Continued Discussion
Facilitators: Cynthia E. Berry, J.D. and Reed V. Tuckson, M.D.

DR. TUCKSON: Thank you all for coming back.

We have some announcements to make very quickly. I'm actually stalling so a couple of you all can get back at the table. But we are starting on time, as we said. I didn't say it was going to be substantive conversation on time.

The dinner tonight is going to be here in the hotel so that you don't have to go out in the slush and the mush. In addition, and I hope this is okay with you, dinner is going to be at 6:00. Thereby, you get to eat and then go read all your briefing books and figure out the answers for tomorrow without being up all night, and the good part of that is so that our talented and wonderful staff are not out here in the mush and the slush going home at midnight, which I just can't have. So we're going to eat at 6:00, okay? Cool?

Now, Cindy has to leave at 5:30, so that means this session will be over at 5:30.

Therefore, take it away, Cindy.

MS. BERRY: Okay. A threshold question I think for this group before we get into the specific recommendations is whether the working group report should be incorporated into our coverage and reimbursement report in some way, and I think it is a valuable tool and a valuable asset for us. The question is should we pull relevant information from it and incorporate it into the report? Should we have it as a stand-alone chapter? Should we include it as part of the appendix? I throw that open as sort of the threshold question, and then we can move on to the specific recommendations.

Hunt?

DR. WILLARD: I've only read parts of it as it was going through, but based on what I read I think we should redact and pull out the parts that we feel are valuable and that we agree with and can validate, and then simply refer to it but not publish it. We'd have to examine it word by word, sentence by sentence in order to decide that we either agreed or didn't agree or that it was validated or not yet validated, et cetera. So I think we should grab what we can use and should use and leave the rest in a file.

DR. FITZGERALD: Just wondering, a follow-up on what Hunt just said. If we do references, is it going to be available to the general public somehow? Do we know if it's going to be published elsewhere or by someone else, or available on the Web, on the NSGC website or something like that?

MS. BERRY: Do you know what the plans were?

DR. WILLARD: I didn't suggest we reference it. I simply said as part of this process we solicited a body of research performed by that work group and then incorporate the findings we wish to incorporate.

MS. BERRY: Debra?

DR. LEONARD: If this report is an appendix to our report, since we have other appendices, does that mean that the appendix is something that we agree with or just something that we solicited as a report? Because I feel a little uncomfortable with pulling out parts and maybe leaving out other parts that we may not think are relevant but may be relevant to other people, genetic counselors per se. So could we do it as an appendix to the report and then pull out the parts that we want to cite in our actual report?

MS. BERRY: Yes. I don't think the fact that it would be included as part of the appendix or in the appendices means that we necessarily agree with all of the statements and findings in there. So I think we can sort of do a hybrid of what Hunt suggested, pull out pieces that we think make our case and bolster the issues that we have raised in the text of the report. We could refer to the report in greater detail and have it included in the appendix but not make any statement in terms of we are adopting this report and all of its conclusions. It's more for purposes of ease for the reader, really, when going through our report, and we're referencing something they'll be able to read in its entirety if we do it that way. That's one advantage.

DR. LEONARD: I would agree with Kevin's issue that if it's not easily available or you can't find it or it's not published, and I don't know if this is publishable, then it's difficult to find. So if we put it as an appendix, since we did solicit this report –

MS. BERRY: I am wondering whether the work group members have a preference, if there is any heartburn about us including the report as an appendix.

MR. FAUCETT: That'd be fine.

MS. BERRY: Andy's on record.

Barbara?

MS. HARRISON: I think it's a significant body of work and something that we formally requested, and they did deliver. I think it would be appropriate to put it as an appendix and highlight as needed within the text.

MS. BERRY: Hunt?

DR. WILLARD: Let me be a little more transparent. My particular issue is with a conclusion sentence that says genetic counseling has demonstrated value and is effective. At least in what I heard presented, I didn't see the data for that, and I fully accept that the working group may conclude that they believe genetic counseling is effective and has demonstrated value, and that would be fine. But to make that as a conclusion when we all just discussed how the data aren't out there to really allow us to look at the evidence and say in an objective manner that that's true, I'm just very nervous about having that attached to our report.

MS. BERRY: What if we had an appropriate -- I don't know if you want to call it a caveat or a little asterisk or a disclaimer in the front of this report in the appendix basically saying that we are not adopting all of the conclusions and -- put it in the heading? Okay. Well, somewhere before the actual report that we're not necessarily endorsing it or adopting all the conclusions, but it is there in the appendix for reference purposes, and leave it at that, so that it's clear that the working group, this is their work product, not ours. We have it there for a reason but are not necessarily endorsing all of its conclusions.

Do you think that would solve it?

(No response.)

MS. BERRY: Any other comments?

(No response.)

MS. BERRY: Is there a consensus on including the report in the appendix to our coverage and reimbursement report with the appropriate disclaimers or caveats?

PARTICIPANTS: Yes.

MS. BERRY: Okay, we've gotten that. Now we can move to the specific recommendations. I'm afraid of this next one, Recommendation 8, because of our discussion earlier about what the Secretary can and can't do, and particularly when it comes to the private sector, we may run into similar problems. I wanted to just flag that with you, and maybe many of you have already thought of that.

But Recommendation 8 really focuses on reimbursement and CPT codes and instructs the AMA to get input from various providers and assess the adequacy of existing codes and, based on what they've identified in terms of inadequacies, address those inadequacies as the AMA deems appropriate. So I throw it open for discussion with the intro that we may have some trouble with this one along the same lines that we discussed earlier.

DR. McCABE: Well, I would just restate my position. I think we can include much of what is here if we focus on the furthermore and use some of the stuff from paragraph one to support the furthermore and make that government programs should reimburse for service codes when documentation supports their reimbursement, use the material in the first paragraph to argue that that's not being done. But I would take out the issues about health insurance plans and AMA and those sorts of things.

MS. BERRY: Hunt?

DR. WILLARD: I tend to agree. I think I would also carefully edit it with respect to the "should" clauses, because it's prejudging a finding which we may not be there yet, and the Secretary certainly may not be there yet. In other words, it starts off saying counseling services should be reimbursed at rates commensurate with the amount of time spent. As I said just before the break, I'd probably modify that to say the amount of time determined to be medically necessary, not the time spent, because that's an open question still. I think there were a couple of issues like that that would need to be carefully edited so we don't look like we're stating a case that we can't necessarily state.

MS. BERRY: Does that capture it, taking out "time spent"?

DR. WILLARD: I'd say "determined to be medically necessary." It's getting to the evidence base again. It's self-serving otherwise.

MS. BERRY: Now, what about the AMA part of it? Ed suggests that we take that out for many of the reasons that we went over already.

DR. FITZGERALD: Could I just ask a more systematic question here? I understand you're following the order of the text and the order of your recommendations, but following up on the point Hunt is making, it would seem to me that if we want to do this in some kind of logical way, number 10 is the one that is getting at the research that needs to be done, the analysis that needs to be done to see exactly what the benefit is going to be, by whom, what the structure might be, that sort of thing.

So I don't know. Is it possible to reorder these recommendations and to say, look, this research needs to be done to answer these questions that have been raised. Consequent to the research, and of course following upon the data, then you go back and take the next step, what do we do next, and that kind of thing, so that we follow a more logical progression in the sense of what one would want to do next. I know it doesn't follow the text, but it might be better for the order of the recommendations.

MS. BERRY: I think it's a good suggestion. It does make a certain amount of sense. Now, some of the options you'll see here under number 10, just jumping ahead for a quick moment, we may end up deciding to delete some of these bullets under number 10, and one of the reasons would be that when we're looking at this analysis bullet, has the working group report already achieved that goal, in which case we don't need another analysis, or is there some other body, a more formal body, that should undertake such an analysis.

So why don't we hold on that? I think it makes perfect sense if we go the route of an analysis and some of the other things that are recommended in this bullet to have that be first. Let's go through, and when we get to number 10, if we decide to delete some of these, then we'll go back to that. But let's hold that because I think it makes sense from a logic standpoint.

Debra?

DR. LEONARD: Over past meetings we've had a number of discussions about genetic counseling, and I remember there being issues about genetic counselors not being recognized as allied health professionals, and therefore they couldn't get a provider identification number in order to do billing, and I don't see that anywhere in here. I don't know how the recommendations of the work group, the three recommendations, relate to the actual things that would have to happen to have genetic counselors be able to submit CPT codes and bill for their services, whether in relationship to a physician or not.

There's something that's lost here that I don't see. Did we decide that that was something that we could influence, or –

MS. GOODWIN: The recommendation regarding the provider identifier numbers was taken out because the UPIN system is being replaced by the national provider system, and it's expected that counselors and other non-physician health professionals that are able to bill any health plan directly for their services will be eligible for a provider number, and that's expected to be implemented sometime in 2006.

DR. LEONARD: Could we make some statement that they definitely should be?

MS. GOODWIN: Dr. Rollins, my understanding in communications with your colleagues at CMS is that counselors and what I just said was going to be implemented. So counselors, for instance, because they are able to bill private health plans directly for their services would be eligible.

DR. ROLLINS: Correct. What you're saying is correct.

MS. GOODWIN: You still think there needs to be some sort of statement made that they ought to be?

MS. BERRY: Ed?

DR. McCABE: I guess I would feel that in the absence of policy at this moment in time, that we should state that fact and not trust that the winds will blow properly between now and 2006. Do you have the old recommendation, Suzanne, or is it gone forever?

Can I ask a question? I don't deal a lot with a lot of Medicare in pediatrics, but there's a way that health professionals, non-physician health professionals can bill incident to. Does that system work in Medicare as well?

DR. ROLLINS: I don't have the answer to that question. I don't know.

MS. BERRY: Kelly?

MS. ORMOND: I can tell you my understanding of the incident to is that if you're billing incident to the physician, the physician has to bill only for the time that they spend with the patient. So if a genetic counselor spends, say, 45 minutes and the physician spends 5 minutes, you're billing for the 5 minutes that the physician spent, and if the physician does not spend any time face to face with the client, then you bill at that very lowest level, which is equivalent to that. So there are significant challenges to using that as your primary payment.

DR. McCABE: My question was more about whether as non-licensed -- all the people I know who do that are licensed health professionals where the licensure was a barrier to that.

MS. ORMOND: I don't believe so.

DR. LEWIS: I can tell you that advance practice nurses do not have to bill incident to in Medicare, at least in some specialties. I believe family nurse practitioners and pediatric nurse practitioners do not have to bill incident to.

MS. BERRY: Hunt?

DR. WILLARD: I'm keeping an eye on the clock here. I would suggest we delete the sentence that says specifically E&M codes, et cetera. To me that's detail and gets to the issue of before and after contact, and I can't think of any medical specialty, and I'm sure there's an exception but I can't think of them, where physicians are reimbursed for the time when the collective office staff is chasing down x-rays from five states away and all those kinds of before and after testing. So I think with absent details and specific examples of what the value added is, which I don't think would be appropriate within a recommendation, I think we're better off leaving it out.

MS. BERRY: How about the sentence before that, again essentially directing the AMA to make this assessment?

DR. WILLARD: That goes to the point Ed was making, and there ought to be a different way to phrase that because we can't tell the AMA what to do, and the Secretary can't tell the AMA what to do.

DR. McCABE: I would argue that then you could say HHS, with input from, should determine the adequacy.

MS. BERRY: So HHS, with input from the American Medical Association?

DR. McCABE: No, no. I'd get rid of the AMA.

(Laughter.)

DR. McCABE: That was not intended as a general statement but in this sentence I would get rid of the AMA.

(Laughter.)

DR. McCABE: I'm going to be drummed out of the AMA.

(Laughter.)

MS. BERRY: Now, is this something HHS as an agency is able to do?

DR. McCABE: Yes. Then I would address the last sentence, some way HHS could do research to determine whether this was adequate.

MS. BERRY: As deemed appropriate, by AMA, delete all of that.

Debra?

DR. LEONARD: Just like we're having an evaluation or recommending an evaluation of the laboratory CPT codes that exist, would it be useful to recommend an evaluation of the adequacy of the genetic counseling services codes that exist by CMS? Because I see that as a major issue that I'm not sure is specifically addressed. So it's not saying that the codes are not adequate. It's just that we're hearing evidence that maybe the codes don't go to a long enough period of time or they can't be utilized in the proper way to cover genetic counselors or other non-physician health professionals.

So could we recommend just like we did, sort of a parallel to the laboratory codes, that there be some evaluation of these codes to make sure that they're adequate for –

MS. BERRY: How would you change the language, then?

DR. WILLARD: It might work better in the next recommendation, where it just says very broadly we should utilize the full range of codes for services provided incident to a physician, and there you could say "or laboratory services."

DR. LEONARD: No, no, I'm not saying to bring the laboratory services into this. I'm saying could we write something that's parallel to. I get lost in all this wording up there in 10. I'm not quite sure exactly what it is we're saying because it's long, and the one that's for the laboratory codes is relatively concise. I was wondering if we could make the adequacy of genetic counseling codes parallel to the laboratory code recommendation.

DR. WINN-DEEN: Isn't the key thing we're trying to address here the fact that there aren't any existing CPT codes for long-duration encounters, so the top you can bill is something like an hour of interaction, and if you spend three hours you can't bill the one hour three times? You just get paid for one hour even if you've spent three hours.

DR. LEONARD: Right.

DR. WINN-DEEN: So we're trying to encourage really the creation of additional codes to allow longer duration encounters to be properly reimbursed. That was my understanding of what we're trying to do with this particular recommendation.

DR. McCABE: But I would argue also that -- I agree with Hunt. In a lot of medicine, not just in genetic counseling, a lot of areas of medicine, I like the terminology "adequacy of" because I think part of the problem is we may not be able to do business as usual. I don't think there's an evidence base that spending three hours is better than spending 30 minutes. So I would like to leave it "adequacy of" because I think the model may have to be evaluated, as well as the E&M codes per se. I would prefer not to come out and say we need reimbursement for three hours because I'm not sure that we know that we need that.

DR. WINN-DEEN: No, I just meant that that was the basic thing that we were -- that the reason this got into the book in the first place was that there was some feedback that these sessions were lasting longer than the longest available code for payment. Let's say we did determine that it was appropriate to spend two hours. Even if you determined it was appropriate, you couldn't bill for it.

MS. BERRY: The second part of the recommendation in terms of "government programs should reimburse prolonged service codes when documentation supports their reimbursement," do we want to regard this like the others Suzanne points out we did earlier, where the first one is the ideal but in the meantime, until new codes, if any, are warranted and developed, that government programs should reimburse prolonged service codes when documentation supports it? Is this sort of a fallback?

DR. WILLARD: We could simply say when documentation supports their need (inaudible).

DR. LEONARD: Is that second part needed in light of the first? Do we know the prolonged service codes that currently exist are not paid for? I don't know that that second little part of Recommendation 10 is needed.

MS. GOODWIN: I think anecdotally we've heard that, that prolonged service codes are not always reimbursed. So this second half of the recommendation would encourage the prolonged service codes to be reimbursed.

DR. WILLARD: The second half just repeats the first sentence in slightly different words.

DR. LEONARD: Right, and it doesn't have the medically necessary part. It's just saying reimburse prolonged service codes when they're submitted, and I don't know that we want to be saying that, because whenever anything is submitted, sometimes it will be paid and sometimes it won't.

MS. BERRY: So is this the prolonged service codes that currently exist? So the second part of it really addresses existing codes, and the first part of the recommendation deals with the possibility of new codes or modifying existing codes to address inadequacies.

Ed?

DR. McCABE: I see the second as being prescriptive to CMS to look at this. The first is let's study it and see what we find. The second says in the meantime, let's pay at the rate if there is the appropriate documentation.

DR. LEONARD: So I guess the question is what is the appropriate documentation, because people must be providing the appropriate documentation now and it's not being paid. Are we going to really change that practice with this recommendation?

DR. McCABE: That would be a question for Dr. Rollins.

DR. ROLLINS: In answer to your question, I think "reasonable and necessary" should probably accompany that last statement, because that's what we would be looking for in terms of reimbursement. But you still have to get past the issue that CMS has certain constraints, and it would be the Secretary who would make that recommendation.

DR. McCABE: So I think those are important helps to us in crafting this, that it needs to be that prolonged service codes, when documentation of reasonableness and necessariness –

(Laughter.)

DR. ROLLINS: Reasonable and necessary.

DR. McCABE: So I think that's helpful, and I think the important point is that again it should be that the Secretary should recommend or should urge I think is a term that we've used before government programs.

DR. LEONARD: Does the Secretary urge or direct? I mean, does the Secretary have the ability to direct anyone to do this, or is it just encouraging?

DR. WINN-DEEN: I would think he could urge Congress but direct CMS.

DR. ROLLINS: Yes, the Secretary can direct CMS once they have been given the authority by the Congress to do that.

DR. McCABE: But I think it's important that we put in there "government programs" and not just CMS, because there are other government programs that might be paying for services as well.

MS. BERRY: Does that do it? Do we need an intro in the second part, another one of these "in the meantime" kind of lead-ins, or is it sufficient standing on its own? I think the intent was we have the analysis but in the meantime the government should do this with regard to government programs. Do we need that or should it just stay as it? Have the lead-in?

DR. WINN-DEEN: Maybe we need them in the opposite order. This now becomes the first sentence of the recommendation. First, reimburse for the things that are there; second, investigate whether there are gaps.

MS. BERRY: Makes sense. Let's do that, flip them.

Any other comments or edits on this recommendation?

DR. LEONARD: If those have to be separated into two separate paragraphs, are those two separate recommendations, or are they one?

MS. BERRY: I think they're all one recommendation dealing with codes. But we do have another, and it's not clear to me why we have 9 separated out from 8.

DR. LEONARD: Isn't the first sentence, now that you have "The Secretary should direct government programs to reimburse," isn't that the same as Recommendation 9, "CMS should allow health providers to utilize the full range of CPT E&M codes"? Is the full range the high-end longer ones, or is there something else that I'm missing here?

MS. GOODWIN: CMS has informed us that when genetic counseling services are provided by auxiliary personnel, the physicians are only permitted to use the CPT code 99211. They're not permitted to use the full range of E&M codes that are available to physicians and other allied health care providers. We had that guidance a few years ago and in the past few weeks have gone back and asked to make sure that that's still true and have been told that that still remains true, and Dr. Rollins is shaking his head yes. So Recommendation 9 would get at that barrier.

MS. BERRY: Does it make sense, though, for it to be a separate stand-alone recommendation? In order to address Debra's point, should all the coding issues be addressed in one recommendation? I guess it doesn't matter too much, but why is that one separated out when the other two are part of the same recommendation?

MS. GOODWIN: I think it's just the order in which the topics were discussed in the report as it is currently.

DR. McCABE: But it's a different issue. I think it's a way of dealing with the one that was deleted, because it's a definition of who is a health provider to CMS, and it may get fixed in '06, but I would not trust that that would occur. I'm going to get drummed out of the AMA, and now I'm saying I'm not sure I trust the government. But I think it's better to just write what we think we ought to have in here rather than hope for the best. So I would argue that we should say CMS should allow health providers, including those health professionals providing genetic counseling services, to utilize the full range of CPT E&M codes available for genetic counseling services provided incident to a physician.

MS. BERRY: "Providers qualified to offer" or "qualified to provide"?

DR. McCABE: Yes, something like that. I don't remember what I said, but yes, qualified health professionals providing genetic counseling.

DR. FITZGERALD: Why not just allow qualified health providers?

DR. McCABE: But they aren't qualified. That's the problem, we're trying to get them qualified.

DR. FITZGERALD: Oh, I see.

DR. McCABE: I was trying to keep it general as health professionals providing genetic counseling services so we weren't locked into one model versus another model.

DR. WINN-DEEN: Do we need "qualified," too?

DR. McCABE: Well, I put in "qualified" because I think we've heard that there are mechanisms to qualify individuals to provide these services, as opposed to anyone who claims they can provide the services. So that was the reason for introducing that, even though I know it makes it a bit cumbersome.

MS. BERRY: Debra?

DR. LEONARD: I don't mean to jump around a lot, but I'm now reading 11.5, which is non-physician health providers who are permitted to directly bill health plans, should be eligible for an NPI. Is that a Catch-22 in that if they can't bill they don't get an NPI? I mean, the way that's worded, are genetic counselors currently able to directly bill health plans?

MS. GOODWIN: Some private health plans recognize genetic counselors and other allied health professionals as being able to directly bill. So as long as one health plan or health program in the country allows them to directly bill, then they should be eligible for an NPI, and that plan does not have to be Medicare.

DR. TELFAIR: I actually have a comment, but first a question. A couple of us are wondering what is an NPI?

PARTICIPANT: National Provider Identifier.

DR. TELFAIR: Okay. Then the second thing is that under the provision in Recommendation 9, there are a lot of circumstances that counseling services are provided which are not necessarily incident to a physician, and I was wondering what about that? Is that part of the recommendation? I was trying to wait until we got to 10 before I brought this issue up because it's a bigger issue than just that, but I can wait until we get to that. We'd have to go back to modify it, but there are a number of issues mostly related to Recommendation 10. There are a good number of incidents where the request for services does not come from a physician.

MS. BERRY: I know where you're going with it, and it's critical. I think we should address it in number 10, and we are probably going to have to come back and modify this one in light of that discussion.

Ed?

DR. McCABE: Perhaps I misunderstood this one, but I read it that they could utilize the full range of CPT codes that provided incident to. In other words, I wasn't sure that we were saying that it had to be incident to, but the same codes that are provided to a physician incident to could also be provided to the non-physician health professional providing genetic counseling. If that was a misinterpretation of this, then the way to deal with it is just to put the period after "genetic counseling services" and not leave it open to misinterpretation.

MS. BERRY: We should get clarification, because I read it the way Joseph was talking about it, which is that if the services are provided incident to a physician visit or a physician service, what was the intent behind it?

DR. McCABE: But those are already available incident to. So I think the big problem is, as we heard, if you bill incident to, then you're billing only for the time the physician was in the room providing the services. So that's what I thought, and we can already do that, so there's no need to remedy that. I thought what we were doing was opening to the non-physician the same range of services currently available incident to.

If we put the period after "services," then we don't risk this misinterpretation, and I think if we leave it open to what I perceive as a misinterpretation, there's no need for that remedy since it already exists. But I just think it's not equitable.

MS. BERRY: Suzanne has edited it a bit, but I think it still reads in the way that Joseph and I were reading it and not the way you interpreted it, Ed. Look it over again and make sure.

DR. LEONARD: Shouldn't the "incident to a physician" be related to the CPT E&M codes as currently used? That's what I think Ed is saying. It's the CPT E&M codes that are used to bill services incident to a physician now should be available for all health professionals providing genetic counseling services to use.

DR. McCABE: What I would do is I would take "incident to" out of this completely and what Suzanne added. That's the way I interpreted it, and I think getting "incident to" out of there is better.

MS. BERRY: Now, how is this different from the other recommendations, then?

DR. McCABE: I think there are two issues. I think this really has to do with the qualification issues, whereas the other has to do with the adequacy of existing codes. So I see it as two different issues. We could determine that the codes are inadequate. We could fix the codes and we would still have the problem of incident to. So that's why I think one has to do with are these acceptable folks to be providing the services. That's I think what we remedy in number 10. I think in number 9 we investigate whether the codes are adequate. I think they're two completely different things.

DR. TUCKSON: So just to be sure, what we wind up doing is looking at your last point with number 10. You have to establish the criteria that allows you to be an independent biller. Then you can talk about independent billing.

DR. LEONARD: So do these need to be reversed in the report?

MS. BERRY: We're going to reverse them because I think the old number 10, as Kevin was suggesting, really belongs up at the top.

DR. LEONARD: Unless you have that, you're talking about qualified people but you haven't defined them as qualified.

DR. McCABE: Yes. We need new members to point out that we need logic in the work that we do here.

(Laughter.)

MS. GOODWIN: And is that wording along the lines of the clarification you were looking for?

MS. BERRY: Number 9 there.

DR. McCABE: I like it better before the most recent edit. I don't think there's a problem for a physician billing for genetics. I think the whole issue is can the nurses and the genetic counselors bill independently for genetic counseling services.

MS. BERRY: But it's not the physician at issue here. Can't an allied health professional, if they can't bill directly, they bill incident to a physician service, and it doesn't have to be that the physician is actually performing the work, that they are as well. So I think it's addressing the health professional, not the physician. It's just focused on –

DR. McCABE: Probably the "both" takes care of it, then.

MS. BERRY: Do you think?

DR. McCABE: As long as it doesn't revert so that we've now allowed them -- if they can bill for the full scope of their services and not just for the time that the physician is in the room, that's what I think was discussed with the panel and that's what I want to be sure is reflected here.

DR. LEONARD: My concern is can health professionals at the beginning of that sentence be interpreted as physicians, or are those non-physician health professionals? Those are the people you're talking about.

MS. BERRY: So should we say allied health professionals?

DR. LEONARD: Well, you get into problems of definition. I would say non-physician health professionals because genetic counselors currently are not defined as allied health professionals. So you don't want to use words that are going to exclude them from the cure we're trying to create.

MS. BERRY: So non-physician health professionals?

DR. McCABE: Yes.

MS. GOODWIN: Is that language correct? Because CMS distinguishes between -- well, there are physicians, but there are also non-physician providers who are allowed to bill directly, and then there's also auxiliary personnel who only may bill incident to a physician. So currently if you're allowed to bill directly, you can utilize all the E&M codes. If you're considered an auxiliary personnel, you have to bill incident to, and you're only permitted to use the 99211 E&M code. Does that clarify?

DR. McCABE: So could we include both of those groups?

DR. LEONARD: Well, I think what Suzanne is saying is that auxiliary this would not be able to apply to, right?

MS. GOODWIN: I think the wording here would apply to them. The auxiliary personnel are those that bill incident to the physician. So the recommendation as it's worded would allow providers who are billing incident to a physician to use other E&M codes besides just the 99211 code.

DR. LEONARD: I guess I'm confused as to whether we're fixing -- we're working with a definition of genetic counselors as it currently exists, or as we're hoping to fix it to exist in Recommendation 10, which is now, I guess, 8?

MS. BERRY: It will be 8.

DR. McCABE: Cindy, could we ask Dr. Rollins?

DR. ROLLINS: Non-physicians, as was said earlier, I think is probably more appropriate, as opposed to auxiliary.

MS. BERRY: Non-physician health professionals?

DR. ROLLINS: Yes, non-physician health professionals.

DR. TUCKSON: So let's be clear. I think what we're struggling around, again, is this idea of making a recommendation that fixes the problem versus making an interim recommendation while we are waiting for this moment. I think if we can just go ahead and be clear, I think that this will intellectually decide that we can say that we know we're going to move 10 up. Let's deal with the issue of this is the way it ought to be. We hope it to be this way. Then say in the interim while that is happening, there is this intermediate transitional step which we recommend being the following, and then be just done with it.

DR. LEONARD: Suzanne, why did you take out "who bill independently" rather than leaving the "incident to a physician"? Because if they bill incident to a physician, they now can currently use the full range, no? Am I missing something here?

MS. HARRISON: I guess going to the discussion of how we're going to frame this toward where we're going or where we are, I just really want to see the incident to go away. I think the problem here is that the genetic counselor is stuck with having to bill under a physician, and the goal would be that they would not have to, the genetic nurse would not have to. Unless we can put something in here to say in the interim or say more immediately or something so that it's understood that this is not our end goal but is something that is okay in the meantime, then fine. But I just want that reflected somewhere.

MS. BERRY: What if we added "and who currently bill incident to a physician" as a way to recognize that we're talking about what people have to do right now but not making a statement as to whether we think how it should be in perpetuity? Take what out?

MS. ZELLMER: (Inaudible.)

MS. BERRY: Because I think only those who bill incident to are the ones having the problem. They're not able to use the full range of CPT E&M codes. So they're the ones facing the most immediate problem right now.

DR. WILLARD: Then the word "currently" works okay without prejudging what we think the ultimate solution should be. So I understand why you, Barbara, and your colleagues want to be able to bill by yourselves, but I don't think this committee necessarily comes down on the side of that because we don't have the information and we don't have a dog in that fight, as they say. Right?

MS. HARRISON: But if we're making the argument -- well, I guess we have to get to 8. If we want to make the argument that there are other people that are qualified to do this work, then those people need to be able to bill for their services.

DR. WILLARD: Either directly or incident to. A priori, it shouldn't matter. It matters to you guys for professional reasons, but it doesn't matter to this committee, at least not this person on this committee.

DR. McCABE: I just think if you leave the incident to in there, you've got to in the body make it clear what the intent of this is, that it's really, the way I read it, to open up the possibility of billing for the full scope of services provided whether a physician is in the room or not.

MS. HARRISON: And I just want to also throw out there that there can be times when, with genetic risk assessment, that kind of thing, where it may be appropriate that there's not a physician involved.

MS. BERRY: Barbara, does this, keeping in mind the concerns that you raised, does this recommendation as it's worded work for you, with maybe some appropriate clarifying language in the text?

Barbara, and then Joseph's got some concerns as well.

MS. HARRISON: Let me read it more carefully.

MS. BERRY: Okay.

Joseph?

DR. TELFAIR: If the point is to make a distinction between those who are in situations where they bill incident to a physician and those who are in situations where physicians are not involved, then this doesn't do it. You need an "or" in there to separate out. Where you have "and," it should be "or," not "and," because "and" is inclusive. "And" means that they are qualified and they are currently billing.

MS. BERRY: Right.

DR. TELFAIR: So I'm saying that it doesn't make a distinction that there are two separate –

MS. BERRY: No, it's not. In this recommendation, it's focused on one group, and these people are qualified but they're also forced to bill incident to.

DR. TELFAIR: So this one is only dealing with that single group, not both.

MS. BERRY: Yes, it's one group.

DR. TELFAIR: Okay. I'm sorry. Never mind.

DR. TUCKSON: So let's just try something a little daring here. I'm watching the clock here. We've got a half hour. Let's just go to number 10 and let's just state what we want the ideal to be right now. Let's get that locked and then come back in and say okay, in the interim, this now defines the reality. I think we keep going back and forth between the ideal and the real. We've

got it 90 percent of the way, so let's pause there and say where we think this thing ought to go and then come back and say in the interim, and then we lock this one in. How about that?

MS. BERRY: So this will be moved up. So this will be the first recommendation under the genetic counseling section of the report, number 10, which is going to be number 8.

MS. HARRISON: Just real quick, is this going to change the order in the report?

MS. BERRY: In the text of the report.

MS. HARRISON: I mean, this 10th recommendation was on page 52. The other was on page 49, and we actually changed it now.

MS. GOODWIN: We can combine all three recommendations so that it falls at the end of this section. So the order of the text will remain the same.

MS. HARRISON: Okay.

MS. BERRY: I think one question to throw out there to help guide us is the first part of the recommendation focuses on an analysis of who is qualified to provide genetic counseling, under what conditions, under what supervision. Do we feel that that is a worthwhile effort? Has it been rendered moot because of the work group's efforts, or are there still gaps that justify this type of recommendation?

Hunt, and then Joseph.

DR. WILLARD: I think we spent an hour saying that we didn't have the data that we needed, despite the fine work of the work group. So I think this is very much still needed.

MS. BERRY: Okay. Joseph?

DR. TELFAIR: I would concur, because one of the things that the work group, in its fine work, did was actually present only one part of the story. The other part of the story has to do with what I keep bringing up, which is that there are a number of people who provide genetic counseling services who do not go to these formalized programs, and they are not even reimbursed directly. Some are reimbursed through HRSA grants, some are reimbursed through the state side of Medicaid, some are reimbursed through private insurance and care, and they're usually attached to a single condition of one type or another. I cite as examples cystic fibrosis, hemophilia, hemoglobinopathies, and metabolic disorders.

There are Master's trained persons involved, but nine times out of ten, particularly in rural areas, there are usually those who are trained specifically to provide counseling and education for those particular conditions, and are reimbursed maybe not directly but indirectly through other means. I think we as a committee need to take into account that that is a big reality when we're trying to make recommendations related to reimbursement.

MS. BERRY: What about the point that came up during the review of the working group report and efforts that the data really just doesn't exist, and they've been through a literature review, and they've conducted a pretty thorough -- but what is the analysis going to look at if it's not already out there?

DR. WILLARD: The analysis is research. It's the research and subsequent analysis is what's needed. There's not an analysis of prior research.

MS. BERRY: Okay. So then we should clarify the language.

DR. WILLARD: To me, the analysis is sort of all encompassing. But if it isn't obvious to you, and therefore may not be to the Secretary –

MS. BERRY: So you would say "further research and analysis."

DR. FITZGERALD: Would it be appropriate, with the working group's concurrence, to use some of their language? Their third recommendation was to support the funding of further studies to assess the value and effectiveness of genetic counseling services provided specifically by non-physicians, which would include your single-disease counselors. So that's one of their recommendations. We could use that recommendation, if that's okay, and then if you want piggyback onto that the intent to recognize non-physician providers with expertise in genetics. The idea is we're going to do this analysis and see are there indeed non-physician providers with expertise in genetics that should be reimbursed.

DR. TELFAIR: And I would agree with Kevin that you have a real (inaudible) set of recommendations.

MS. BERRY: Do we want to recommend a specific body to conduct this research and analysis?

DR. McCABE: I would argue we shouldn't recommend to the Secretary who within HHS, which group within HHS do this. It may involve different agencies, but I really think that's the Secretary's decision.

MS. BERRY: Reed?

DR. TUCKSON: I think, again, this section, as I understand what we were saying, is that we are recognizing the idea that there is a genetic counseling activity that needs to be defined but that can be independently engaged and billed for outside of anybody else's supervision. So it's different than the people that Joe is talking about in the sense of the single condition stuff that's done with a doc. We're talking about an independent function.

At least a point that I would like to argue is that we recognize that there is such a need and that there are certain people who theoretically, for lack of a better word right now, can do that function. I think the first recommendation from the work group is actually pretty good in the sense that it's saying that we do need to recognize that there are non-physician providers with expertise and who should be credentialed by a national genetics organization.

I think the way to handle who should do that, then, as an example is we had the report earlier today from the Office of Information Technology. One of the ways in which they are working to create the interoperability standards for the electronic medical record is to create the Certification Commission for Health Information Technology. The government caused it to occur, but it's a private/public sector joint venture that is creating the certification standards. On this group sits the Office of Health Information Technology, CMS, but also the private software vendors, et cetera.

So what I'm getting at is there are models by which government can cause the stimulation of a multidisciplinary group charged to create the standards that are ongoing. So I would give you all something to shoot at and disagree with, but we would call for the government to stimulate the development of a credentialing group that allows this credentialing to occur to include at this point in time the AC -- those three, and to be augmented as necessary.

So you get at this idea of saying there is this group, the charge to this group ought to be pretty specific. It ought to be to create the criteria and to continuously update those criteria based upon Recommendation 3, which is where Hunt started out as well, and that is that there needs to be ongoing studies. But I guess where I'm differing a little bit from my colleagues is if you decide that you can't start unless you have everything in order, you'll never get anywhere. So you've got to have something that gets you started.

Based on that, then we can start to move to those who have to practice with somebody, and then we can get to the interim with the other thing. Anyway, that's just something to shoot at.

I didn't give you language, did I?

MS. BERRY: No, you didn't. You were totally unhelpful.

(Laughter.)

MS. BERRY: I'm kidding.

How about, as a suggestion here, because you touched on the licensure issue which we haven't yet gotten to, you'll see in the recommendations in the bullets we've got further on down under this Medicare demonstration idea, I don't know if we want to propose a demonstration project or not, take that off the table for a second. Looking at the alternative that's presented here in the bullet, it talks about studies that assess barriers to billing and reimbursement and whatnot.

What if we combine all of that in with the first analysis? So we have here where we're talking about research and analysis to determine which health providers, blah blah blah, add to that this business about barriers to billing and reimbursement so it's all part of one study or one analysis, and then the second recommendation would deal with the licensure component which you identified. Are those two reasonable ways to attack this? Does that get at everything?

DR. McCABE: Cindy, I think what it doesn't deal with is the CMS demonstration project, which I think if we're going to work through CMS and Medicare, we're ultimately going to need that. So as long as we leave in there somewhere the CMS demonstration project piece.

MS. BERRY: So merge the two sections that deal with further research and analysis, then add the demonstration suggestion, and then the third piece would be licensure, which actually I think we need to talk about a little bit more because I did note in the report that there was some discussion about what licensure can and can't do. I don't know that there was the case made that that is absolutely critical and that there's been any documented harm to consumers when there's been a lack of licensure. So I'm not sure if we necessarily want to recommend that or whether we want to wait until the analysis is done.

DR. McCABE: A bigger problem has to do with just the structure of how we operate. There won't be national licensure. That's a states rights issue, so it's not going to happen. I don't think

that's one that we should even go after, and there are already certifying bodies, so I'm not sure that we need another certifying body.

I think we need a group that just brings together the various segments of the non-physician health professional community providing genetic counseling to be even more inclusive than the panel we had to address some of Joseph's issues, to really look at how one could go about maintaining quality in terms of certification, but making sure that we're certifying all of those individuals who ought to be certified.

DR. TUCKSON: I think that's a more precise way of what I was trying to get at. I mean, at the end of the day, I think people have convinced me, maybe not Hunt yet, but they've convinced me that it makes sense that even though we don't have all of the evidence and every piece of data in yet, that the idea that a certified counselor may well in fact add some value, enough so that I'm prepared that if there were a real body that could certify that there are real disciplines here, real rigor, and that these folks are not fly by night but they actually have some training and some competence and can demonstrate at least a starter set of competencies, I'm prepared to think that then maybe those people ought to be given an opportunity to do their thing and be compensated.

I'm prepared to accept that that needs to be studied rigorously and continuously updated, and I'm prepared then to do that under the conditions that there is an organization that has some legitimacy that is actually controlling this. So you've got the CCH and the AMG, et cetera, that they can be pulled together under some umbrella that has some rigor and some discipline so that fly-by-night certifying Agency A doesn't just jump up there and say, okay, all my people are now certified, but that there's some rigor to it, some controls.

MS. BERRY: Agnes?

MS. MASNY: But I would just kind of reiterate what Judy Lewis had mentioned earlier about that. If we limit it just to a specific genetic organization that would set the criteria or provide the credentialing, then you're going to overlook the various groups that already provide credentialing for specialty organizations. From my own perspective in oncology, the oncology certification, the oncology training provides a background in genetics, and nurses are credentialed as advance practice nurses, and many of those advance practice nurses that weren't reflected here are actually providing cancer genetic risk counseling.

So when you looked at the number of nurses who were credentialed, there were only 30. But through organizations, through ONS, there's over 150 nurses who are providing cancer genetic risk counseling. So the appropriate credentialing body would be the Oncology Nursing Society. For a variety of other health care providers, the situation may be similar.

DR. TUCKSON: Maybe they could appeal to the group and let the group work it. I don't think we could ever work that level of detail out.

DR. WILLARD: I just don't see why we're even getting into this. To me it's prescriptive, potentially. I mean, let's do the analysis. We can't predict where it's going to go after that or say what if. We're going to need certification, we're going to need licensure, we won't, we will. To me it's getting way beyond where we can go with a recommendation to the Secretary.

MS. BERRY: Suzanne?

DR. FEETHAM: As part of this discussion, I think we also need to look at this saying which health providers are appropriate. Again, I think you're back to identifying descriptive studies which identify the qualities and characteristics of the providers, but I think you're opening on this whole theme of discussion a huge can of worms about scope of practice, licensure, everything else. I think you're making a better contribution if you say "to identify the qualities and characteristics of the providers," not saying you'll identify which are those providers. I just think that's part of this discussion, a track you may not want to go down.

MS. BERRY: Yes, Emily?

DR. WINN-DEEN: I agree. I don't think we should get into the whole issue of licensure in particular, but I would like to throw out to the colleagues who presented on genetic counseling to us that they maybe think about a mechanism to "certify" individuals, particularly individuals who are providing specific disease characteristic kind of counseling and who are not going to go through a full-blown Master's in genetic counseling program, but who could be certified as an officially deemed counselor for CF or sickle cell or something like that, so that those people did have some training and uniformity in the way they're providing services to the community.

MS. BERRY: We are running out of time. Do we have a consensus that we should eliminate the licensure recommendation and stick to the first two, which are the analysis and the demonstration project for this recommendation?

DR. TUCKSON: I may be the only one -- and, by the way, certification was my thing, not the licensure. If I am the lone person for having the certification group set up and then study simultaneous, if I'm the only one, then we should run me over.

DR. LEONARD: You're not the only one, definitely not.

DR. TUCKSON: Then stick to the study first, and then let the study direct what happens after that, which is I think another point of view.

MS. BERRY: Debra?

DR. LEONARD: I've been sitting here listening, and I'm really kind of upset, but I'm not quite sure how to voice what's really bothering me. I think part of it is that I have many colleagues who are genetic counselors who are professionals, and I highly value their education, their certification, and they have a certification process, and that's been described to us by the working group. GNCC and ABGC have a certification process. They've described the criteria for that, which seems relatively thorough in the training that these people have to have.

Now, you can argue that analysis is needed for the value added, the outcomes, results that genetic counselors get, but these people are professionals, and I feel that we are sitting here and discussing their professional stature, and it's insulting to them and to me, who works with these colleagues. So I agree with Reed that we should set up some process to acknowledge these people as professionals, some way of saying this is a group of people who are qualified to provide genetic counseling services, and then that body can deal with the people who only counsel for CF and Ob/Gyn offices or other ancillary groups that aren't doing a full-blown Master's.

But you have people who are highly professional, and we're talking about having to do an analysis that's probably going to take two or three more years before there's any result coming out, and they're already certified. So I would agree with Reed that there should be a certification

process. Licensure, I also agree with Ed that licensure is not something -- that's a state by state basis that I don't think we can influence much. It's a whole legislative process. But the certification, so that then if these people are recognized as certified by this body, then they would have the right to bill either incident to -- I mean, then you could work on the other things that maybe need to be analyzed under this analysis section.

I am just finding the whole conversation insulting.

MS. BERRY: All the folks who were involved in putting this thing together, the intent was not to insult anyone but it was actually to face the very real situation, which is to get reimbursement from government programs or from private programs. It's not that we're questioning their qualifications and their value. It's the fact that these plans and Medicare and others do require a certain amount of proof. They don't just let anybody come in and bill for anything.

DR. LEONARD: But ABGC and GNCC are not providing that kind of proof? I think they are in their certification process. It's fairly stringent, with an exam.

MS. BERRY: I think they should be, but I think there are some programs and plans out there that apparently aren't recognizing that. Otherwise we wouldn't be faced with this problem that there are some difficulties in billing and reimbursement. I mean, that's the sense that I have, that there are some real barriers out there that shouldn't exist for these professionals who are providing these services. So whatever it takes to convince the payers, that's what these recommendations are focused on, not to insult anybody but to help them make the case so that we clear away these barriers.

DR. FITZGERALD: I was just wondering, at least in some discussions, particularly with Andrew, I'm not sure that the assessment and valuation period is going to be that long nor that difficult for the very reasons that you point out. I think there's a good bit of evidence that's out there. I don't think it has been pulled together and structured well so that it can be analyzed in a way that gives people the sense of the kind of outcome measurements that they want to have. So in that sense, I agree that whatever works is what we're trying to get at, and if it's a structure that says pull the certifying groups together under some coordinating entity, that's fine.

Let's get moving on the analysis and evaluation so that the professionalism of these people and these groups can be demonstrated to the criteria that's been used by the reimbursement agencies. Obviously, there's a gap, and I think the effort is to close that gap as soon as possible just because we know of the professionalism of these people and we've got to do whatever we can to help close that gap.

DR. TUCKSON: I think in some ways we're starting to get closer here. Maybe it is that we signal what we are attempting to do. We're saying this ought to occur. We're saying that there is a place to start so that you've got this foundation. Then we're saying that we have some critical questions that need to be answered very quickly. Then I've heard Hunt and a couple of others saying that we really want to know the answers to a couple of things here, building on the foundation that exists now. So maybe there's a hybrid in there somewhere that lets this thing move.

DR. COOKSEY: Could I just add a couple of points of clarification from about 10 years of doing workforce-related research, because there's some confusion of issues that's making this more difficult than it needs to be, I think.

Licensure is something that every identified health professional group would like to achieve. Licensure is a very political process at the state level. I have a sense that there is probably uniform sense from the committee, but you could get clarification on the issue, that genetic counselors are clearly a defined health profession, a new health profession, a health profession that has come about because of the growth and expansion of genetic services, and as advisors on that I think you could send very strong signals. I don't quite know how you'd have to do it, but if you recognize that genetic counselors are a new profession, they're not recognized with licensure, but that would strengthen the genetics workforce.

How you do that in your very tight constraint about what you can recommend to the Secretary or not, I think there's a way to do that. Licensure is political. It's somewhat costly to states. You've heard the reasons. A profession wanting to get licensure does not have to show to anybody generally that they're cost effective or anything. It's contained in general within the profession to define who is eligible to be named as a licensed genetic counselor and whatever.

I would strongly say that it would be against conventional certification or whatever to try to establish a superstructure. Certifying boards tend to be very profession specific, and you have a well established certifying board with the American Board of Genetic Counselors, and well defined credentials, training programs and whatever. That's not broken in any way. So they would easily, when they have political support or whatever within the state, become licensed. They're tiny. That's part of the problem right now, and they're a new profession that people don't very well understand, and it has to be done carefully so that, as was mentioned, you don't exclude others from the legislation.

But I think the genetic counselors can deal with that. I think what they're asking from this group is recognition. It's different than reimbursement. Reimbursement is a whole different set of rules.

DR. TUCKSON: The GNCC and so forth are not in the American Board of Genetic Counselors, are they?

DR. COOKSEY: I'm not in the American Board.

DR. TUCKSON: Does the American Board solve the problem of letting the GNCC in, as an example?

DR. COOKSEY: No, but that's a different issue that the nursing profession has to work on. But the profession of genetic counseling, getting licensure, is ready to go if this group feels that licensure is appropriate from all the evidence that you've heard and years of presentations by genetic counselors and years of cumulative experience of working with genetic counselors. I have a feeling that there's consensus that the time has come to recognize them as a profession. How you do that can be worked out, but getting a sense of the board would be useful. That's very different than reimbursing issues and proving you're cost effective to payers and whatever. Very, very different issues, but related. But you can take a step at a time.

MS. BERRY: What about this last iteration here? We wouldn't be recommending licensure. It's not really within our purview, but recognizing that there may be states that do not have licensure, that public programs and private health plans should recognize certification by someone, and I don't know if these two are the ones we want to name or do we name anyone as equivalent to licensure.

DR. COOKSEY: You're trying to merge reimbursement issues with licensure issues. I think what we were asked to sort of present evidence -- genetic counselors are a relatively new profession. They're very small, they're growing, they're extremely important to the delivery of genetic services in the country for the current and near term, and I think a statement that would be fashioned in such a way that would say the committee recommends recognition of the profession of genetic counselors, one of the few highly trained professionals that is not licensed –

MS. BERRY: The reason we're linking it is because it's a coverage and reimbursement report, and the lack of licensure or some refusal by some plans or programs to recognize certification has been identified as a barrier to coverage and reimbursement.

DR. COOKSEY: Yes, that is correct.

MS. BERRY: So that's why it's in here. If we need to delete it entirely, we could do that too.

DR. COOKSEY: It could be a two-step thing. But I guess what I haven't heard you say, and it was brought up by Debra a little bit, is what is the sense of the group around licensure for this highly trained, highly professional, needed new profession?

DR. TUCKSON: As the moderator, or whatever I am, let me stop for a minute and do a process check here. We have a challenge.

First of all, thank you. Appreciate that. Cindy's got to go. We're past the 5:30 mark. People are tired as well. You guys have worked really hard today.

Now, our challenge is that we've got a heck of a schedule tomorrow, and we've got to bring some recommendations to closure. What's the snow look like out there?

PARTICIPANT: It's snowing and it's going to freeze soon.

DR. TUCKSON: I was more worried about tomorrow morning. First of all, do we think we'll be here tomorrow?

PARTICIPANT: It's supposed to stop snowing around 1:00 a.m. or something.

DR. McCABE: We'll be here. The question is whether we leave.

(Laughter.)

DR. TUCKSON: Well, I think what I'd like to do is this. I think we'd like to start at 8 o'clock tomorrow. The question is can Cindy Berry be here tomorrow?

Are you going to be around tomorrow?

MS. BERRY: Yes.

DR. TUCKSON: Good.

The second thing is I think what we need is to have a few people try to sit today with Cindy and with Suzanne -- the Federal Register says that we can't start until 8:30 because we did it at 8:30. So let me ask this of the rules. Can we have a work group meeting to work on things, and then at

8:30 talk about what we've created? Can we meet as a committee of the whole, as a work group, and then rehearse everything we did at 8:30? We can't do that either.

MS. GOODWIN: As long as there's no decisions made during the work group discussions. If there are any recommendations, that they're discussed in public.

MS. CARR: But I don't think you can start at 8:30. I think we'll have to do it later in the day because we really have to get going on the -- don't we? Or do we have time for this in the morning? No. We have to start with large pops.

DR. TUCKSON: All right. So we have to re-look at the schedule, and we'll do that then. We're allowed to continue tonight?

MS. CARR: Yes, you can have it tonight if you want.

MS. GOODWIN: Continue the discussion right now?

MS. CARR: Oh, yes. You can continue.

MS. GOODWIN: You're just not allowed to start earlier, but you can continue later.

DR. TUCKSON: I don't think that this committee should be subjected to the tyranny of having to keep working on this right now. I think people are tired and their nerves are frayed. I think what I'd like to do is to have a small group of people try to frame the issues very carefully for tomorrow. Hunt, if you won't kill me on this, I'd like you to sit with Cindy and with Suzanne, and I would like Ed to sit for a few minutes and try to lay out the issues in terms of what are the debate points here, and at least lay out in stark contrast what we see as being the sequence, starting with the way we want the world to be and whether or not you actually have certification criteria for independent billing, what would it take to be able to make that happen.

I can't do this twice. You've got to write this down. This is it, man. The assignment is to just lay out in clear terms what the debates are, starting with if you could create certification, what would it take, what are the critical questions that have to be answered to satisfy people. Secondly is what can the Secretary recommend about that that's relevant. Third is what do you do about the folks who are not independent but incident to, and then finally what do you do in the interim. Try to lay it out in terms of what are the debate points and clarify them as precisely as possible, give us the language to choose from, and let's try to get something.

Cindy's got to go. That's what the whole problem was.

So can you all do that at 8 o'clock, from 8:00 to 8:30? You won't be here. Okay. So, Amanda, you'll be here tonight? So let's try to get that done this evening, sometime either before dinner or right after dinner. So we'll do that. Thank you.

Do you want to do it tonight or at 8 o'clock? Ed McCabe, Hunt, and Cindy. Well, Cindy won't be here. She will be. Cindy will be here in the morning. Okay, and Cindy. Who else wants to volunteer? Barbara. Can we do it at 7:30?

DR. WILLARD: In the morning?

DR. TUCKSON: In the morning. Is that okay? They keep telling me who is going to be here and who is not, so I'm getting crazy. 7:30 in the morning we'll meet right here and we'll just have it laid out. Joe wants to join that. We've got the whole committee coming. That's good.

No, I'm just kidding. So Joe is going to do it. 7:30 they'll do that. Now, then we will find some time in the day, some kind of way to work on this. We'll figure that out. What time is dinner?

MS. CARR: Six.

DR. TUCKSON: Six. Where? In the room.

You all have worked very hard.

DR. McCABE: Can I just ask, because there was another subcommittee put together that I was going to have meet briefly tomorrow morning, but you've just coopted half of us.

Debra, Hunt, Kevin and me, could we meet for 10 minutes right now, please, to talk about definitions?

DR. TUCKSON: Definitions, okay.

Dinner is right where we had lunch.

Thank you all very much. Good day's work.

(Whereupon, at 5:40 p.m., the meeting was recessed, to reconvene at 8:30 a.m. on Tuesday, March 1, 2005.)