

Full Committee Discussion of Draft Report
Facilitator: Cynthia Berry, J.D.

MS. BERRY: Any comments? Debra?

DR. LEONARD: Can we just take out the "and" in front of "informational utility"? We had those two things linked, so it is kind of like there's an extra "and" where we're making a list of items. This would be in the now second sentence. "Prevention, rare disease tests, informational utility and therapeutic benefit." We don't need to link informational utility to therapeutic benefit anymore. They're two separate items.

MS. BERRY: Take out the "and." Does anyone else have any comments on this first recommendation? Suggested changes?

Emily?

DR. WINN-DEEN: I just agree with what Debra suggested. I think they were really intended to be two separate things.

MS. BERRY: Agnes?

MS. MASNY: This is just a question. As we are looking in the recommendation to establish particular criteria to guide this decisionmaking for appropriate genetic tests, I wondered what sort of bridging work we could do with the work that Muin had described this morning.

Now, I know that was on the direct-to-consumer marketing, but looking at some of the outcomes of this specific genetic test, and this might be extremely helpful to help in establishing some of these criteria, that there may be some bridging work that could be done between that committee and these criteria.

MS. BERRY: Do you think, Muin, the reference to EGAPP in the recommendation does the trick? Or are you talking, Agnes, about something else?

MS. MASNY: Well, I think here we're describing establishing sort of criteria that would guide analytic validity, clinical validity, and clinical utility. I think when we get into the area of clinical utility, we are starting to address some clinical outcomes. It sounded this morning from Muin's report that these were some of the measures that they were going to be looking at, and that if there was any overlap, that maybe his committee could help guide some of the criteria.

DR. KHOURY: I'm going to give the committee a more detailed update about EGAPP tomorrow. But what I was describing this morning was a very specific set of activities in relation to measuring outcomes in communities of direct-to-consumer campaign, both in terms of people's knowledge, attitudes, and behaviors, as well as health outcomes.

Now, as part of the EGAPP discussions, which I'll present tomorrow, there will be, I mean, the purpose of such a group, one of the purposes is to review what we know and what we don't know, identify the gaps and areas where more data need to be collected. Those two things will probably dovetail into each other in the long run. I don't necessarily see anything you need to change with respect to this paragraph right now.

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I mean, you just have to watch and see. What you're saying, this is an example of the activities. If this committee likes what that group is doing, you can make stronger recommendations in the future.

MS. BERRY: Any other comments on Recommendation 1?

James?

DR. EVANS: Many insurers, both public as well as private, do not take cost or cost effectiveness into consideration when considering a technology. I'm not saying that it should be removed, but it does say should address. For those insurers which do not look at cost before approving a technology, that might cause a problem.

MS. BERRY: Do you think the wording is broad enough that it would enable this group, whatever form it takes, to look at it and then determine well, perhaps that's not an appropriate factor to include in guidelines? Or do you think it's problematic that it's even in there?

DR. EVANS: I think the word "should," you may want to alter it slightly and say "could consider." But "should" sort of implies that something should be done.

MS. BERRY: "Could address"?

DR. WINN-DEEN: I think we have the word "for example" right in front of that list. I think the intention was that you should address this list of things as appropriate, or maybe you want to add some kind of caveat like that. But I think the intention of what we were saying by putting "for example" in, you can see that was something that was added.

MS. BERRY: Or how about, "should consider." Does that soften it a little bit, saying that they should consider these things, and then however they come out on that is their decision?

DR. LEONARD: You could use the words "may include" for example. Rather than "should address," is "may include."

MS. BERRY: "May include"?

DR. WILLARD: I think this is getting to be wordsmithing. "Should address" covers all the other entities or suggestions we just covered. It doesn't say which side of the line you have to come down on. It just says you have to address it. I would urge us to just leave it as is.

DR. TUCKSON: I think we're in violent agreement, here. So with that, on that one, the question, Madam Chairperson, is it time to call a vote on this issue? Or do you want to add a couple of other things and lump them together? Or do you want to go issue by issue?

MS. BERRY: You want to go recommendation by recommendation?

DR. TUCKSON: Yes, I think so. So are there any other things in this recommendation? Nothing else changed.

Let me give everyone a chance quickly to scan the rest of the recommendation. This is the only change. So take a good look at the rest of the recommendation.

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Now, what are these here? Just ignore that.

MS. BERRY: Did you have a comment?

DR. McCABE: I was going to move approval.

DR. TUCKSON: That's what I'm looking for. Which are we approving? "Should address," or "may include"?

MS. BERRY: "May include" is up there now.

DR. TUCKSON: "May include." Done.

DR. FITZGERALD: Leaving it at "should address."

DR. TUCKSON: We're approving "should address." The legislative intent of this is transparent and clear. We all know what we mean by it, so we think we're there. Should address.

All right. We have a motion to approve this recommendation. I'm looking for a second.

PARTICIPANT: Second.

DR. TUCKSON: Good. By a show of hands, again, knowing that unfortunately our new colleagues are not in the position to vote today, but for all those that can vote, please raise your hand yes.

(Show of hands.)

DR. TUCKSON: Those who are no?

(No response.)

DR. TUCKSON: For the record, that's unanimous.

We move onto the next recommendation.

MS. BERRY: Recommendation 2 really addresses the issue of the general desire that people would have that public and private payers would have the same types of coverage and reimbursement policies, and that we would want to make sure that those types of services and tests for the prevention or screening component that are beneficial should be considered.

It recognizes that we're never going to achieve the ideal. So with regard to the private sector, what we could recommend that the Secretary do is to have a supportive role and make sure that private payers have all the necessary information at their disposal so that they can make their own proper coverage determinations about what they're going to cover.

The change that we made is that we did receive some comments about the specific mention of pediatrics. There was another change asking that we include the word "especially" to emphasize the prevention and screening types of services. So we put those changes in in response to the public comments.

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Are there any additional suggestions or comments with regard to this recommendation, Number 2?

(No response.)

MS. BERRY: They're not all going to be this easy, I know.

DR. TUCKSON: We see no change. Motion, please, for acceptance?

PARTICIPANT: So moved.

PARTICIPANT: Second.

DR. TUCKSON: All those in favor?

(Show of hands.)

DR. TUCKSON: Anyone opposed?

(No response.)

DR. TUCKSON: The motion carries unanimously.

Next?

MS. BERRY: The third recommendation has to do with the mixed national local coverage decision making process that we have at CMS. There was a comment which we received which the task force felt was very constructive and worth consideration. So we incorporated it in this version of the recommendation, and wanted to have the full committee look at it and provide feedback on it.

That was if there were a certain number of local carriers who determined that they were going to cover something, and no one suggested a particular number, but if a certain critical mass occurred, then that would or could trigger an automatic trigger for a national coverage review process at CMS.

If a certain number of local carriers said we're going to cover this, then that all of a sudden bumps the issue to CMS to issue a national coverage decision on that item, on that service, on that test. We thought that was an idea worth considering. We certainly did not consider it at the last meeting.

We put it in as a placeholder revision to this recommendation, but wanted the benefit of the full committee's feedback and response.

DR. ROLLINS: Actually, that's something that CMS already does.

MS. BERRY: What is the threshold number?

DR. ROLLINS: I can't give you a specific number. I can't give a specific number. But if there are a number of local decisions, especially if there may be some inconsistencies in those decisions, CMS will look into the possibility of creating a national coverage decision on the topic.

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MS. BERRY: Is it something that they can do, or they might look at? Someone might sort of flag and say hey, here is an issue we should consider? Or is it more of an automatic trigger, which I think this commenter was suggesting an automatic thing. That there really isn't discretion. There would be a certain number, and then boom, CMS has to take a look at it.

DR. ROLLINS: There is no automatic trigger. It is something that is looked at, and then a decision is made.

MS. BERRY: Do you think there is any benefit to an automatic trigger? Or to put it in the reverse, is there a problem with an automatic trigger? Do you think that that would create difficulties for CMS if we suggested something like that?

DR. ROLLINS: I think that depending on resources available, that might be a problem in terms of establishing an automatic threshold. So it would depend on the resources available.

MS. BERRY: Ed?

DR. McCABE: Maybe with James' comment, we may want to consider a mechanism that would automatically initiate.

DR. WILLARD: I'd split the difference and say they should consider establishing a mechanism.

DR. McCABE: Does that give you a little more leeway, James, within the agency?

MS. BERRY: So "should consider establishing."

DR. FITZGERALD: Why not just "should consider"? You don't need "establishing." I mean, if they consider it, they consider they should establish it, they'll establish it. If they consider it and they consider not --

DR. WILLARD: But there are two separate things, Kevin. One is considering establishing a mechanism. The other is considering what the mechanism should be if you've chosen to establish it.

DR. FITZGERALD: Right. That's what I'm saying. So if you throw "establishing" out, that includes both of those.

DR. LEONARD: We could also get rid of the "should" or "want to" or anything, just saying that this committee recommends CMS establish a mechanism. Because then it is our recommendation, they can do what they want with it.

MS. BERRY: James, are you saying that there is already a mechanism in existence? It is just perhaps not an automatic trigger for it? Is that the case?

DR. ROLLINS: There's not an automatic trigger. We do look at local coverage decisions. If there is inconsistency, then we do consider establishing national coverage decisions.

DR. WILLARD: But I think the value of the sentence is the automatic trigger, which is how it is worded. So the first part matters a little less. It depends on where we learned our English grammar on which is the better phrase.

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MS. BERRY: Does this capture the way it is currently worded as edited? Eliminating that "may want to"? "CMS should consider a mechanism that would automatically initiate a national coverage review process."

DR. WINN-DEEN: Do we mean to have "SHOULD" all caps? That sort of shouts at you.

MS. BERRY: We feel very strongly about this recommendation.

(Laughter.)

MS. BERRY: Any other comments and suggestions?

(No response.)

MS. BERRY: Hearing none, Reed?

DR. TUCKSON: Can we entertain a motion and second it?

PARTICIPANT: So moved.

PARTICIPANT: Second.

DR. TUCKSON: All in favor?

(Show of hands.)

DR. TUCKSON: Anyone in disagreement?

(No response.)

DR. TUCKSON: Motion carries unanimously.

Next?

MS. BERRY: This is a tough one. We sort of eased into it, right, Reed? We wanted to start out with the really easy ones. We're building.

This recommendation addresses the problem that we identified in the report having to do with the screening exclusion in Medicare and the challenge that that poses for so many genetic tests and services.

We have not revised this recommendation since the last iteration. We did receive some public comments on this, and we have also solicited some input from CMS because this most directly affects them, how the statute is interpreted, how the Medicare statute is interpreted.

The first part of the recommendation basically recommends that preventive services, including predispositional genetic tests and services that meet certain evidence standards should be covered under Medicare, and it's not really a recommendation. It's more of a declaration.

Then we move onto the second part which urges the Secretary to work with Congress and urge them to add a specific benefit category for preventative services so that CMS could determine

through its national coverage decisionmaking process whether something is reasonable and necessary and could be covered.

This recognizes that there is a need for a legislative change, a change in the Medicare statute in order to cover these types of preventative services and tests.

But the third part of the recommendation is the real nettlesome part. That is where we tried to think outside the box. If you'll recall, we discussed this a bit at the last meeting. In some respects, it is trying to fit a square peg into a round hole. It has been done before. We thought in the interim, because congressional action really is very difficult, and it's a long process. We know that it is years and years before you might ultimately see any final piece of legislation signed into law, we thought well, is there some creative thing that we can do that the Secretary can do within his existing regulatory authority to help cover at least some subgroup of genetic tests and services, keeping in mind what the parameters of the statute are and CMS' guidance.

We did solicit some input from CMS. We feel, we don't have a formal opinion from anyone on this, but in looking at the Medicare statute, it is our determination, staff and myself, that the screening exclusion is not something that is specifically identified in the Medicare statute itself. It is something that pops up in the course of regulatory either regs or guidance documents that

CMS has issued over the years, interpreting the general Medicare statute.

We thought, and I should bring out my little handy dandy cheat sheet. Okay. The screening exclusion. CMS has interpreted the Medicare statute in the past as prohibiting coverage of screening services, including laboratory tests furnished in the absence of signs, symptoms, or personal history of disease or injury, except as explicitly authorized by statute.

So if you don't have signs of a disease, you don't have symptoms, and you don't have any personal history, it is considered then a screening test, and therefore would not be covered under Medicare. So we thought, and I can't remember now who is responsible for this, I take no credit for it or blame, but I think it's creative that what if an individual has a significant family history of particular disease, say breast cancer? Say every woman in the person's family has breast cancer.

Could that family history then be interpreted as being part of personal history, which then would say in that case, a genetic test would be a diagnostic test. It wouldn't fall within this screening exclusion. So that's the point of this recommendation, which is to get the Secretary to use his authority to in certain circumstances, however he would want to identify them, say that family history of a particular disease constitutes personal history which would then take the test out of the screening exclusion box and put it into the diagnostic test box, and therefore be eligible for coverage.

Here is where it gets really tricky. I think CMS' official position is that in general, any type of coverage for tests that could be considered screening tests really requires a legislative change, a statutory change. We don't have a formal legal opinion from CMS or anyone else at HHS confirming what I stated earlier, which was we think the Secretary has the authority to do this. Whether he wants to is another question. But does he have the legal authority to do it? I think he does.

We don't have any formal written or verbal opinion to that effect. So we want to consider whether we should leave this recommendation in as revised based on comments that you all may have, or whether we want to take it out, recognizing that there is just some controversy, I think,

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within HHS or CMS as to whether this would be an appropriate thing to do, or whether CMS would even consider, or whether the Secretary would even consider doing it.

DR. TUCKSON: I think, if I understand where the issue is, is after done homework, it is unclear. So the bottom line is that what we are clear about is that we want this issue to be explored. So what I would sort of, and this is not with my chair hat on, but just a committee member's hat.

What I sort of see us doing here, cognizant of my admonitions earlier about what is in the power of the Secretary and being relevant in terms of what we send him, is there is an issue of which there is unclarity, but there is a course of action that we think needs and deserves to be studied.

I think we ought to ask him to in fact study this issue. If it turns out that he after exhaustive detail says that he doesn't have the authority to do it, then that's the answer. But I think we're being responsible about sending something forward because in fact we do not know after a lot of homework, whether or not he does or does not. So let's go forward, ask for the answer, and then let the chips fall where they may. That's my suggestion.

MS. BERRY: Yes, James?

DR. EVANS: It does seem relevant, isn't it, that Medicare criteria currently for the coverage of BRCA1 and 2 testing includes clinically unaffected patients with a family member with a known mutation. So this is an unaffected person, and it certainly seems that a known mutation in the family is in many ways akin to family history. So it is already covered by Medicare, right? It's a short jump. I'm no lawyer, but it seems a short jump to go from there is a known mutation in the family, the person is unaffected, it is already covered by Medicare, to saying that family history could be --

DR. ROLLINS: But in that situation, that is a local coverage decision. That's not a national coverage decision.

DR. EVANS: Is that right? Okay.

MS. BERRY: Agnes?

MS. MASNY: My question is that before we would send this to the Secretary then to explore this issue, could someone from CMS actually give us an answer on this, whether a change like could be made without legislative -- in other words, we'll just take one step to check this out before we start asking the Secretary to.

MS. BERRY: We've been trying to do that. I think we will have difficulty in getting anything formal. Some formal here is our written opinion as to this, I don't think that they would be willing to do that. It would have to be kicked up to the level of the administrator and perhaps the general counsel.

We have more informally solicited that type of information from others within the agency, but I'm not sure that we'll succeed in getting anything more formal.

DR. FITZGERALD: Right. So on that thing, and to follow up on what Reed brought up, what about saying the Secretary should explore the possibility of directing CMS to clarify. So if the possibility isn't there, it's moot.

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DR. LEONARD: But if it does exist, we do want him to do the directing.

DR. FITZGERALD: Right.

DR. LEONARD: I don't think he has to explore the possibility. If he takes this recommendation seriously, then he will explore the possibility of doing it. I mean, that's the next step. I don't know that we need to state that in there.

MS. BERRY: Leave it? Is the consensus to leave it?

Ed?

DR. McCABE: Yes, I would leave it as it was. And I would move approval.

DR. TUCKSON: Looking for a second. We have a comment on the motion.

DR. WILLARD: Can we remove the split infinitive in the first sentence?

DR. TUCKSON: Who taught this man high school English?

DR. WILLARD: Have it be to benefit clinically, not to clinically benefit.

DR. TUCKSON: We knew that. All right. We are looking for a second.

DR. McCABE: I don't know if I accept that amendment.

(Laughter.)

DR. TUCKSON: We are looking for a second on the motion. Do we have a second?

PARTICIPANT: Second.

DR. TUCKSON: All those in favor, with the correction of the split infinitive, say aye.

(Show of hands.)

DR. TUCKSON: Against?

(No response.)

DR. TUCKSON: All right. Thank you.

Next issue?

MS. BERRY: All right. Recommendation 5. We made a real whopping change in this one. We actually just referred back to Recommendation 1. This is that we're trying to encourage the Secretary to disseminate to states given the fact that they run Medicaid programs, as much information as is necessary and appropriate to help them make the best decisions and assess the evidence-base.

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We refer back to Recommendation 1, because of course that's the body that the Secretary would establish to come up with criteria, principles for coverage and reimbursement. We received no points of debate or disagreement from the public on this particular recommendation.

PARTICIPANT: Move that it be accepted.

DR. TUCKSON: Looking for a second.

PARTICIPANT: Second.

DR. TUCKSON: All in favor?

(Show of hands.)

DR. TUCKSON: Anyone opposed?

(No response.)

DR. TUCKSON: It passes unanimously. As, by the way, for the record, the one prior to that as well.

We go to the next recommendation.

MS. BERRY: Recommendation 6 pertains to payment rates for genetic tests, recognizing that in many cases, the reimbursement is below the cost of performing the test. Until the fee schedule can be reconsidered in a comprehensive way, the recommendation asks that the Secretary direct CMS to use its inherent reasonableness authority to adjust, where appropriate, certain payment rates for certain genetic tests.

We received no points of debate or disagreement in the public comments on this particular recommendation.

Debra?

DR. LEONARD: Can I ask for a note of clarification? Are there rules now that direct how inherent reasonableness evaluations will be done? We may be suggesting a recommendation for which CMS currently has no mechanisms to do this. Therefore, this recommendation would go nowhere.

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

DR. LEONARD: I'm just concerned that the evaluation process that we're asking CMS to use, they don't have access to yet. So therefore, nothing would be done. The overwhelming comments that we got was agreement with having this done.

So I think we at least have to evaluate whether or not the mechanism by which we're recommending having this done exists.

MS. BERRY: It's my understanding they have the authority to go down this path, but they may not have established a path for exercising that authority, if that's what you're getting at.

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DR. LEONARD: Well, right now we have been working for three years to have them do an evaluation of HCV viral loads to pay the same amount as HIV viral loads. They say they just keep going around in circles because they say they don't have the inherent reasonableness guidelines to work with yet.

MS. GOODWIN: I think at the time it was true that they didn't have the authority, but recently, at least within the past year, whatever freeze there was on that authority has been lifted. Now I think they are looking to --

DR. LEONARD: The freeze has been lifted, but they still are saying there are no guidelines by which to take action through inherent reasonableness mechanism.

DR. McCABE: Well, then I would suggest, and I think this is an extremely important part of the recommendations. I would say if there is no mechanism for use of the inherent reasonableness authority, then we would recommend that such a mechanism be established rapidly. You could wordsmith it. But basically get it done.

MS. BERRY: Do you think the language as is currently written kind of like in our earlier recommendation where we didn't say he should consider establishing, we just said do it. That sort of implies that he's going to consider the process. Is it sort of the same thing? Or if we leave it as is --

DR. McCABE: No, I was just adding another sentence. I was just adding another sentence to try and block the bureaucratic sidestep. If there is no mechanism to accomplish this, then please establish the mechanism.

DR. WILLARD: Rather than add a sentence, why not just delete the phrase, "through its inherent reasonableness authority." We are just telling them to solve the problem. If the authority is there, great. If it isn't there, figure it out.

MS. BERRY: I think that inherent reasonableness authority is sort of a roadmap. If you don't have it in there, the response may well be, well, there is this freeze in the statute where we can't adjust the fee schedule because of the freeze in rates.

So by adding the inherent reasonableness authority, it is sort of explaining yes, we recognize that, but you do have this authority that allows you to make some adjustments here and there.

DR. WILLARD: I thought that was the question. You don't know if the authority is there.

MS. BERRY: The authority is there, but they don't have guidelines for how they actually utilize the authority to achieve the particular objective.

DR. WINN-DEEN: So maybe we need to add something to sort of strengthen the need. Instead of just saying through immediate implementation if its inherent reasonableness authority, or something that sort of stresses that it is one thing to have the authority, and it's another thing to implement it. Or through timely implementation, something like that.

DR. FITZGERALD: Or say something along the lines of through its inherent reasonableness authority, and you used the word "guidelines," right, Cindy? If guidelines for this authority do

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not yet exist, they should be generated as soon as possible. Something along those lines. Then you can just add one simple sentence like Ed was saying.

DR. LEONARD: I think the last sentence can go if you just say, "The CPT codes through immediate implementation of its inherent reasonableness authority," or "expeditious implementation." Like Emily said, I don't think you need the last sentence, then.

MS. BERRY: Take out the last sentence.

DR. McCABE: James, is there a problem? Is this not doable?

DR. ROLLINS: I think it's doable. My only concern is the word expeditiously." That's all.

DR. McCABE: But since we move at glacial speed, then expeditious is sometimes in the next decade.

DR. ROLLINS: You and I know what glacial speed is based on our conversation here. But CMS might not.

MS. BERRY: In the next millennium.

DR. WINN-DEEN: I think from the point of view of a recommendation, I think what we're trying to convey is that this is not something that we want to just sit around and whenever CMS happens to get around to it, it happens. We are trying to convey that we would like to see this happen expeditiously. Whatever that means in the context of the speed at which government bureaucracies make forward progress.

DR. ROLLINS: Expeditiously or in a timely manner.

DR. LEONARD: I like the word "expeditious" better.

DR. ROLLINS: I like the words "timely manner" better.

DR. TUCKSON: I would suggest that we need to be clear that we want this done expeditiously. What CMS can do, that's on them, but we can't buy into, I don't think, the inevitable inertia.

Jim is doing a good job of making sure, you know, he makes a comment for his agency. At the end of the day, we want this done expeditiously.

MS. BERRY: Any other comments?

PARTICIPANT: Move acceptance.

DR. TUCKSON: We have a motion for acceptance.

PARTICIPANT: Second.

DR. TUCKSON: We have a second. All those in favor, raise your hand.

(Show of hands.)

DR. TUCKSON: Those not in favor?

(No response.)

DR. TUCKSON: It passes unanimously.

Next recommendation?

MS. BERRY: Recommendation Number 7 pertains to genetic counseling. This is going to be another tough one. I think what I'd like to do, I will go over all of these bullets, because it is a multiprong recommendation. I'll summarize them briefly.

I think 2, 3, 4, and 5 are not going to pose the same challenges as the first one, so I'd like to go through those and then go back to the first one, which I think we'll want to spend a little bit more time on and be very thoughtful about.

The underlying premise, of course, is that qualified health providers should be allowed to bill directly for genetic counseling services. The inability to bill directly was identified as a barrier, a problem, a barrier to access. So the very first bullet which we're going to discuss, I think, in depth, encourages or asks the Secretary to determine an appropriate mechanism for assessing the credentials and criteria that are needed for a health care provider to be deemed qualified to directly bill.

The second component of this recommendation asks the Secretary to direct government programs, federal programs, to reimburse prolonged service codes when reasonable and necessary, recognizing the fact that oftentimes genetic counseling sessions are much longer than a traditional office visit, and therefore it would be in those circumstances, appropriate to recognize and reimburse and use prolonged service codes.

The third bullet says that HHS with input from a variety of input from organizations and providers should take a look at existing CPT E&M codes, and any inadequacies that are identified should be addressed as deemed appropriate. We don't specify how they should be addressed, but urge the Secretary to take a look.

The next part of recommendation states that CMS should deem all non-physician health providers who are currently permitted to directly bill any health plan, public or private, deem them eligible for a national provider identifier.

The last bullet, the Secretary should direct CMS to allow non-physician health providers who are qualified to provide genetic counseling and who currently bill incident to a physician to utilize the full range of CPT codes that are available for genetic counseling services.

We received a good deal of feedback from the public in the public comments. I would say the one that I want to call particular attention to is the very first prong of the recommendation in terms of how do we appropriately recommend who should be able to directly bill for these types of services.

There were some comments, and again, I mentioned earlier in the presentation suggesting that we specifically recognize particular organizations, ABGC and GNCC, recognize them and their

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members as being currently qualified to bill independently, and therefore exempt from the proposed review mechanism.

We received a lot of comments, different versions and iterations of that. I think the difficult questions that we need to ask ourselves is how specific do we want to be in this particular recommendation? Do we want to name particular organizations? Do we want to identify particular providers, or should we leave it more generic so that it is something for the Secretary to determine, and for this body to determine?

Because associated with the ability to directly bill has to do with scope of practice. Is someone capable of and permitted to provide services without the supervision of a physician? Is that something that we can assess here, or is that something best left to a body that specifically is tasked to undertake that?

DR. TUCKSON: Just for foundational sake again before we launch down this road. I don't know whether you are in a position now, Cindy, to summarize, or Suzanne, a position to summarize what we spent a couple of hours on at the last meeting regarding this point.

Let me just stop there and ask. Are you in a position to summarize why the committee had difficulty at being able to wave a wand and say we believe that these two named organizations ought to be anointed with the ability to be this certifying body, or should there be some other mechanism that needs to be in place.

The other part of that discussion was should we leave it to the Secretary to try to use his convening power to be able to create the discussion that solved that dilemma? The question really becomes are we in a position to recommend that those folks be appointed with that role, or does there need to be a process that figures that out.

That is really what I think our debate was about. But let me just make sure, Cindy, that we're accurately restating how we got to the decision not to anoint in the recommendation itself.

MS. BERRY: Right. There was some testimony presented and some written comments and feedback provided by various groups that we had requested, some of which addressed specific questions that we asked. In other cases, our question about what are the reasons, or how do you justify a particular provider being able to directly bill.

Some of those answers were not provided. Some of those questions were not answered. So we felt at the full committee level we had an extensive debate at the last meeting about that. Who do we pick? Did the organizations present sufficient evidence for us to make that assessment? Or are there still gaps in our knowledge?

At the task force level, we struggled with it a little bit as well, because we said it may be very difficult to just pick and choose at this stage. Who are we to say well, this group of genetic counselors is qualified, but this group of some other type of professional is or is not. If we start naming organizations and provider categories in this recommendation, we may be leaving some folks out who otherwise should be included in there.

So at the task force level, we thought it best to leave the recommendation more general and leave it up to the Secretary to task a qualified body to make those assessments.

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DR. TUCKSON: One other thing I'd note, and I see Ed's hand up, and others to comment, I just want to make sure, again, that everybody is playing with the same database as you ask your question.

So one other question, Cindy and Suzanne, I want to be clear about. We were pretty clear in our discussion as we struggled over this question of how do you solve some of these problems? How do you know whether it should be a Master's level person or a bachelor's person? Who gets to create the organization that supervises this? Should it be something like an American Board of Medical Specialties for Genetic Counseling? How do you do these things?

We struggled with all of those things and could not resolve it. Thus we got to the recommendation we got to. My question is for foundational sake, in the public testimony that we have received, or any consultation that we have received since our meeting, do we have anymore specificity of guidance around how to solve those problems, other than testimony since we have met that says you ought to anoint or appoint?

What I'm wondering is did we learn anything that we did not know that would inform the committee's deliberations around these kinds of specific questions that we didn't have available to us at the last meeting.

MS. BERRY: We have not received anything formally at the committee level or at the task force level that addresses all of the issues that we've identified.

I should point out, it is on page, well, it says it is page 2, but it's not really page 2. It is behind Recommendation 7. You'll see a chart. Page 2 of that chart in the middle of the page you'll see, "Proposed Revision to Recommendation 7A (Cindy and Reed)."

We had a discussion that we wanted to put forth, and this was sort of the result of that discussion, as a way to reword that first bullet, that first prong of the recommendation to more concretely identify the issues that we face with regard to direct billing.

I think we should give folks an opportunity to read that. But in answer to your question, Reed, we still lack some information that I think would enable us or any group to make a comprehensive review or assessment as to who should bill, who shouldn't bill, and who is qualified or not.

So that's why we came up with this alternative recommendation, or alternative wording.

DR. WINN-DEEN: Cindy, I think it's important to point out that we did as a task force add the footnote, which refers you to the appendix and talks about the fact that there are groups out there that may be the right groups, but we just weren't prepared to make that comment.

DR. TUCKSON: Well, I'm scared about butting in in front of Ed again, who has had his hand up. I just want to be very precise about foundational data.

Cindy, I think you sort of responded to my question, but I want to be very specific about my point. That is not around the question of who is qualified. It is around the question of how do you create a mechanism that decides who and how you determine the organizations or organization that says that people are qualified for certain scope of practice activities.

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That is a point that we were very clear about needing guidance on at the end of our last meeting. We were extremely explicit about the dilemma that this committee faced on that specific point. What I'm trying to make sure, because I think it is very determinant for, at least in my mind going forward, I'm trying to just get it straight, is have we learned anything more about that specific point than we did when we left out of here last time. It sounds like we do not have comments on that point.

I just want to make sure everybody knows what we know and what we don't know based on where we were last time. I'll leave that there, because that helps me at least to know whether I'm missing something, or whether I'm not as smart as I ought to be about solving certain problems. So now please entertain the conversation.

MS. BERRY: Yes, Barbara?

And then Ed.

MS. HARRISON: Similar to what I said at our last meeting about this, I guess I'm a little unclear about what remaining questions there are. I mean, we asked the genetic counseling workforce to come up with a very detailed report, which they did. It just seems like given the amount of public comment that was given on this, and we had also said that was something we would take into account when we relooked at this recommendation when we had our last meeting that we would put this out for public comment, and we would get that public comment back.

There was a significant amount of comment. The majority of which, vast majority of which support both the ABGC and the GNCC being listed specifically in the recommendation.

On top of that, I think it's also clear that even the way the recommendation is worded now, that is not to the exclusion of other health care providers. It is just simply stating that at this time, these professionals that are part of these credentialing bodies, or members of these credentialing bodies have the appropriate training to be able to provide this service, and that there may be others out there. But that information is lacking, because you know that information wasn't given to us.

So I guess I just want to put out there once more to challenge the committee to put those two organizations in this recommendation.

MS. BERRY: I'll just address that, and then go to Ed. We received a lot of information, as you mentioned, the last time in public comments, verbal and written, about the nature of the profession, about the value of genetic counseling services and the members of these organizations and the worthwhile efforts that they undertake and the services that they provide.

There is no question about it. Where we still are lacking information is yes, they can provide genetic counseling services. They do admirably. It is all worthwhile. But then the next step, and I'll call your attention to this flowchart that staff have put together. It is also in this same packet of materials where it guides us through the decision making tree as to whether someone should be able to directly bill, whether it's Medicare in this case, or a private health plan.

As far as genetic counselors, you immediately go to the yes column when you ask the question are they qualified to provide genetic counseling services. I think a resounding yes. There would be no dispute about that based on all of the information that they gave us.

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The next question is are they qualified to provide genetic counseling services without physician supervision? If it's no, they have to bill incident to a physician. If it's yes, then they can bill private payers directly, but still there is another decision tree that they have to follow in order to bill Medicare.

These are scope of practice issues as to whether someone should be able to bill, or someone should be able to provide services without physician supervision. There is also the question of the credentials that a particular organization, the credentialing requirements that a particular organization has.

Are there specific criteria that we think any credentialing body should have so that any blessing that they give to their members is deemed adequate to them directly bill? I don't think we received any detailed information along those lines that would enable us to make a very specific recommendation in that regard.

That's why we were struggling at the task force level. Fearful of going down the path of naming particular organizations when we really didn't have all of the information that we might need in order to make a declaration like that. It's sort of a long winded response. I know Ed has some points, too.

DR. McCABE: I guess I disagree with Barbara. I think by having Appendix B, I thought the footnote was a masterful way of dealing with the issue without appearing too self-serving as genetic professionals.

You would use the criteria for those two organizations obviously in Appendix B, so you do sort of single them out as the ones that are established, but you don't put it in the body of the recommendation. I prefer that approach to it.

The other thing about Reed's comment about an ABMS-type structure then, because someone could set up a fly by night genetic credentialing service for non-doctoral level people, I don't think that's our business. I really think that's the business of the genetics community to establish that in order to prevent that from occurring. I don't see that as a federal issue.

DR. TUCKSON: By the way, just for the record, I don't disagree. I was trying to just get clarity. If I could put on my regular hat here for a minute, I think you're right. I think the point is what we got to in that discussion, as I recall, was we could feel the pressure and the pain from the genetics counseling community for faster action. So what we had been debating and kicking around was could, and by the way, clarify where we were in terms of how we got to where we were. Especially to those who are new to the discussion.

Because we felt the pain and the frustration of the genetic counseling community to get this moving faster, we were sort of wondering, could we request the Secretary to use his good offices to stimulate that kind of conversation? To be a convener that would move it forward so that it would support the genetics community in getting that done, and what we were sort of looking for and hoping for, we would get some advice and guidance in the public comments about how do you in fact make something like that happen faster.

So I agree with you. It was just a sense of trying to respect the impatience and jump start the process, as I recall our discussion.

MS. BERRY: Agnes, and then, well, let's see. Agnes, Ed, Hunt, Barbara, and Sylvia.

MS. MASNY: Sort of just reiterating what Reed had said is at the last meeting, I think that one of the key issues that we wanted to address as a committee was the issue of genetic counselors becoming recognized providers being able to get reimbursed for the services they provided.

I agree with Ed, though, that I think that it is appropriate that we don't specify a particular organization because in many ways, what we want to see happen is genetic counseling services whether it is "genetic counseling" or genetic services provided by other providers integrated into medical care.

I think the Oncology Nursing Society in their comments have actually asked us to define what we were talking about when we said genetic counseling and other types of services. I'm even wondering whether we shouldn't even ask for reimbursement for genetic counseling, but for the counselors, but that they be recognized as providers who are doing these services that are reimbursable under the regular evaluation and management codes.

That's what we're asking for. So rather than making sort of genetic exceptionalist terminology of creating another category for billing, genetic counseling, let's integrate that into what is existing, but get the genetic counselors recognized as billable providers.

MS. BERRY: Who's next? Ed?

DR. McCABE: In follow-up to Reed's comment about the Secretary in convening authority, I would think the people sitting around the table already have that message. If we wait for it to go up to the Secretary and come back down, that's going to take quite a long time, as we've experienced. But perhaps we could ask groups like CDC, NIH, HRSA to think about and perhaps report back to us what it would take to convene a group of these genetics professionals, genetic providers, to begin to think about developing this.

So without the government being responsible, could it at least be a catalyst to bring people together outside of this group that reports back to us of what they found.

Is that clear, Reed, what I'm asking for?

DR. TUCKSON: To me, as one listener, it's very clear. It's a different strategy. I think at the end of the day, what I'm hearing here is another member of the committee expressing an interest and a desire to try to move forward to accomplish a goal that is so clearly articulated to us by 100 different presentations by the genetic counseling community. You're trying to solve that problem by instead of waiting for the Secretary to use his individual power, take the ex officio members who are here from those agencies and try to mobilize them together to try to get that done. I think if I'm hearing you, that's just another way of trying to fast forward the process.

DR. McCABE: So with representatives from HRSA, NIH, CDC sitting at the table, would you be willing to try and put together a group that could begin to think about what it would take to have an umbrella that would say this is a legitimate genetics provider credentialing group so that we could prevent what will undoubtedly happen without that sort of umbrella?

DR. KHOURY: Can I just say, Ed, I'm not sure that these are mutually exclusive categories, what you are recommending.

I think if you put a recommendation to the Secretary, the Secretary will come to us anyway.

DR. McCABE: It'll just take a lot longer.

DR. KHOURY: Right. But, I mean, a lot of the activities and recommendations that this and other committees have been making have been taken up by the agencies. By elevating them to the level of the Secretary, I think this committee is more likely to make a more lasting impact.

In other words, what I'm suggesting, leave the recommendation here, but a group of us can begin a process of the interagency discussion about how is the best way to do this without waiting for marching orders from the Secretary. I think you can have your cake and eat it too, but it's not going to be easy or simple either way.

There is no need to exclude it from your recommendation to the Secretary. If we have already started the process, the Secretary will ah hah, there is an existing process. If we haven't, then he or she will lean on us, whenever that's appropriate.

But if this issue was easy to solve by the feds, I have a feeling that it could have been solved many years ago. I think it would require deliberate efforts and partnership with professional organizations on the best way to do it.

DR. McCABE: Well, I don't see that that recommendation is here now. Is there a recommendation for the Secretary under the convening authority of the Secretary to do this? That's not here. So this would be a new recommendation.

DR. WILLARD: That's an appropriate mechanism. It's just unspecified, which is in the spirit of what we had decided to do. It's just that we don't have the authority to make specific recommendations of the path he should go down, but simply urge him to go down a path that he feels is appropriate.

My comment would be, and I applaud the chairman for his efforts to be extremely even-handed here, and you're being very successful at it. But on the other hand, I would urge us to focus on the words, which we're trying to get to a recommendation that we all can support, or the most possible of us can support.

I don't sense an enormous amount of disagreement around the table, and I agree with Ed. I think this was a masterful decision by the task force to add this footnote. I think it gets us as close as we could possibly get to providing the helpful information that is necessary.

It may not satisfy every group, but at least from what I've heard around the committee, most of us think there are legitimate reasons for not going anymore specifically in that direction. So I would urge us to stare at the language and decide whether we can support it or not support it, and keep to that task.

MS. BERRY: I think it was Barbara, Sylvia, and then Emily, and then Agnes.

MS. AU: I can understand Ed's comment about trying not to appear self-serving. I think that the majority of people, I don't think anyone would argue there is evidence, the majority of people who provide genetic counseling are genetic counselors or advanced practice nurses.

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I think that in this recommendation, to reduce it to a footnote that they should consider the credentialing of ABGC, or the advanced practice nurses, reduces it to a footnote. I think that somehow the wording should be put in the actual recommendation.

Because a lot of times I'll get the recommendation, but the footnote won't be included. I don't want that to be lost in the recommendation.

MS. BERRY: Some of the comments, though, that we received were not to the extent of just mentioning those organizations specifically, but also saying that anybody who is a member of those organizations and credentialed by them should be exempt from this review process. That's a different step. That goes beyond simply recognizing the organization.

MS. AU: So my comment is that I agree with Ed that to actually name the organization that they get exempt would be self-serving, and that's not what we want to do. But I don't want to reduce it to a footnote in the recommendation because I believe that as we said, we are looking for foundation, the evidence is that the majority of people who provide genetic counseling are genetic counselors and advanced practice nurses.

So I want to move the footnote to a more prominent part as part of the recommendation. I'm not saying that you exempt these people. I'm saying use the wording that you look at those organization's credentialing procedures in the recommendation, not at a footnote.

DR. LEONARD: I don't think there's any problem with putting it, instead of as a footnote, putting it as part of that bullet with the exact same wording that's in the footnote. I agree with Sylvia.

DR. McCABE: And you could even specify what is in Appendix B. So you could say a number of professional societies such as, have developed credentialing standards, and then put it in Appendix B, if that's a significant issue.

MS. BERRY: Emily, Agnes.

DR. WINN-DEEN: Okay, so I also agree that this is maybe a good compromise. I think my biggest concern was I didn't want to give any appearance that somehow this committee has anointed itself as a professional practices committee that can deem groups as having certain categories.

I think that that has to be left to groups that actually have that authority. We're an advisory committee. We're not a committee that is going to have active oversight or interviewing of different groups to determine if they indeed should be allowed to be billable entities as genetic counselors.

On the other hand, we've heard a lot of testimony that there are some really good credentialing organizations out there, and we want to recognize those.

MS. MASNY: That's a nice follow-up, Emily, because just to mention as an example, that the Oncology Nursing Society has their own certification organization that has already been in touch with GNCC to look at collaborating and helping ONS actually come up with their own certification or credentialing for nurses who are working in this area of cancer genetics. That, I think, will happen.

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Again, if we just give the examples professional organizations that already have credentialing or certification bodies, we'll then just make use of the criteria or the template that the ABCG and the GNCC already has to help them in establishing certification.

I think that the issue, just giving the examples of the qualified health professionals, though, as a second point, is a better way to go. When we even say to recognize the GNCC-certified providers, nurses who are advanced practice already can bill, so they do not have to go through the mechanism of even going through the GNCC, but nurses are just trying to get an extra credential to show that they have the specific specialty in genetics.

So they're already billing, and I'm coming back to that point, under evaluation and management codes. I don't know whether in this whole document whether we are actually asking to create another billable entity for genetic counseling. I still would suggest that we look at it as an integrative process and have the genetic counselors be able to bill for the regular Evaluation and Management Codes, rather than establishing a specific service for which people are already billing other qualified providers that have their UPIN numbers, which will soon be the NPI numbers, are already billing for those services.

DR. FITZGERALD: My question is, is that the wording that you have up there right now? That's what we've been talking about, right? Because it looks good to me right now.

MS. BERRY: What this is is sort of the Tuckson/Berry amendment to the original recommendation. It has since been modified to reflect the comments that we're hearing here. We took the footnote, it was previously a footnote, and moved it into the body of the recommendation.

This is really an attempt to really clarify the issue of direct billing, and kind of going through the decision tree in an actual sentence structure, as opposed to the chart.

DR. LEONARD: But Cindy, because you are taking out the first bullets, so you're removing then the bullets, and this is the full recommendation without any of the bullets below it?

MS. BERRY: This is just the first bullet. This replaces the first. So in your packet --

DR. LEONARD: The first non-bulleted part?

MS. BERRY: Under Recommendation 7 in your thing here, you see Recommendation 7 has one, two, three, four, five bullets.

DR. LEONARD: Right.

MS. BERRY: This wording up here is intended to replace just the first bullet.

DR. LEONARD: Okay. So it's just not bulleted, and we can't see the intro thing number seven that is still there?

MS. BERRY: Right.

DR. LEONARD: Okay.

MS. BERRY: Agnes?

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MS. MASNY: Just one other comment. We're at the provider should be able to bill without supervision of the physician as deemed by the State Practice Act. Because in Pennsylvania, nurse practitioners cannot provide services except incident to the physician. That's deemed by the Nurse Practitioner Practice Act in Pennsylvania.

So although they're allowed to be billable providers, some of the supervision of the physician will be based by the state practice acts.

MS. BERRY: Or should it be "state scope of practice laws"? Are they all in statute? Or are some by regulation at the state level? What's the best way to characterize?

DR. LEONARD: From what Agnes said, it's not the professions scope of practice, it's the state.

MS. MASNY: But it is the state's scope of practice for that particular profession.

DR. WINN-DEEN: So as deemed by each state.

MS. MASNY: But it's the state.

DR. WINN-DEEN: Each State, State with a capital S, probably. I think you have to add at the end of scope of practice, for each professional group, or whatever Agnes said.

MS. BERRY: All right. The question is, the next sentence was really designed to get to that point. It wasn't as direct and didn't mention states specifically. Should we just eliminate that sentence, then? Does the addition of the language we just put in there about the state scope of practice laws, does that obviate the need for this next sentence?

DR. McCABE: Before we leave that sentence, I would get rid of "laws," because I think you're going to find a mix of laws and regulations. Make it "policies," and then it covers whatever it is.

MS. BERRY: Or "requirements."

DR. McCABE: Or "requirements."

PARTICIPANT: In the next sentence, "The criteria used." It needs a D on the end.

MS. BERRY: The issue that Suzanne points out, is it just genetic counselors or others that may not have any state scope of practice criteria or laws?

MS. MASNY: That's a thing, I mean, I know that the genetic counseling community is actively looking at this. In each place where they are looking to get licensure passed, that's one of the things that they have to define is their scope and standards of practice.

So I think the organization in general will be looking to develop the scope and standards of practice that then could be presented to each state when they look to get licensure or practice in that state.

MS. BERRY: I'm going to advocate a little bit for the version prior to the additions that we just made. If you think, and if we can tweak this next sentence, the criteria used to address what you're saying, because I think adding all this other stuff up earlier makes this sentence really unwieldy and very difficult to understand.

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If we can get it back to the way it was before, and then start a new sentence and add, that might be better.

DR. LEONARD: So why can't you just take out what was added and put it in the criteria used to guide these physicians should consider that addition that we made to the first sentence.

DR. WILLARD: It says scope of practice.

DR. LEONARD: But it's not state.

DR. WILLARD: Correct. But it's all inclusive. It doesn't matter whether it is state, local, federal.

DR. McCABE: I agree. I would take out the additions that we made to that prior sentence, leave it the way it was. If we're going to wait for each state to pass laws or regulations to accept genetic counselors, it will be even slower than glacial.

DR. WINN-DEEN: Can we get clarity on states versus federal? I mean, I don't think any of this stuff, it was my understanding that you had to be licensed at a state level, and then you could bill wherever.

DR. McCABE: But there will be issues like with the uniformed services where if they don't come under state, again, I think it's good to leave state out.

DR. WINN-DEEN: Okay.

DR. McCABE: Because there will be areas where that would not hold up.

DR. TURNER: (Inaudible.)

DR. McCABE: But even when you're overseas?

DR. TURNER: (Inaudible.)

DR. SHEKAR: What I think we're both agreeing on is that even though it is the case that federal practitioners have different requirements than those in private practice, the fact of the matter is that you must be licensed in at least one state or jurisdiction. So ultimately licensure is at the state level for all practitioners.

MS. BERRY: Agnes?

DR. McCABE: I would still recommend that we leave the state out, because it will come up, then. If that's the scope of practices, then it will come up.

MS. BERRY: We're not excluding them, in other words.

MS. MASNY: I'm fine with that, but I'm going to come back to a thing that I've already said, and this will be my third time. So three strikes, and then I'll be out.

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I think we're missing a tremendous opportunity with some of the wording that we currently have in there of looking at how what we're talking about could apply to all of health care practice. This is I think one of the things that we've been chartered to actually do is to look at how genetic services are going to move into all of health care.

I give as the example that in cancer care, we are already providing genetic services and genetic information to patients who are now having genetic tests done for their tumors. It looks like even for the area of colon cancer, a recommendation is out there to have MSI or genetic testing done on every single colon cancer patient.

So then that in turn will mean that health care providers have to be knowledgeable about genetic information and possibly even going on then to provide HNPCC testing for a select group of patients so that those will probably be referred to genetic counselors, but that health care providers in general, nurses, oncologists, surgeons, are all getting involved into providing this genetic information.

I'm just going to say that I think we need to keep this integrated approach in our minds, and that maybe another group that we should include in our list, not that it is a certification organization, but would be NCHPEG. NCHPEG has already come out with established competencies for all health care providers of what they need to have in place to be able to integrate genetic information into the up and coming health care systems.

If we need any further information about that, I see Jean Jenkins in the audience, who actually helped develop the core competencies. The U.K. health care practices already have integrated the competencies that were put in place by NCHPEG into their recommendations for all health care providers must have these specific competencies. I would hate to see us miss this opportunity for helping all health care providers to integrate genetic information into their practice by just focusing on those who will be working in the specialty area. That's the third time, and I won't say it again.

DR. LEONARD: But Agnes, it's not a coverage and reimbursement issue for physicians. I mean, a lot of what you're talking about are physicians knowing what to do with this information. They can bill for that already, so it's not really a coverage and reimbursement issue as much as it is an education issue.

MS. MASNY: But I think where we start to look at determining the qualifications of providers, then it does become an education issue.

MS. BERRY: I was building on what Debra said. We might want to look elsewhere in the report where this issue can be addressed. It is a coverage and reimbursement report, but we do address other related issues in boxes and other sections of the report.

Keep in mind, the problem that we have right now is that these recommendations, we're looking at wording in isolation. They fit within certain chapters or sections of the report dealing with very specific barriers.

The barrier here was that people who provide genetic counseling services, a lot of them can't directly bill. So this recommendation is designed to address that. What you're talking about is something bigger, broader, and has a pretty big scope, but it might be appropriately addressed someplace else in the report. Perhaps not in this recommendation, but maybe we should take a look.

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DR. LEONARD: Basically what you have is, I mean, this one is addressing people who are trained to do genetic counseling who can't bill. The other is those who aren't trained to do genetic counseling who can bill.

MR. LESHAN: Cindy, I just want to support what Agnes is saying, but I agree that there is no need to have it necessarily in this recommendation. But I think the intent of what she's saying should be reflected in the report somehow.

PARTICIPANT: The recommendation would be in Number 8, the next one.

DR. McCABE: There is a section of provider education and training, where it would seem to fit naturally.

MS. BERRY: Right. So I think that might be a good spot for it.

Barbara?

MS. HARRISON: What we have come to has settled better with me than what we had before. I also just feel compelled to say that I think we also need to appreciate that this is more than just a self-serving issue on behalf of genetic counselors or genetic nurses. It really is an access issue.

That was kind of the whole purpose of even going down this path was to increase the amount, to allow more of the public to have access to these types of services. As we talk more about it, it is just very much linked to this coverage and reimbursement issue.

So that I guess just to take the focus off that it's not just because genetic counselors want to be paid to make a living, it is really because it becomes an access issue. As was shared by some of the public comments, sometimes the genetic counselors, there is only one in a large regional area who needs to be able to bill. Without that, individuals in that community would have to travel hours and hours to get to quality genetic services. So I just want to make sure that that stays in the front of our minds as to what was the purpose of this whole recommendation.

MS. BERRY: Are folks satisfied with this Tuckson/Berry amendment as further amended? Are there any other changes, edits, suggestions, comments to this version up here for the first bullet of Recommendation 7?

(No response.)

MS. BERRY: We haven't gotten to the other ones yet. This is probably the hardest one.

Let's go back to the other bullets. Go back to your Recommendation 7 list. Do you want to vote on each bullet?

DR. TUCKSON: I was actually just sort of thinking that.

What are you saying, Deb?

DR. LEONARD: Why don't we just do all of 7?

DR. TUCKSON: All right.

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DR. LEONARD: Are there other issues?

DR. TUCKSON: Well, we'll go through the other ones, but let's just say that even without a formal vote, we'll do it. So if anybody goes back over this again, you're in deep trouble.

(Laughter.)

DR. TUCKSON: So we got this one. It's locked away.

Go ahead.

MS. BERRY: All right. How do we get this Number 2 bullet? The second bullet has to do with prolonged service codes. Secretary, directing government programs to reimburse prolonged service codes. Does anybody have any problem with that? Objection? Edit, wordsmithing suggestions?

Emily?

DR. WINN-DEEN: So the only question I have on that was I thought one of the issues was that even the prolonged service codes are prolonged enough for some of the genetic counseling services. So do we need to say something about establishing codes that have appropriate time frames for genetic counseling?

MS. BERRY: Do you think about the following bullet where we go into assessing CPT codes, E&M codes, to determine their adequacies?

DR. LEONARD: Maybe we should reverse the order of those two bullets.

MS. BERRY: That might help.

DR. LEONARD: Yes.

MS. BERRY: Does that do the trick you think? It's hard to tell. We are having formatting issues. We've just moved the third bullet to be ahead of the second bullet.

Hunt?

DR. WILLARD: Well, my memory on that issue was that although Emily's point was one of the points we considered, we didn't want to be on record as trying to tell people what the right amount of time was for genetic counseling services. There are physicians who are supposed to see patients every 15 minutes, and yet I don't think any physician would claim that was adequate to do what they're supposed to be doing.

PARTICIPANT: The other bullet addresses that.

DR. WINN-DEEN: I'm fine with just changing the order and having it handled that way.

MS. BERRY: We've kind of moved to Number 3, so let's take 2 and 3 collectively. Any suggested edits and changes to either of those?

(No response.)

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MS. BERRY: Hearing none, the next bullet, this has to do with the National Provider Identifier.

DR. WILLARD: Can you clarify the problem that this is supposed to be addressing? I'm stumbling on the use of the word "currently" here. The word "currently" suggests that if the Secretary changes anything, or if CMS ever changes anything, then this recommendation wouldn't carry forward to new people who are added to the list. So is the word "currently" actually needed here?

MS. BERRY: No. Plus that, it's a split infinitive.

MS. GOODWIN: The word "currently," the provider identifier system that CMS currently uses is in transition at the moment. So currently they use the UNI provider identifier number as our system. Right now any health care provider cannot bill Medicare directly for their services that's not eligible for a UPIN number.

In 2006, they have a new system that's being implemented called the National Provider Identifier. In that case, anyone who can bill any health plan directly in the U.S., public or private, is eligible for a national provider identifier. So the "currently" is inserted just because of the transition point.

DR. TUCKSON: Is there a way to refer, rather than using this term, which, I mean, I agreed with Hunt until you made that point, but it's kind of an arcane point of what the interpretation of "currently" is.

What is the system referred to now? I mean, could we just specify so that somebody is not reading this in 2008 and thinking currently in 2008.

DR. LEONARD: Can we insert under the whatever the current identifier number is system?

DR. McCABE: Can we name the system that is currently in place?

DR. LEONARD: Can we get the attention of Cindy and Suzanne first, and then we can ask that question.

MS. BERRY: We're trying to figure out is there a way to mention the current existing mechanism.

DR. McCABE: Can you say "prior to 2006," or "prior to implementation of the National Provider Identifier" would be another way.

MS. BERRY: Who suggested taking this out?

MS. AU: I think that there was some testimony saying that it was not. You should take it out because you can do it already. Could it just say starting in 2006, they'll start it? By the time this report comes out, they'll probably have it.

DR. TUCKSON: So James, do you know the answer to this? I mean, is it already done?

DR. ROLLINS: Currently, we use the UPIN number. But as of January of '06, it is going to be the National Provider ID Number. I'm sorry, National Provider Identifier Number.

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DR. McCABE: Will there be a natural transition? I mean, everybody who is currently under the current system will move over to the new system?

DR. ROLLINS: I will make the assumption. I'm not sure.

DR. TUCKSON: We've got some people in the audience who seem like they really know. You're going yes, yes, yes. Heads are bobbing up and down.

DR. McCABE: So then I suggest we delete it.

MS. BERRY: Well, apparently there are some people who do not currently have a UPIN. Therefore, they wouldn't be swept up in the transition to automatically receive the National Provider Identifier. So this recommendation is aimed at that little group. For the life of me, I couldn't tell you who they are. But apparently there is this group.

So if they don't have a UPIN, we want to make sure that when the NPI takes effect, that they would be eligible for that if they can directly bill.

DR. McCABE: But that's not what this says. I mean, it is getting more and more arcane the more we discuss it.

DR. TUCKSON: In other words, isn't it simply saying, are we overreading this? That basically if you are able to bill directly, you need a National Provider Identifier? So we are simply saying that they should all be eligible to get it. If they are automatically eligible, then the point is moot.

DR. LEONARD: As long as they're permitted to bill directly.

DR. TUCKSON: Right. Who are permitted. So take out "currently" and you've got this done. "Currently" goes, and you're solved. Going, going, gone. Next?

MS. BERRY: Do you want to take out the word?

DR. TUCKSON: Just take out "currently." It's a philosophical issue. So you're now down to the last one. Don't get happy, because you're still going to have to work. You've still got one more thing to do after you approve this.

MS. BERRY: All right. The last bullet here, this addresses the issue identified in the report that having to do with the inadequacy of certain codes. It is asking the Secretary to direct CMS to allow non-physician health providers who can provide genetic counseling services and who bill incident to to be able to utilize the full range of CPT and E&M codes available for genetic counseling services.

I think there was somewhere in the report a mention of the fact, if I recall correctly, that there were some codes that were not widely used. They can only use 99211 CPT code. So there are others that may be more appropriate.

So this bullet within the Recommendation 7 is aimed at that particular problem. Any suggestions or edits?

DR. TUCKSON: What is the change from professionals to providers? What was the difference there?

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MS. GOODWIN: Consistency in terminology.

DR. TUCKSON: Consistency in terminology. Thank you.

DR. TURNER: Is the attachment going to go as part of the document? Because I would offer a correction to it, if it is. The chart.

MS. BERRY: The chart? No.

DR. TURNER: Okay.

MS. BERRY: That's just for our discussion.

DR. TURNER: This terminology of certified nurse specialist is clinical nurse specialists is how the profession addresses that group of people.

MS. BERRY: The chart won't be part of the report.

DR. TURNER: Okay.

MS. BERRY: Or the recommendation.

DR. TUCKSON: The chart was to keep us straight.

MS. BERRY: Deb?

DR. LEONARD: Could I also suggest that we move this last bullet up under what is now the second bullet? So that we talk about evaluating the E&M codes, that those E&M codes can be used to bill, and that they pay for them would be now the third bullet.

MS. BERRY: Does that capture it? We just moved it up.

DR. TUCKSON: All right.

MS. BERRY: Hunt had something.

DR. TUCKSON: We are going to listen to Hunt.

DR. WILLARD: I would like to react to Barbara's comment earlier for the preamble here, and consider adding in the second sentence. It currently reads as such, "SACGHS recommends the following." Say something like, "As such, to ensure full access to genetic counseling services for all Americans, SACGHS recommends the following." Just clarify our motivation and get it out there and take the high road. I think Barbara's point was an excellent one, and we should jump on it.

MS. BERRY: Say that again.

DR. WILLARD: "To ensure full access to genetic counseling services."

MS. BERRY: She is angry again here. She needs some anger management.

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DR. WILLARD: I would leave "as such." There is nothing wrong with "as such." "To ensure full access to genetic counseling services for all Americans."

DR. McCABE: I liked it in all caps.

DR. WILLARD: "For access to" or "for access for."

MS. BERRY: Access to.

DR. WILLARD: "All those who live in the" --

DR. TUCKSON: All right. We have a pretty clear statement here. Does anybody have any issue with this? I think it's actually a very nice addition. Is anybody concerned about it?

(No response.)

DR. TUCKSON: If not, we have a full range of recommendations for this Number 7 that we have discussed at length. I think a very productive discussion. I am looking for a motion.

DR. McCABE: So moved.

DR. TUCKSON: I'm looking for a second.

PARTICIPANT: Second.

DR. TUCKSON: All approve, raise your hands, please.

(Show of hands.)

DR. TUCKSON: Anyone against?

(No response.)

DR. TUCKSON: This is important to note. It was unanimous.

Let's move onto the next one.

DR. McCABE: I just want to applaud the committee for being both logical and consistent.

DR. LEONARD: Can I make another motion to take a break now? Or do we have other stuff?

DR. TUCKSON: Okay. That's actually a pretty good thought, actually. Here is how it works, though. We want to be fair to you and your brains. At 4:00, our friend Raynard Kington comes in for our ceremony, which we are looking forward to. Then we come back and continue to work. So it is sort of an artificial break.

Why don't we do this? Let's take a 5-minute break now, and then we just keep plowing through until Raynard comes, and then we come back and finish up. I'm more than happy to do that. A 15-minute break? We're way ahead? All right, 3:30 is a convenient, round number. So 3:30.

(Recess.)