

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

DR. TUCKSON: All right. We're going to move to something which, again, we need to be very disciplined on our discussion of this billing and reimbursement. You have a page in front of you.

Does everybody have it? I'm going to just take you through really quickly just the logic of this. Then when we discuss it, we need you to be focused in on the logic and on where you are on the page. We can't have people going all over the universe today on this. We've got to bring this to closure.

Number one. What this paper says is let's get on the table or off the table. The question of whether or not today genetic counselors who are certified ought to be able to bill independently, because they in fact have a certification that would thereby make that possible.

So the language sort of says right now, do we believe that there is sufficient reason, is there a reason overcoming the barriers that we identified in this report, is there a reason to warrant, and are there sufficient evidence, criteria, and processes that would support a recommendation that non-physician health professionals who provide genetic counseling services that are deemed qualified should be able to bill directly for their services.

Would this apply to all payers? Or only public insurance? Such a recommendation then would in fact allow these health professionals to independently practice genetic counseling. That's first.

If we said that that were true, if we believe that that is a recommendation that we would want to make, then the question would be how you would implement something like that. Would you take as a strategy that licensure where available, then be able to use it because they had licensure in a certain state?

In those states where it was not available, that because you were recognized by the ABGC, or the GNCC, that that would be sufficient to allow that to occur. Or that you'd leave out the licensure part altogether and just simply say, let's just make it the certification. Or that the Secretary would use his leadership to influence the establishment of a single body that would oversee the certification of providing these genetic counseling, similar to the role played by the ABMS for physicians that would have the functions as listed there.

This "or" after that should not be there. It should simply be that this needs to be done expeditiously if it were to occur. So again, it would be that the train would start to leave the station, and while it is leaving, the Secretary would be asked to use his influence to help facilitate the creation of this body that would continue to study it, even while the event was already begun.

If you believe that there is not sufficient evidence to do this today, that we're not going to make this recommendation and we can't make that recommendation, would we then say okay, we've got to urge the creation of a body to answer the questions that we are unsure about, and that that needs to be done expeditiously with perhaps some hope for time scale to determine the answers to things like which providers are qualified under what conditions, under what supervision, and how they should be reimbursed.

This analysis should also assess the effectiveness and value of genetic counseling as delivered by various health providers in different settings, assess how barriers to billing and reimbursement are

affecting patient access, and so forth. So those would be the things that would be called for urgently and quickly to get done.

Then in the interim, while those things are happening, whatever it is that is going on, because it will take time, either one, Option A or B, there are certain things that we worked hard on yesterday to agree on.

That was in the interim, the Secretary should direct government programs to reimburse prolonged service codes, HHS with input from the various providers of genetic counseling service should assess the adequacy of CPT and E&M codes, non-physician providers who are currently permitted to bill directly under any health plan should be eligible for an NPI, and then finally, that for those who are billing incident to a physician should be able to utilize the full range of CPT and E&M codes. So that's the logic, that's the flow of it.

So the first thing to get on or off the table is what do you believe about the need and/or, relatedly, the ability to make the determination right now that genetic counselors who are in some ways certified should be able to counsel independently and bill independently? What is your thought about that? Put it on the table, or take it off the table? The floor is open.

And Debra Leonard is not here. Let me just get her point in right away. Debra has been emphatic to the point of she jabbed me in the chest when she was talking, make no mistake that she believes that the answer is yes, that they should be able to. I'll get to what her strategy for implementing that is. But she is one person that says it should be done now.

Barbara?

MS. HARRISON: And I as well say an emphatic yes. Under yes, I think that we should say the first statement wherein states licensure is available, skip the second one and go to the third one where the Secretary would use his leadership. Also --

DR. TUCKSON: That's all. You only get on that one.

MS. HARRISON: Just for clarification.

DR. TUCKSON: Okay.

MS. HARRISON: The "in" in the interim part is going to be there regardless? Is that what you were saying?

DR. TUCKSON: Yes.

MS. HARRISON: Okay.

DR. TUCKSON: Yes, that's already there. Okay.

DR. FRIES: I also fully agree that there is sufficient reason to recommend that they be able to do this. I think that genetic counselors and certified nurses have established a training program and an evaluation process.

I think it is very clear. I think we also had adequate demonstration of that before. I think that if you look at the proof of practice, it is already demonstrated. So I emphatically believe that yes is

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the answer for this. I would recommend that the third comment there, "Secretary using his leadership and influence to establish a body of certification," I think that would move towards assisting this group in obtaining licensure.

Once they had licensure, this would be a no-brainer. It would already be established.

DR. TUCKSON: Okay. Other comments, please?

Yes, sir?

DR. ROLLINS: I think that licensure and certification is not sufficient to make a recommendation that non-physicians be able to bill directly for services.

From our discussion yesterday, as I said, if we're going to be using evidence-based medicine as a basis for making recommendations, they did not provide evidence that non-physicians were able to effectively make those type of determinations compared to other groups.

There were not enough studies from an evidence-based perspective which would justify my opinion.

DR. TUCKSON: So we've got three that are saying yes, and one so far saying no.

MS. BERRY: I would say yes with the caveat that when we were talking about Medicare and I deferred to James and others, we can't, and the Secretary can't just declare, we are going to now allow these folks to directly bill Medicare. I believe it would require some sort of change in the statute.

Correct me if I'm wrong. If that's the case, then our recommendation should be more towards urging the Secretary to work with Congress on legislation that would do that. In doing so, it would be incumbent upon the different groups to convince the sponsors in Congress and to convince the Secretary to provide the evidence that James is talking about.

DR. TUCKSON: Okay. So James, you have to take away your philosophical hat. We are not at a technical question purely in terms of if we were to make such a recommendation, now we are talking about the language.

So can the Secretary cause this to occur, or does it have to be a Congressional change?

DR. ROLLINS: I think it would require a Congressional change. But also, I would say that if there were some type of demonstration through the use of some types of studies which show that they were as effective --

DR. TUCKSON: Different issue.

DR. ROLLINS: Okay.

DR. TUCKSON: Okay. So the answer is that for those who are saying yes, that this should happen, the technical way in which a yes gets transmitted to the Secretary is that we recognize that he or she may not have the power to by the stroke of a pen, cause it to occur, but it has to work through the Congress. That would be the language. So that's just a technical issue.

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MS. BERRY: Just for Medicare. Now, the private sector, that's a different thing.

DR. TUCKSON: Right.

MS. BERRY: We can make all sorts of recommendations that is harder for the Secretary to influence.

DR. TUCKSON: All right. So we're at four to one.

DR. FITZGERALD: I would also like to say yes. Maybe take into consideration the fact that when we talk about evidence-based medicine, we always have to look at who were the people who set the standards for what counts as evidence? How do we go about getting that evidence? What sorts of motivations have there been in the past to get that evidence?

If this profession is seen in its proper role as a profession to be reimbursed, then of course that will also help I think instigate more research into how it can be done better, which of course will be based on studies that will look at the evidence. I'm sure the evidence will confirm what we're saying, but it will also lead to the sorts of improvements and the sorts of gathering of data that we're talking about that would also be a good thing.

So in one sense, there is a bit of a Catch 22 here in the sense that there hasn't been the motivation, and there hasn't been the emphasis in the past to gather the evidence in such a way as to answer those specific questions. I think people's experience can also be seen as evidence.

DR. TUCKSON: We're at five. By the way, I did a disservice to the conversation by not making one statement up front. Let me rush to make it. It is this.

We had a lot of discussion yesterday about this issue that got to the nature of respect for these professionals. I have talked with almost everybody on this committee at some length about these issues. The one thing I want to take off the table for this discussion is that there is not a single person around this table who has anything but respect for the professionals who are working so hard to do this kind of counseling.

Those who may feel differently about this issue do not come at it because they don't care or respect their colleagues in this field. I want to just make sure that that is on the record.

I think it is a very important point, because otherwise, it could have the effect of chilling the discourse. If you are viewed as whether or not you are up or down on genetic counselors, you get beat up when you walk to McDonald's.

I don't want that to be on the table. That is not appropriate to do that to anybody on this committee. Let's move around and see if there is anybody else.

DR. TELFAIR: Thanks, Reed.

You saved me from having to say that. That was going to be my comment, because I'm voting no on this. I'm voting no because I do think that it will be a stronger case if you take the effort of building the evidence.

Clearly what is in place right now, from my understanding from yesterday, and if I heard it wrong, I apologize. It is still in the early stages. Everything is in the early stages. Even those

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who have received this level of verification are only two or three years out. So there really hasn't been enough time to build that evidence.

It seems to me that we need to really push doing that a little bit more. So that's where I'm coming from. I am one of the ones that really pushed to expeditiously get it done. I think it can be.

DR. TUCKSON: Agnes, Hunt, and then we'll go around.

MS. MASNY: I would say yes, that we should go for the first proposal. The one thing I think that when the committee presented yesterday is that I don't think that they were asked to actually present all the evidence base about what we're discussing now that the genetic counselors or people that are providing these kinds of services actually do provide efficient, cost-effective, or whatever it was.

I think that maybe if in fact we wanted that, that we could ask that specifically for this committee. But I don't think that would be necessary. I think that maybe if it had to go to Congress, that that information could be presented from the group itself to go along with that recommendation to Congress.

I would though say that I would rather have that without reference to licensure, because I think licensure is affected mostly by states. I don't, again, from the Secretary's perspective, know whether he has jurisdiction over state effects, certification by AGCC, GNCC, and other certifying organizations, since there are other certifying organizations.

DR. TUCKSON: But for right now then, you are on the yes side?

MS. MASNY: Yes.

DR. TUCKSON: Hunt?

DR. WILLARD: Just a point of clarification and correction for Joe. The profession of genetic counseling has been around for 20 years.

DR. TELFAIR: That was not my point. That was not what I was saying.

DR. WILLARD: But it was interpreted that way by some. Good.

I'm still where I was yesterday. I'm persuaded by the statement, particularly from James, that there is just not a base of evidence sitting in the literature that tells us yet, those of us who have done this on the front lines, that this is in fact a critically important field that is making a valuable contribution, and a contribution that is absolutely in the middle of the road in terms of how to bring genetic information to the public at large.

So I recognize that there is a gap, that the profession of genetic counseling is likely to be critical to filing that gap, and yet I don't see in the medical literature the data that would be necessary to make the case to the Secretary that in fact the drastic changes that I think are needed will be needed soon.

So I'd have to vote no, but would then urge that we change some of the language to be much more forceful about the expected role that we see for the profession of genetic counseling as we go forward.

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DR. TUCKSON: Okay. We'll come back to that, then. All right. I missed a hand here.

DR. FRIES: Yes. I just wanted to point out that while evidence-based medicine is a wonderful tool for all of us to evaluate our practices by, unfortunately evidence-based medicine does not apply to every medical practice that we do and that we reimburse for.

For example, there is not a lot of large randomized, blinded, control trials just about anything in genetics. So if we use that to drive our old policies, I think we are being premature in this. Much of medicine does not have that basis. That doesn't mean that it is not justifiably reimbursed.

DR. TUCKSON: Good. All right. Here is what we're going to do. I'm sorry. A comment?

DR. ROLLINS: I was just going to make a response to that. It is true that a lot of activities that we do in medicine, there have never been randomized clinical trials to show that they work. But that doesn't mean that observational studies were not performed.

You might even have to resort to such things as a cross-sectional study to use as an evidence base. But it is sort of like what David Eddy has said. Seventy percent of the things that we do in medicine have never been tested to see whether or not they work. We just do them because we think they work. Because of that, we tend to justify what we continue to do.

DR. TUCKSON: All right. This has been a very good discourse. Very rarely do we actually take votes on stuff, but right now I need to just sort of take a vote of the committee.

I wanted to have the ex officios who weighed in, I counted your votes, because first of all, you're valuable here, and it is important to hear you. You had a lot to say about this.

I want to see right now for the committee members that are here. Wait a minute. There are seven? Now, we had Debra. She clearly left. So does she count in the seven? I think she was pretty clear. There was no question about it.

MS. CARR: She makes eight.

DR. TUCKSON: She makes eight? All right. Of the eight committee members that are here, those members who are here who are voting yes, would you raise your hands?

(Show of hands.)

DR. TUCKSON: So we've got one, two, three, four. Okay. And those that are voting no, what do we have?

(Show of hands.)

DR. TUCKSON: One, two. So four to two. I'm trying hard to be diplomatic.

DR. FITZGERALD: I'm not a voting member yet. I haven't passed through the hoop of fire.

DR. TUCKSON: You actually would have tipped it more towards the five to two than the four to two, if I understand you correctly. So that's what that is, which is an important sense of the committee. So I think the committee has got a sense of it. That's where we are on the issue.

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Now the question becomes how do we phrase the recommendation about how this would go forward? So now, let's specifically focus in on, and I'd like to put as the first way of focusing in on this would be, I'm looking for the greatest agreement possible.

I'm wondering whether that is around the language of the Secretary using leadership to expeditiously cause something to happen. I'm just trying that first to see where that takes me. Now everybody has got to get on board. We decided that we're going to make a recommendation.

Now the question is how do you make that recommendation work? Who has got a thought there now about which of these options is the best way to make this recommendation happen? What is the most responsible way of getting this done?

DR. TELFAIR: Reed, a point of clarification before we get started.

DR. TUCKSON: Please.

DR. TELFAIR: Does the vote for yes negate the need to gather information independent of how it is done? There are varying ways. I agree with James that there is more than one way to gather information. I am just wondering whether those who voted yes, because that is not on the list.

DR. TUCKSON: The answer is that what I was trying to do by making that sort of point of departure now by saying the Secretary gets involved, and that all those sort of gathering the information things are the things that we urge the Secretary to cause to happen, is a way of trying to close the gap between the yes's and the no's.

Now, you can decide of course to do it a different way, but I was being fairly transparent, or trying to get everybody at least on a common next step. But it may not work. So please, who has a suggestion about how now based on the things that are on the page and/or something new, about how do you achieve this.

It has got to be a specific recommendation, it has got to take us from Point A to Point B. We can't talk about the theory of it anymore.

DR. FRIES: I was going to ask Barbara specifically as a genetic counselor herself, what area does she feel would specifically benefit the field the most.

MS. HARRISON: I think a general recognition of genetic counseling as a legitimate field, legitimate service, is really what would be most helpful. I think everything after that will fall into place.

DR. TUCKSON: So you got that. That is already done by the vote. So now what do you do? How do you implement it? So let's be specific.

Do you say that everybody who is right now an certified ABGC or GNCC would be someone that we would urge the Secretary to, and go back to the language that Cindy said again, the Secretary for the government has got to urge Congress to say that if you have those degrees, those certifications, you should be able to go right in and do it now? Or do you say that you want the Secretary to cause the right people to be pulled together to give the best advice as quickly as possible to answer these questions about how to do it, and then take that to the Congress? Do you take it as one step, or two steps?

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MS. ZELLMER: Maybe I'm totally misunderstanding. I think the things on back about direct billing for prolonged services in the CPT codes, I think all are very important. All of the things on the front, to me, I'm not really sure. I think they affect licensure, which I don't think we would have any role over, or certification, which again, I don't know that it's that important that we have some kind of national certification.

Maybe I didn't get the point of yesterday. But I think that do we need to even go here? I mean, I agree with all of the recommendations on the back, but are any of these recommendations under yes, something we really want to do?

MS. HARRISON: I think the issue of licensure and certification, I agree, may not be an issue that we specifically have purview over. However, the main impetus behind us even getting into this is an access issue. It is an access issue, and it is a quality of care issue.

That's where I think the licensure and certification comes under. So we're trying to make sure that the people who bill for genetic counseling services are qualified to do so, and I think we agree as a committee that genetic counselors are qualified to do that, that nurses are trained are qualified to do that.

That is where I think the licensure and certification comes in. Mentioning licensure here is no more saying that the Secretary has purview over that no more than me mentioning certification here. I don't see why it has to be either licensure or certification.

DR. TUCKSON: Kimberly, the issue really just became one of, and you are raising an important option. It is to stay moot about it. The question is how do you make sense out of who is in fact a legitimately qualified person. Right now, there does not seem to be any real organization that allows you to figure that out.

MS. ZELLMER: I'm not convinced that 95 percent of the physicians who give advice on genetics are qualified. I don't really see this as an access issue. I think that it is important that you get information from qualified professionals, but I think that that issue is a totally different issue.

I think it deals with the broader medical profession in general. I don't think that we should limit it to say we've got to get qualified genetic counselors.
I think we've got to get medical professionals who have a basic knowledge of genetics.

DR. TUCKSON: Good point.

Next?

DR. FITZGERALD: As far as the certification, I mean, one way since you're talking about it, could there be multiple steps to this. We have certification processes, and the training and everything like that. Could you start by saying here is the starting point. Genetic counselors and nurses who have gone through the certification program are going to be accepted as certified. Now you need some group to come and look and see if, as Joe was mentioning yesterday, are there others that would be included under that umbrella?

I mean, I think you've got a starting point with the ABGC and the GNCC. Then you can see from there where you might want to go.

DR. TUCKSON: All right. This is a very specific recommendation. That's a very specific step. So if we understand it here, it is the idea.

Kimberly, I'm trying to figure out what to do. But again, at the end of the day, there is a sense by many people, there is a need to try to understand. If somebody is going to say, I am a qualified person and I therefore should be able to bill for this service, and I should be able to do this service and get reimbursed, any reasonable paying organization is going to say well, who are you? Under what criteria are you saying that you are in fact legitimate and able to do it?

You're right, Kimberly. Your point is that you've got doctors and others who may not, but we're looking at this issue here. So the notion is that what we have as a specific suggestion is that you take the certifying bodies that exist today, and you say okay, this is a good starting point. Then you urge the Secretary, if I understand you, to create, or to try to use his influence to try to create or stimulate the formation of a body that would then deal with all the one offs that are going to come up, the single gene people, somebody without a Masters degree, who know who decides. I'm in the club, put me in the club. So somebody has got to figure that out.

You are asking for two things at once. Start one place, and then create an environment that figures out how to do it with all the people that are not in this group right now. That's a suggestion. So you've got something to shoot at. Now, let's decide. Is that the way to do it or not?

DR. TELFAIR: Can I just make a friendly amendment to this? I think it's important to take this suggestion if we're going to take it, and it be very clear about the nature of it.

There is a siloing of risk here. You need to eliminate that. If you're going to get groups to work together, it needs to be on common ground. So if we're directing or making a strong suggestion, then we need to make sure that the group, whatever is formed, is a group that works towards the common ground in a collaborative way to make this happen. I just want to add that language.

DR. TUCKSON: That's a very important point. And by the way, I want to make the moderating comment that Cindy's point is I think very, very important in a realistic way.

This is going to be subject to a public discourse beyond our recommendation. So that I think what we're doing is we're signaling a direction. We are also signaling caveats that need to be carefully considered in the interim period while this goes through the public policy discourse.

Again, the Secretary cannot just with the stroke of a pen make any of this happen. So we are signaling things that ought to occur, and hopefully stimulating a lot of people in this room, and those that are on the webcast who are listening to this carefully, to create the details that are needed. So we're fast forwarding this whole field simply by the recommendations that we're making.

That is what I think is ultimately occurring in this room right now. Somebody's hand I missed. All right. Specifically, is Kevin's point the one that wins or not? Somebody has got to knock it down, because right now it is gaining momentum.

DR. FEETHAM: I would just remind everybody of Barbara's comment. I mean, to me the three messages are the need for genetic counseling services, and we have been consistent on that language, by qualified providers who are of many disciplines.

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The point of access, I mean, this bottom line, again, for the good of the American public, what are we talking about? Those are messages. By the way, to do this, we need reimbursement.

DR. TUCKSON: All right. Kevin has got it on a going, going, gone basis.

Agnes?

MS. MASNY: Well, I think that if we went with Kevin's recommendation, what would happen is that that would actually limit the number of health care providers that people would have access to. I think we want to make sure that people do have the access.

The main point that I think we're trying to continually get at is that the public needs access to qualified health care professionals, and that genetic counselors are qualified. They should have access to reimbursement.

DR. TUCKSON: Now, I'm not sure though, and I want to respect your point, even in rushing this thing through. But I'm not sure that I see the limitation.

I think what Kevin is saying is you've got a place. You are signaling that we accept that there are some people who have created something that makes sense. Then he is saying expeditiously let's get to the process of how do you create the requirements, the conditions, and the processes that allow others to be designated. I don't see how that is diminutive.

MS. MASNY: Not diminutive, but in terms of limitations that we are now going to create another sort of more centralized body for certification.

DR. TUCKSON: Right. Now, the philosophy here, just to make sure that everybody is clear on this, is that you could then, the alternative, and I don't know whether this is what you have in mind. The alternative would seem to be that every organization with an interest in this could then certify, designate, and say okay, well, me, too.

So at some point, you are sort of left with if you are trying to pay for this, or you have to administer this or make use of this, or worry about a malpractice of this, it is like well, who are you? I mean, somebody somewhere along the line, and I think what he is saying is he has to make sense out of this so you don't have the wild, wild, west. I certainly don't want them coming to us.

DR. FRIES: It appears to me that there is some sort of a parallel for this in thinking about it in the capacity of certain physician skills. For example, if I am someone who wants to just simply do spinal surgery, I must first of all qualify as an orthopedist, and then perhaps do a subspecialty in spinal work, and then I only get to work on the sacrum.

I have made that my derivative. The same way for someone who is a single-disease counselor. That person must first of all qualify in the general capacity before they can then focus. So the point I'm trying to make is that there is an existent certification process for someone in general. If someone chooses to be in a very minor part of that practice, they must first achieve that, and that's already in place.

DR. TUCKSON: So what I think you're saying, for the purposes of this activity, is A, we are not trained, smart enough, or have the time to figure all that out. B, we know that somebody needs to

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figure it out, and we are urging the Secretary, therefore, to figure it out, or to use his influence to convene those that are necessary to figure this out.

DR. FRIES: That's sort of an overview of what I was commenting on. But the point that I'm saying is that there already exists sufficient certifications in place.

DR. TUCKSON: So those are models that might be used to apply to this activity. Or are you saying push this into existing forums that are already created to do this kind of work?

DR. FRIES: Certification in some field. For example, to become an OB/GYN doctor, I go through a board examined to certify. That's already set in place. Same process for genetic counseling.

Licensing, as we all know, is a state process. The reason I raised my question to Barbara was not that I think the Secretary has to do this, but whether that would be politically the most advantageous thing to the genetic counselors, or whoever is going to do it, to help them move forward.

DR. TUCKSON: All right. I saw one other hand. I want to do that. I missed you. In fact, it was you, Kimberly.

MS. ZELLMER: The only question I had is whether this is really what the genetic counselors want. I think if they would like us to give the message to the Secretary that we need some national certification to make sure that people are qualified who are giving genetic counseling services, I'd be much more supportive of it.

But I guess I just would want to make sure that that is what they are interested in.

DR. TUCKSON: I guess the challenge we have there, and Kimberly, I appreciate that. We did hear wonderfully from the genetic counselors yesterday. They gave us good input. At some point I think the committee has to decide what it thinks it wants to do. We got a lot of input. We have differences of opinion even around our own table. So I appreciate the point.

The genetic counselors were able to express, if I can try to summarize what we heard, that they have their mechanism. There were a couple of organizations that spoke eloquently about what they do. Even in their own discourse, there were some issues that came up as to whether or not you only have Masters level nurses. They have their own challenges that they have to work through together.

What they did not do, and were not asked fairly, according to Agnes' point, they were not asked to, but they did not teach us about what to do with the single gene people and all the other permutations of issues. So we don't know quite what their guidance is on that point.

To conclude this. I'm trying to do a quantum calculus here to get your point in here. I can't figure out a way to do it, other than to simply say that I don't think that we can be more prescriptive than what we have gotten to.

I don't know whether it should be that this all goes and just gets pushed into the ABMS, which it can't, or something like that. At the end of the day, we can only do the best that we can in terms of this recommendation, and then let the process unfold as it needs to. We are making a pretty clear statement.

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This is a bold statement, I think, to make, quite frankly, in terms of moving this field forward. One that is of concern to a couple of our members. So I think we have pushed this pretty far. I think what the next step is, and again, by the way, the other issue here is that the reimbursement committee report is going to go out for public comment, so we're going to get a whole lot of stuff back anyway. This is not the last time we're going to see this. We are probably going to get beat up on all sides. Then we'll have done our job wonderfully.

Cynthia?

MS. BERRY: Can I just make a recommendation that sort of builds on what Kevin had articulated? That is, following the model of registered dietitians, the way they got some coverage under Medicare for medical nutrition therapy for certain cases, I can't remember now whether it was diabetes or cardiovascular disease, but anyway, something like that, there were a couple of indications was that Congress put into the statute that the National Academy of Sciences would conduct a study and look into many of the same issues that we have at the top of the back of this paper here dealing with cost-effectiveness, appropriateness, and all of that.

Then based on that study, and it was done, Congress looked at it and said, oh, for these two indications, it does make sense for these individuals to be able to directly bill Medicare for their services. Therefore, we will allow that to happen in those cases.

So what if our recommendation is asking the Secretary to direct NAS, or to fund some study mirroring, using the registered dietitian model. That would be a next step closer. It would obviate the need really for Congress to step in initially and actually authorize the study. I mean, the Secretary theoretically could direct some funds that way, but it may ultimately be that Congress has to get involved. At least that would move the ball forward.

DR. TUCKSON: I would be surprised if there is anybody here under the reality that we've already moved the ball to the next step that wouldn't think that we don't want to wait for Congress to have to do that. I think your suggestion makes all the sense in the world.

Even those that were not in favor of the proposal were all in favor of expeditious. So I think you're talking about jump-starting that, and I think that none of us would disagree that we wouldn't want to say okay, we've got to go to Congress and get permission to do the analysis. No. So I think your point wins the day. I don't see anybody rushing to disagree.

DR. FEETHAM: I would just like to remind everyone that HRSA and NIH funded a three-year beginning study on the genetic workforce, which was interdisciplinary, looking at specialists, non-specialists, and primary care providers. If we could build off of that excellence --

DR. TUCKSON: That helps. Cindy has that and needs to roll that in. Here is what we're going to do next. We're going to bring this to closure. Here is what happens. I need a reality check from Sarah and Cindy.

The reimbursement policy coverage thing has been kicking around now for a good while, and has gotten better every day with all the input. What is our timeline for when we absolutely expect and must have that report go out for public comment?

MS. BERRY: Can I ask one thing? I don't know how you want to handle it, whether you want to blow them off or what, but we have two remaining recommendations unrelated to genetic

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counseling. I think, and I don't want to jinx it, but they're probably in the no-brainer category where we might get some pretty quick consensus.

Do you want to turn to those?

DR. TUCKSON: I'll suspend it for just a second. Thank you. Thank God you raised it. But just for the moment, what is the timeline of when this report has to go out?

MS. CARR: Right away.

DR. TUCKSON: Right away is the answer. So in other words, I think what that means, and let me just make sure, does that mean, therefore, that the one thing we are not going to do is to put in the things that we've done today and yesterday, all the work that we've done, and then come back and revisit it at the next meeting? We are actually intending that it goes out before the next meeting?

MS. CARR: Well, let me just say, it's always up to you. If the committee doesn't feel that at the end of this meeting they are ready to go out with the report for public comment, we can wait until June. I mean, I think you want to do something. I think your goal was to have the report finished.

DR. TUCKSON: All right. Second question. Would you, Cindy, be willing, and again, you tell me about the process, that given how much work we did on that report this meeting, that the committee, subcommittee, redo a last draft on this, and then it will go out before June, but giving folk if they have just any little comment they want to make, you can decide if we use it or not, but you can make sure everybody sees what it is going to be before it goes out for public comment.

Knowing again that going out for public comment means just that. It is not absolutely perfect. We're going to get some comments back, and then we'll come back and change it again. I think we're agreeing we're not going to wait until June to send it out.

The question I'm asking then specifically is would you object to having people at least send in some email comments on what will be now the last draft?

MS. BERRY: That will work.

DR. TUCKSON: That will work. Okay. With that, can anybody find their last two recommendations from yesterday? Those, by the way, who are public comment people, I hope none of you have to catch a plane, because we're coming to you, not too many minutes late.

MS. BERRY: The last two, it is on the summary document that was in everyone's folders. They deal with the broader issues.

Just to summarize the first one pertaining to provider education and training, it addresses the fact that there is a lot more work that needs to be done in making sure that the current medical workforce is adequately schooled in genetics and genomics such that they can provide the requisite care to their patients.

So this recommendation essentially pulls from something that was recommended to the Secretary last year. You can read it. It basically asks the Secretary to develop a plan for HHS agencies to work with state, federal, and private organizations essentially to help medical professionals so

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that they have the tools they need. It also urges the Secretary to incorporate genetics and genomics into HHS initiatives. That's the first one with regard to education and training.

DR. TUCKSON: Does anybody have any big issues with that?

DR. WILLARD: I move we accept it.

DR. TUCKSON: Going? Going? Going?

(No response.)

DR. TUCKSON: Done. Next?

MS. BERRY: All right. The last one. Public awareness recognizes the lack of knowledge or complete information available to the public with regard to genetics and genomics. States the fact that we need to get out to the public reliable and trustworthy information about genetic technologies.

It talks about the development of performance and efficiency measures based upon evidence-based clinical guidelines that would better enable consumers and patients to evaluate health plans and health providers.

Now, it's sort of vague and fuzzy. I don't know if we want to be more specific than that. It really doesn't say who will develop these things. It would be good to get some input from members of the committee as to what we might suggest here.

DR. WILLARD: This one doesn't actually read like a recommendation. It is just a statement of motherhood and apple pie, which is fine as a statement. That's actually in the text. We're not actually making a recommendation to have the Secretary do anything. So I'm not sure we actually need it. The text I think stands pretty well by itself.

DR. TUCKSON: Yes?

DR. KHOURY: The only thing that might apply to HHS is to provide direct recommendations about initiatives like the Surgeon General Family History Initiative, which is something that HHS is spearheading anyway to encourage, suggest, or whatever language you want to use.

By the way, if such a recommendation is changed, I would suggest to add the words "family history" somewhere.

DR. TUCKSON: Well, I think what this is getting at, I mean, I think everyone understands it, but again, this is the consumerism movement where now people are having to make more choices that are financial risks for them about where they go for care, and the nature of the benefit packages that they are offered.

So what this is sort of getting at is saying I think what the recommendation would be, Hunt, is be more around the Secretary of Health making available through government Internet websites, information that helps a person make better and more informed choices in this regard.

Including family history would be part of it. So I'm one of the people that are addicted to the National Library of Medicine website.

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DR. FITZGERALD: PubMed.

DR. TUCKSON: PubMed, that's it. So in other words, the Secretary would sort of help make sure that this kind of information was on a PubMed kind of site.

DR. WILLARD: But do we have enough information? At least I don't feel I have enough information to say whether that should be the Surgeon General's site, or it should be a CDC site, or any other site.

DR. KHOURY: It should not matter as far as this committee. You ask HHS to do it, and then we figure it out.

DR. TUCKSON: So you are saying use such resources to make this information available to the public. Guidance and education to the public. That is what this is getting at.

So with that as perhaps a friendly amendment, we would urge the Secretary to make HHS resources appropriately available to guide people in making these kinds of choices and decisions. Okay, done.

We are going to conclude this and move to the public comment. Let me just say this. Let me ask one favor of you in terms of the report that Cindy sends back out.

It would be this. Normally I'm not a big fan of people who if you send them an email to a multiple list, and then they've got to tell you yes and send it to everybody so that you've got 1,000 emails that don't make sense. In this case, I think it does make sense that if you make a comment on the report, you might want to click everybody, so everybody sees the comments that are going back and forth.

At the end of the day, Cindy and the committee have the responsibility for taking that stuff and weaving it into a final document. But I think in this case it is probably better that we all sort of share our thinking and thoughts. But you don't get to reargue the issue, that's the only thing. The issue is resolved. Now the question is how do we do it?

You all are terrific. You guys are a terrific committee. Even when people don't agree, you work together. You are a model of democracy.