Medicare Payment Rates and Decision
Donald Thompson, M.S.

MR. THOMPSON: I was sitting in the back listening and taking an interest in Dr. Ferreira-Gonzalez' presentation, and it was so good, about halfway through I started thinking what idiot is in charge of the Medicare physician clinical lab fee schedule? And I realized that was me.

(Laughter.)

MR. THOMPSON: So not considering myself an idiot, I'm going to talk a little bit about how we do new determinations for payments, and then a little bit about how we got to where we are, because when I first took this position and I looked at the Medicare clinical lab fee schedule, I came to many of the same conclusions that some of the earlier presenters have came to. You have to dig a little to kind of understand the tortured history and kind of understand a little bit about how we end up in a position where you have some of those slides that were presented earlier that have such payment anomalies surrounding them.

But first, let me talk a little bit about how we handle new lab tests. We have two methodologies primarily for handling payments for new clinical lab tests under the Medicare clinical lab fee schedule, gap filling and cross-walks.

By the way, everything I'm saying here applies to all new technology under the Medicare clinical lab fee schedule. We don't have anything specific to genetic technologies.

So gap filling and cross-walking. Gap filling is a process where we essentially go to all of our carrier medical directors, all the medical staff in our contractors, and we say we have this new test that CPT has created, because the beginning of this process is a new CPT code. That's how this comes about. So we get a new CPT code that gets created, we go to our contractors, and we say we'd like you to kind of go through, examine this test, and look at a variety of factors that I'll touch on in a later slide, and determine a payment amount for your area. That's the gap-filling process.

The cross-walk is done in Central Office. So in cross-walking, what we say is we have a new lab test and a new CPT code, and we think that this is similar in certain respects to an existing test. We just cross-walk the payment amount to an existing test.

So those are the two ways. Gap filling, it's a decentralized process where we send it out to our carrier medical directors. Cross-walking we do in Central Office where we look at what existing tests under the clinical lab fee schedule might be appropriate and we cross-walk the payment to that.

We don't do this in isolation. We have public meetings. We have public input on this. The one for 2005 will be on Monday, July 26th, for those of you that are interested. Any interested parties can give testimony. The test kit manufacturers can come in. ACLA can come in. It usually comes in. AdvaMed gives presentations. Everyone gives us recommendations about how they think we should either gap fill or cross-walk and, in the situation of cross-walk, what code they think we should cross-walk to. We then take these tentative determinations and we post them on the web for additional public comment, and we make the final determinations usually around the early part of November, and that would be for the 2005 tests.

Gap filling. Let me say at the outset I'm not a huge fan of gap filling. It is a great process in concept, not fantastic in execution.

What we say on gap filling is a carrier should examine a variety of factors, and we do not weight these in any way. These are just kind of guidelines for them. Charges for the test, routine discount to charges -- so look what the lab is charging for it -- and look at the resources required to perform the test. Look what other payers are doing in your area, although as an earlier presenter mentioned, that's somewhat circular because to the extent that they're all keying off the clinical lab fee schedule, it's hard to look at what they're doing because they're waiting to see what we're going to do. Then charges, payment amounts, resources required for other tests that may be comparable or otherwise relevant.

Then in addition to kind of those core items that they look at, it's also clinical studies and information provided by clinicians practicing in the area. They obviously have a network of physicians that they can tap into. Manufacturers and other interested parties are allowed to submit comments to each of the carrier medical directors when they're making their gap-fill determination.

So kind of against this backdrop, which is how we've been doing it for some time, which is this gap filling versus cross-walking methodology, you have the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. There were two primary provisions in there that affected the clinical lab fee schedule and more of a secondary one that might have some long-term impacts, but let me talk about these two first.

As an earlier presenter mentioned, no updates to existing lab fees until 2009. That is a blanket freeze. There is no administrative discretion there. So there's not a whole heck of a lot we can do at CMS in terms of adjusting lab fees for existing tests until 2009. So some of those slides that you saw earlier that had some of those payment anomalies in will continue to exist for some time, and there are many stories in the clinical lab fee schedule like that. That is isolated to genetic testing by any means.

Then the other section, though -- there is a small ray of hope here -- in 942(b), Methods for Determining Payment Basis for New Lab Tests, it goes into a little bit about the need for us to publish regulations in this area. We have not had regulations in the past. Most of the payment methodologies under the clinical lab fee schedule have just been a past practice. They've kind of arisen over time and they have kind of self-perpetuated, but we do not have formal regulations, and our general counsel would indicate our past practice has the force of regulations. If we have an established process, we can't just say, you know, we think next year we're going to change the whole thing around. So the fact that we have past process means that if we want to change that, we have to go through a regulation and now what Section 942(b) does is say, okay, we're required to go through a regulatory process.

The odd thing, though is when you look at what Section 942(b) says, it describes to a certain extent what our current process is. So it didn't give a lot of guidance in terms of what Congress might have intended for us to under 942(b), other than one could envision the kind of process that we were currently using, which is get public input, the cross-walking, the gap filling.

So we're struggling with -- my last point there, differences from current process -- we're struggling with this and what we intend on doing is going through a formal notice and comment. So we will this year have a formal regulation, a proposed rule that we're going to put out, and we'll kind of go through what we think our interpretation of 942(b) is and seek public comment

on that. I'm very interested myself in seeing what kind of comments we get, and then we'll go through a final rule process after that.

So the issues for reform, we touched on the relative payment rates are essentially frozen, and this is for two reasons. Not only the explicit freeze in the MMA, but in addition, going into some of the history of the clinical lab fee schedule, it is the oldest fee schedule in the Medicare program. It dates back to the early 1980s. It is very archaic at this point.

However, there's no mechanism for revising it. There was some optimism that perhaps in the recent law we would get authority, that CMS would get authority, to revise the clinical lab fee schedule in its entirety. I mean, not just for genetic testing, but in the whole thing, look at it comprehensively and say what do we have here? We have a system where the clinical lab fee schedule was established in the early 1980s and life is a lot different now, but yet we still have these same relatives locked in place from the early '80s and it's difficult to get at them.

In addition, maybe give us a different methodology for adding new tests. The 942(b) was helpful in that respect, but it would have been nice maybe if Congress had more explicitly provided some guidance, but we will struggle through that from a regulatory standpoint.

To a certain extent, going back to some of the earlier slides, this is where the problem is. You have this 1980s fee schedule that we've attempted to kind of modify over time, even though the basic construct stays the same and we don't have any statutory authority to revise it. We've tried to modify it over time to make it work for new lab tests.

But as you can imagine, one of the immediate issues that comes about, think about cross-walking. Okay, you have a new test. You say this is kind of like this existing test, but the payment rate for the existing test was locked in in the early 1990s. So you're in a situation where the logical choice for the code -- you say okay, this definitely walks right to this code, this is similar, and this is how you should pay it, but the payment amount for that code doesn't necessarily make sense. So you're kind of in a bind.

So at that point, what do you do? You say, okay, we'll throw it out to gap filling and see what happens there, but because of the decentralized nature of that, sometimes the proponents of the CPT code can be nervous sometimes about going out to that gap-fill process.

It's a little bit of a Catch-22. You're cross-walking to what may be a mispriced code or you're sending it out to gap filling, which is a decentralized process where you have to deal with all our individual carrier medical directors.

So where does that kind of leave us? Not in a great spot. One of the things that we'd like to look at is there was an Institute of Medicine report that talked about revising the clinical lab fee schedule and they had a lot of excellent thoughts and suggestions about how we might go about doing that. Now, we have no statutory authority to do it, but at least we might make some more progress thinking about those thoughts.

Along those lines, one of the recommendations in that report was to look at kind of a competitive bidding process. For those of you familiar with other sections of the MMA, there is competitive bidding now for durable medical equipment, there is competitive bidding for Part B injectable drugs that will be coming up in 2006, and there is a demonstration project to do competitive bidding for labs. So that's one concept one might use in thinking about revising the lab fee schedule in total, is that kind of competitive bidding approach.

Another one might be negotiated rulemaking. That's worked successfully, for example, on the ambulance fee schedule. That's another road we might go down.

There was some optimism about looking at charges for this. For those of you familiar with the kind of Tennant fiasco and some of the problems we had on outlier payments, that's thrown a little cold water on the concept of using charges, but it still might be something worth looking at.

So those are kind of the options out there, but again, no statutory authority to implement them. The only thing we can do, with respect to some of the older technology tests, we do have an authority in the statute, inherent reasonableness authority. What we're allowed to look at there is things that are inherently unreasonable, payments that are inherently unreasonable, and there's a process in the statute.

There was a moratorium on using that authority. That moratorium has been recently lifted, and one of the things we're examining very early in that process, once we issue instructions to our contractors, is in fact the HIV/HCV viral load that was mentioned earlier, where you have the payment rate for the HCV load is roughly half of the HIV for what is almost the identical procedure.

So that's an early candidate for us, is inherent reasonableness. It may be difficult to revise an entire fee schedule brick by brick, but the inherent reasonableness authority is one avenue we could go down and we're interested in using that. Hopefully, this year we'll have those instructions out and be able to at least start with some of the more egregious examples.

I can take questions during the roundtable.