

**Overview of Public Comments on SACGHS' Draft Report**  
*Cynthia Berry, J.D.*

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DR. TUCKSON: Now we're going to move into an important section of the meeting. We'll devote in fact almost the rest of today until 5:00 with a break for a very wonderful awards ceremony for some people who seem eager to leave us so they can get more involved in activities.

As I noted last year, as I noted earlier, we determined last year that the coverage and reimbursement of genetic tests and services were a high priority requiring in-depth study. We started working at it in our March, 2004 meeting.

We gathered perspectives on the issues from experts on this issue on public and private coverage payment policies and genetic tests and service providers. We appointed a task force to investigate the issues more deeply and discussed the finer points of our recommendations at the February/March meeting.

After the last meeting, we solicited public comments on our what we considered to be our really ultimate draft report. Cindy Berry, who has been just terrific leading our task force on this issue, will provide us in a moment with a summary of the public feedback and lead our discussion.

You have in your briefing books a compendium and summary of those public comments in Tab 4. I want to tell you that the task force members, Emily Winn-Deen, Debra Leonard, Mark Williams, Muin Khoury and Jim Rollins at CMS, have really done a terrific job and have worked hard. I also want to acknowledge Suzanne Goodwin, who has been nothing short of terrific in providing support for this committee.

Now, let me just sort of say, again, as I sort of alluded to at the beginning of the meeting. We really worked hard at the February/March meeting to get some decisions made. We made some decisions. Now, that meeting was challenging, not only for the complexity of the decisions, but also we have a lot of people moving in and out, people here and not here, I mean, it was just really hard work.

I think that the committee owes it to itself today to be fairly disciplined about how it approaches this. Cindy and Suzanne have worked real hard to give a fundamental foundation of sort of the recommendations. How we got here. What the decision points are and were that sort of led us to where we are. By the way, this is the 18th time we've gotten public feedback. We have been getting public feedback and rewriting this thing. This is the 800th draft of this thing. I want to tell you, it has been seen by so many people and gone through so many revisions.

The point I'm getting at is I hope that we'll listen carefully to the public comment and our comments and see how they fit into the decision points, not starting us back all over again from ground zero. How do specific comments fit into yes/no decisions. Go down this road, go down that road, does it change it. But let's just stay focused on the task at hand as opposed to going all over God's green earth again. So I just give you that in my role as being the bad guy.

Now I'll turn it over to the good guy. So Cindy Berry, take us away.

MS. BERRY: Reed doesn't want me to tell you this, but he's got a little buzzer in there. So if any of us gets out of line, we get shocked with some juice there.

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I also wanted to thank Suzanne and others on staff. Tremendous, tremendous, work. If you can imagine, you've seen the report and you've seen the different iterations, how difficult it is to not only write that report, but then to synthesize, analyze, and incorporate all of the public comments to the extent that they could be incorporated into the report, organize them. It was a lot of difficult work, and I certainly was not responsible for that. So I wanted to mention that.

This afternoon, this small presentation, which is a preface to our discussion and our rolling up of our sleeves to finalize the report will cover three things. Provide an overview of the report, we'll go over some of the public comments on the draft report, and then the third part of course as I mentioned, where we do the hard work, where we actually finalize the recommendations.

As you will recall, the report had several objectives. We identified a problem in the committee based on testimony that we've heard and other evidence that we gathered that coverage and reimbursement of genetic tests and services was a problem, and as a result, access was limited. We needed to do something about that.

So the purpose of the report was to describe the current state of play. What is going on in terms of coverage and reimbursement of genetic tests and services? Who is covering them under what circumstances? What is covered? What's not covered? Then the second purpose of the report is to offer recommendations to the Secretary on what we can do to fix some of the barriers that we identified.

The ultimate objective of course is to improve access and appropriate utilization of genetic tests and services throughout the health care system.

We came up with, as you will recall from our last meeting, nine recommendations. The report of course goes into great detail, as I mentioned, of the current state of play and all the different elements of our health care system. Peppered throughout the report are these nine recommendations.

This is the timeline we were operating under for the new members. This is just a quick overview for you. We did receive formal presentations by experts in March of last year. We had several drafts of the report that we were reviewing that we wrote and rewrote and considered. We put out a request for public comments formally in the spring of this year. We held a conference call within our task force to consider the public comments and determine what could be incorporated into the report, what revisions were necessary. Of course now we are in the phase where we are reviewing at the full committee level the public comments and trying to finalize the recommendations.

We hope to have another iteration of the report, a final version of the report sometime this summer, and transmit it to the Secretary in the fall of this year.

Briefly, I will describe the public comment process. As I mentioned, there was a notice that was published soliciting public comment. This comment was received, the deadline was May 6th of this year. We had other outreach mechanisms. We have a website, of course, as you are aware, the Federal Register notice. We have a distribution list which reaches almost 1,000 individuals, and through notices via that distribution list, we solicited comments from individuals and organizations. Then we did a targeted mailing to 34 individuals and organizations that we thought had particular expertise and that could help inform us on key issues that should be considered in the report.

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We received a total of 86 separate comments. Sixty-one individuals commented, and 25 organizations. There is a pretty broad base of stakeholders represented here in these comments. We have health providers, including physicians, genetic counselors, hospitals, public health agencies, nurses, health plans, academia, patients of course, and we even had some students commenting.

There was a school, let's see, Westfield State College in Massachusetts. They deserve special recognition for their public participation in exercising their civic duty. But they really actually had no choice in the matter. It was a final exam.

(Laughter.)

MS. BERRY: Their professor of human genetics, it was a human genetics course at the university, asked them to submit public comments, and they did. We of course read all of them. We considered all of them. Actually, I shouldn't say that we were surprised, but some folks might have been a little surprised at how thoughtful and insightful they were. So we thank them for those comments.

As I mentioned earlier, we had a conference call of our task force where we reviewed the public comments. Everybody had a copy, and everybody here at the full committee level has a copy. There was a chart that was also prepared for us so that we could organize the comments. We organized them in terms of the types of comments that they were, and what they were addressing.

Then we considered modifications to our recommendations based on the public comments. We did this at the task force level, because as you can imagine, when you have 86 different comments from different organizations and individuals, it's very difficult to weed through all of those at the full committee level. We don't intend to go through them now one by one.

What we thought we would do, and what we have done so far is to do that at the task force level. We waded through all of it. Then what we're presenting to the full committee are the public comments that address specifically the nine recommendations that are in our report. We are not going to go over today all of the other comments that dealt with language changes in the body of the report and some technical change and whatnot. We are incorporating those. They will be reflected in the new draft.

What we're focused on this afternoon are the comments that specifically address the nine recommendations. I also want to make a point that just because you don't hear, if someone in the audience who is listening doesn't hear their particular comment addressed, it's not because it was not reviewed and not considered and not even incorporated. What we're focusing on now are the areas where we made a very specific change to the recommendation, or it may be an area of controversy, or it may be an area that needs fuller committee debate and consideration.

So rest assured we have considered all of them, we have read all of them, and we are incorporating as many as we can. Today we are going to be a little bit more focused and precise.

As I mentioned, we had a list, and I think, is it in the binder, or is it in sort of the chart that catalogs all of the different comments? It is in the binder. You'll find it there. These tables and the charts that are in your briefing book, they have a list of the modifications. You have copies of the public comments. If you want to review the full panoply of comments, we can do that now. But you can refer to your charts as a way of better organizing your thoughts.

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We can talk a little bit about some of the themes that we saw in the public comments presented. In general, folks were very positive about the draft recommendations. They thought that we were addressing something very important, and they in general agreed with our committee's approach to addressing them.

There were some concerns expressed about how we characterized the extent of the access barrier. Some organizations felt that perhaps we may have been overstating it a little bit. Some individuals and organization have proffered different approaches for refining their recommendations. Then of course as I mentioned, there are others who provided more technical points and comments with regard to the language in the body of the report.

Carrying on the discussion of themes from the public comments. A common thread was the anecdotes that people were readily providing to us, illustrating the link between inadequate coverage and reimbursement and access problems that they face. We have a quote here where one of the commenter said, "My Medicaid patients cannot get the testing performed, which is recommended since they are unable to cover the remainder of the cost out of pocket." That's just an example of the types of comments we received there.

The second bullet goes to the comments that we received having to do with the problems resulting from inadequate reimbursement and billing mechanisms for non-physician genetic counseling providers. We received several comments there, concerns about out of pocket payment by patients, their reluctance to refer patients, problems finding and maintaining employment, salary issues.

I can read to you an example of some of the comments we received there. One commenter said, "As I cannot bill incident to my supervising oncologist, I cannot bill Medicare, and most private insurance and HMO plans are directly under my name. Patients, therefore, must pay for my services out of pocket without hope of insurance or Medicare reimbursement."

Someone else commented, "Many institutions are unwilling to hire enough of these skilled certified professionals because there is no reimbursement available for their services." Those are just a few examples. We had several to illustrate that point.

Many of the commenters encouraged us to specifically recognize ABGC and GNCC, the American Board of Genetic Counseling and the Genetic Nursing Credentialing Commission, in our recommendation regarding direct billing. Another series of comments had to do with considering the impact of the recommendations on health care resources and the long-term financing capacity of the health care system. Folks want to make sure that we keep in mind that any recommendations we put forward for coverage and reimbursement consider the fact that we do have finite resources in this country, and that we need to be cautious as we move forward. That last bullet characterizes the nature of those types of comments.

Now we'll go through some specific public comments on the recommendations, and how our task force proposed addressing them. We'll go through each one, making sure that we have the input from everyone on the committee, and that we can further refine our suggestions and recommendations. We'll get this up on the screen.

DR. TUCKSON: By the way, for the new folks, as this is going up on the screen, the other thing to keep in mind, which is one of the real struggles that we all have to do is because we all want to do a lot of things to change the world.

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We've got to keep remembering that these are recommendations and things that the Secretary of Health can do. We are an advisory committee to the Secretary of Health. This is one of the other issues that we have to stay focused on. Stay within the realm of what's possible, given our authority and mandate. That's key.

MS. BERRY: If you want to follow along, was this in the folders now? I just had it on the top of my chair.

MS. GOODWIN: It's in the packet.

MS. BERRY: Right. Where you have the first part of this packet as the slides that I just went over, behind that is a document entitled "Coverage and Reimbursement of Genetic Tests and Services: Revisions Proposed by SACGHS."

Follow along with that document, because that document contains the recommendation, it contains the edited changes that the task force has made, and then below that, it highlights some of the public comments, what we received, what we decided to accept, and the changes that we made. That will help facilitate the discussion.

The first recommendation pertains to the Secretary tasking a group or body to develop a set of principles to guide coverage decision making for genetic tests. We made a few changes there. Some comments we received saying that the second sentence of the recommendation that was originally in there, and you can see the blue line edits. People had some heartburn about that. They felt that that was either inappropriate or could cause some trouble. So we had some folks suggest that we actually just take that sentence out. We didn't really need it, that the rest of the recommendation adequately addressed the problems that we were focused on.

Another comment that we had, folks were concerned about the wording "therapeutic versus informational" benefit, and suggested instead some alternative language. We tried to address that comment there.

So you will see the two changes in blue in your document. We eliminated the second sentence of the original recommendation, and then addressed the issue of therapeutic and informational benefit.

I don't know, Reed, if you want me to go through and read the full text of the recommendation as it is, or just give everyone an opportunity to just review it themselves, and then solicit comment from the group.

DR. TUCKSON: I think giving them just a couple of quick minutes. Discussion is always informed best by actually knowing what the heck we're talking about. So we'll give you a couple of quick minutes, like study hall, but a couple quick minutes, and then go forward.