY: All right. Thank you.

Page 110 SEMAC, 5-25-2010 1 as there was for stroke or trauma centers, but I 2 guess we were informed, and this will be clarified, 3 that there will not be. In fact, all 4 P.C.I.-capable -- the -- the Regulations -- the 405 5 Regs. now allow all P.C.I.-capable hospitals to be 6 considered STEMI centers, as -- as -- as we were 7 told at the meeting. 8 MS. BURNS: We need to research 9 this. 10 DR. HENRY: Okay. We'll get that 11 document out to you. There was something sent 12 through the Hospital Associations about new regs 13 for cardiac centers in terms of volume and whatnot, 14 and it also addressed emergency capability. So, 15 that was two or three months ago, and actually part 16 of that was -- no, that was about two or three 17 months ago I believe. So, we'll -- we'll -- we'll 18 research that, and get it out to you on a Listserv. 19 Other questions, or --? 20 DR. DELAGI: Just to add that 21 this is particularly important to us from a Q.I. 22 perspective, because the regulatory change actually 23 required Q.I. participation between the hospitals 24

Page 111 SEMAC, 5-25-2010 1 and the E.M.S. agencies with regard to -- to having 2 robust programs in place for -- for quality 3 improvement from the patients entry into the nine 4 one system through rehab, ultimately back to 5 discharge. 6 And also, because it required 7 both P.C.I.-capable centers and noncenters alike, 8 to have transport agreements in place to be able to 9 transfer STEMI patients either if the table was 10 full, and they couldn't care for that patient, or 11 if they weren't doing P.C.I. as a -- as a 12 noncenter. So, that's why we've been watching this 13 so closely. 14 DR. HENRY: Good. Any other 15 discussion or questions? 16 Okay. From the Education 17 Committee, are there any action items or 18 information we should discuss? 19 Yes. Please. 20 FROM THE FLOOR: There are no 21 items to bring forward for a vote. We did have 22 discussion, a notice from the E.M.S.C. Committee 23 with direction for money available this year for 24

29 (Pages 110 to 113)

Page 114 SEMAC, 5-25-2010 1 good -- offices of Martha Gohlke and Ed Wronski and 2 Lee Burns, we were able to invite the Commissioner 3 of Health to give keynote remarks at the recent 4 meeting, which took place about ten days ago in New 5 York City, May 13th -- eleven days ago, I guess 6 now, twelve. 7 And the purpose of that meeting 8 was really to effect, or begin effecting the 9 provisions of Subdivision 1 of Section 30785 of 10 Article 30(c) of the Public Health Law, which 11 mandates that the Department will develop and 12 maintain -- maintain a system for identification of 13 facilities that are able to provide pediatric 14 emergency and critical care services for critically 15 ill and injured children. 16 As all of you know, neonatal care 17 has been regionalized for some years. Pediatric 18 trauma care has been regionalized for some years. 19 However, pediatric emergency and critical care are 20 not explicitly regionalized under state statute or 21 regulation. So, the purpose of this meeting was to 22 gather stakeholders from all over New York to think 23 through the issues and come up with some solid 24

Page 115 SEMAC, 5-25-2010 1 But I wanted to thank you all so 2 much for the support that you have given me over 3 the years, but especially the support you've given 4 to the Emergency Medical Services for Children 5 programs in New York State, up to and including the 6 most recent stakeholder meeting that I want to 7 comment about briefly in a moment. But without the 8 support of -- of all of you, E.M.S.C. would never 9 have come anywhere near as far. 10 I want to thank the Department of 11 Health for its incredible support over the years, 12 Dr. Henry and the SEMAC for their support. Always 13 asking good questions and -- to keep us on the 14 right track, but always, always supportive of 15 the -- of the mission of making sure that our kids 16 are -- are well cared for. 17 So, thank you again from the 18 bottom of my heart for the support for the 19 children, and for your very gracious round of 20 applause earlier in the meeting. 21 Having said that, I am very, very 22 pleased to report, as Lee indicated I would a 23 little bit earlier in the meeting, that through the 24

30 (Pages 114 to 117)

Page 118 SEMAC, 5-25-2010 1 This, of course, is a process in 2 evolution. It -- it really began with the 3 institution of the E.M.S.C. program. A major 4 milestone was the E.M.S.C. legislation that this 5 body supported. And now, we're actually into the 6 implementation phase. 7 And once again, nothing -- 8 nothing good comes easy. It's taken some time, but 9 we're getting there, and I want to thank the 10 Department and the -- the SEMAC for their -- for 11 their strong support of these initiatives over the 12 years. 13 I'd be happy to answer any 14 questions, but I think Lee Burns may have a comment 15 to make about the -- about the process, because she 16 made a similar comment at the STAC last week. 17 MS. BURNS: I made it already. 18 DR. COOPER: You made it already. 19 Okay. All right. 20 Questions? 21 Okay. Thanks. 22 DR. HENRY: Okay. Thank you, 23 Art. 24

Page 119 SEMAC, 5-25-2010 1 And in answer to questions 2 before, about the cardiac regs. It's -- Lee looked 3 them up. 4 MS. BURNS: Actually Anna did. 5 It's 405.29, and I've lost track of exactly which 6 number it's under. 7 DR. HENRY: It's under 2. 8 MS. BURNS: Yes. It's further 9 down, 2-B, "P.C.I.-capable cardiac catheterization 10 laboratory centers must maintain capabilities to 11 perform emergency percutaneous coronary 12 interventions, including but not limited to 13 percutaneous coronary intervention for the 14 treatment of S.T.-elevation myocardial infarction 15 on a twenty-four-hour a 16 day/three-hundred-and-sixty-five-days-a-year basis, 17 and must be capable of assembling a dedicated team 18 within thirty minutes of activation call, to 19 provide coronary interventions twenty-four/seven. 20 "Exception to this standard shall 21 be made only for temporary and extenuating 22 circumstances, and when number one, local emergency 23 medical services have been notified, and 24

31 (Pages 118 to 121)

Page 122 SEMAC, 5-25-2010 1 this, and have a discussion at our next meeting, 2 how we -- how this -- the inner workings of these 3 regulations. I'd ask Lew, maybe in between to ask 4 interested parties to have some phone discussions. 5 It's been so long since we've had a facilitated 6 discussion. 7 All right. Thanks. Any other 8 unfinished business? All right. 9 MS. BURNS: Is this where you 10 want to put the demonstration project piece or do 11 you want to --? 12 DR. HENRY: Okay. Yeah. Either 13 or new business. We'll do it under new business. 14 Any other unfinished business? 15 DR. DAILEY: My apologies. I 16 think I have something that really fits under old 17 business, which was the Article 63 Regs, which were 18 the H.I.V. Testing Regulations that we then placed 19 on a committee with the AIDS Institute in order to 20 do some work on. 21 There were a couple of things. 22 Bob -- Bob DeLagi, Don Faeth and I have been 24

Page 123 SEMAC, 5-25-2010 1 participating in those -- in those calls along with 2 Gary Tuttle from the Department, and among the 3 things that we felt should come to this body were 4 two items of -- of language that we felt were 5 relatively important. One, in the -- in the 6 regulations it -- part of the language says that 7 hospitals "may" share the results of existing 8 H.I.V. testing information with the physician 9 caring for an exposed healthcare worker or public 10 safety employee, however the language exactly goes. 11 And one of the things that Bob 12 and I were talking about is that really needs to be 13 "must" not "may." There, in the middle of the 14 night, should not be any question whether or 15 not the information -- prior existing H.I.V. 16 information should be there to treat our people. 17 And the other second section that 18 we felt was important is there is a list of 19 exclusion criteria for what does not constitute an 20 exposure. And I think that's important from an 21 educational perspective that does not necessarily 22 need to be there in regulation. 23 In particular, it says that an 24

32 (Pages 122 to 125)

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1 nicely into our demonstration project algorithm.
2 DR. JOHNSON: You'll be getting
3 the handouts here in just a second, and I want to
4 go over the handouts a little bit, but just to give
5 a quick history on this, as you know, there's been
6 many questions even today on demonstration
7 projects, and when they start, when they end, what
8 objectives are we supposed to get out of it, what
9 deliverables, and so forth, and that seems to be
10 the big hot topics on every demonstration project,
11 research project, bio project, whatever you want to
12 call them, that come forward to this body.
13 As you know, there is regulation
14 that talks about demonstration projects, so the
15 Bureau, in conjunction with executive staff in the
16 Department and the Commissioner's Office, developed
17 an algorithm so we have a better control over
18 demonstration projects.
19 And again, we use that term a
20 little bit loosely, because we realize that
21 demonstration projects from the '80s that were put
22 in Part 800, need to be different today. Whether
23 it's through research or actual treatment on

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1 patients, experimental or not experimental. They
2 take all different avenues. So, it -- it can't be
3 limited to just a skill going from one level to
4 another.
5 So, there's actually two parts to
6 it, but this was approved by executive staff in the
7 Department, and as Lee mentioned earlier, the
8 commissioner takes note of what we do in E.M.S.
9 The commissioner does have an interest in E.M.S.
10 That's not to say that the previous commissioners
11 didn't, but this commissioner has shown a very big
12 interest, and the commissioner is responsible for
13 signing off on our protocols, our demonstration
14 projects and so forth.
15 In the past, that was very
16 loosely done, but with the number of demonstration
17 projects over the years, the most recent years,
18 there has to be a little bit of a better process
19 put in place.
20 So, the first document is
21 two-sided. It goes over step one of two, and the
22 first thing to do is to look at a proposal and
23 determine whether or not it actually needs to be

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1 lower level of care, scientific verification of
2 E.M.S. concepts? As you know, there's not a lot of
3 verification of what we do in E.M.S. And you may
4 be looking at doing that. Could it interfere with
5 any existing trial or project that's currently
6 going on?
7 If you answer yes to that, then
8 it would be a demonstration project. If you answer
9 no to that, you really need to assess the logistics
10 in New York State of whether or not this project
11 needs to move forward, if the resources have to be
12 used for it or not? And what are we really going
13 to get out of it by doing that project or research?
14 So, if you do decide it's a
15 demonstration project, that we're going through the
16 algorithm, and consulting with the Bureau, then you
17 just flip over to the other side where it outlines
18 what you need to do for the demonstration project.
19 A demonstration project must be
20 approved by the REMAC and REMSCO before it comes
21 forward to the Bureau and to SEMAC for review and
22 approval.
23 Medical Standards, SEMAC and

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1 SEMSCO will -- will review it, and they'll review
2 not only the project, but the -- the curriculum
3 that may come with it, and we'll get into that a
4 little bit.
5 If there is approval, it moves
6 down to the D.O.H. commissioner for approval, to
7 the Bureau.
8 If the SEMAC or Med Standards or
9 SEMSCO doesn't approve it, for whatever reason,
10 maybe they want to make changes to it, then it gets
11 kicked back to the REMAC and the REMSCO for further
12 information.
13 If the commissioner does have to
14 look at it for approval, the commissioner can
15 either say yes or no to it, with the Bureau's
16 assistance. And if the Bureau -- if the
17 commissioner says yes to it, then we have to
18 outline through the commissioner, the duration of
19 the project, which we would like most projects not
20 to exceed eighteen months. Some projects may be as
21 little as sixty days, we don't know, it all
22 dependent on the project.
23 The evaluation requirements that

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1 or -- REMAC or REMSCO should be aware of a project
2 before it comes, you know, to the Bureau. If it's
3 coming from a region or -- or a program agency or a
4 service in a region, that the -- at least the
5 region should be aware of it before it goes through
6 the process on step one of step two, which is kind
7 of what step two is.
8 MR. JOHNSON: Right. And it's --
9 it's our hope that the draft proposal is going to
10 be coming up through the region. The draft
11 proposal should not be coming just from a specific
12 agency. The draft proposal should be coming up
13 through the region, the REMAC and the REMSCO that
14 have talked about it and want to submit forward
15 that proposal.
16 Yeah. We can add -- we can add
17 that in there. I think it was kind of just what we
18 thought that it was automatically coming from the
19 region, not from a particular agency or entity.
20 DR. MARSHALL: Otherwise, I think
21 it's great.
22 DR. DAILEY: I -- I think, Andy,
23 from a process perspective, this makes a lot of

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1 sense, and I really like the fact that we're going
2 to delineate it clearly, because I think this
3 transfer of information is something that hasn't
4 been clear all the time. This is going to help a
5 lot.
6 The problem is that all of our
7 demonstration projects may not fit into this so
8 nicely, and may lead us to problems where we've got
9 to go to I.R.B.s for what really are quality
10 assurance projects that we would have been working
11 on otherwise, and we've already been granted
12 permission to do under our mandate -- our mandates
13 from the Department of Health.
14 And our I.R.B.s don't necessarily
15 have jurisdiction in all the environments we're
16 going to be working in.
17 MR. JOHNSON: Correct.
18 DR. DAILEY: So, you know, for --
19 for example, a demonstration project to -- to show
20 that morphine could be used safely on standing
21 orders, frankly, I'm not sure I would have been
22 able to get an easy I.R.B. approval on that, and at
23 the same time, that was a quality assurance

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1 everyone at that meeting. You know, at this point
2 in time, I need to take action at the next meeting.
3 MR. JOHNSON: Sure.
4 DR. HENRY: All right. Yes.
5 DR. COOLEY: It mentions under
6 the -- on step one, the third shaded box, along the
7 left, "any new E.M.S. concept, drug or device;"
8 what's your -- what do you mean by "new drug?"
9 I mean you could argue that if protocol change -- you
10 could argue that this now encompasses a lot of just
11 protocol changes now have to be demonstration
12 projects.
13 MR. JOHNSON: No, it's not
14 getting that particular. I mean we're talking
15 about a new medication maybe that was -- it's not
16 involved in E.M.S. It could be a wider range of
17 things -- a wide range of different things. But
18 we're not looking to do the protocol approval
19 process through this.
20 DR. COOLEY: So, every new use --
21 new -- new drug use in E.M.S. needs to come through
22 this process?
23 MR. JOHNSON: No, it has to be --

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1 we have to discuss it prior. If it's something
2 that's not a standard of care and it's not in any
3 of protocol, we -- we need to discuss that ahead of
4 time to determine.
5 DR. COOLEY: Let's not sure the
6 term "standard of care."
7 MR. JOHNSON: Excuse me?
8 DR. COOLEY: Let's not use the
9 term "standard of care."
10 MR. JOHNSON: Well, I will use
11 the term "standard of care" as I'm from the
12 Department. I'm saying that -- that not everything
13 is black and white, and if you -- I can't answer
14 that unless the drug is actually brought to our
15 attention.
16 DR. COOLEY: Okay.
17 MR. JOHNSON: It's not our intent
18 to make every single protocol approval of a new
19 medication that's not on state formulary to come
20 through an I.R.B. or to go through this process.
21 DR. COOLEY: Okay.
22 DR. HENRY: Good. Thank you.
23 Any new business to come forward?

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