MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building
International Trade Center
Horizon Ballroom
1300 13th Street, N.W.
Washington, D.C.

Thursday, April 24, 2003
9:40 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
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CAROL RAPHAEL
ALICE ROSENBLATT
DAVID A. SMITH
RAY A. STOWERS, D.O.
MARY K. WAKEFIELD, Ph.D.
NICHOLAS J. WOLTER, M.D.

AGENDA ITEM:
Payment method options for Medicare-covered outpatient drugs 227
-- Joan Sokolovsky

MR. HACKBARTH: Joan, you'll pick up with the discussion of the payment options.

DR. SOKOLOVSKY: I know this is a very long day and this is the fourth time that I've been speaking to you on this subject. So I'm going to try to go quickly through this and hope that you'll stop me and ask any questions that you have or comments.

This is the overview of the chapter. As you probably saw in the mailing materials, it's been slightly changed from previous drafts but essentially covers the same issues.

Talking about the overview of the sector, here I do have some new information which you may have noticed in your mailing materials. Although in 2001 was the last year for which we have full data, since our last meeting we now have preliminary estimates of Part B drug spending for 2002 from CMS. I want to emphasize that these are preliminary unofficial estimates and subject to change. But nevertheless, they've estimated that drug spending for last year may equal as high as $8.5 billion, which would be an increase of almost 35 percent over last year.

These are the problems with the current payment system that we've been talking about for a while. Last month I reported that as CMS had agreed, ASCO had submitted a new survey of practice expenses for oncologists. It was analyzed for CMS by the Lewin Group. And Lewin had concerns with the data and CMS had not accepted the survey. Since then, ASCO has appealed that decision and, among other points, they reported methodological problems with the Lewin analysis.

For example, the analysis includes some extreme outliers in the data, one salary of $1 million for an individual employee. And also collapsed under the category of clerical workers, some high salaried administrators, along with other office workers.

No final decision has been made but as of now discussions continue between CMS and ASCO.

This is the framework that I used to analyze the proposed new payment systems. I wanted to know whether the proposed new method would affect the payments Medicare makes for drugs, whether it would affect beneficiary access to needed medications, whether it would create new administrative costs both for CMS and also for providers, and how the new system might affect the prescription drug market.

It's important to note here that not all changes are bad. In fact, some changes, like reducing costs to the program and for beneficiaries would be the goal of making a change. But I tried to look at each possible system in terms of those categories.

I also wanted to know whether any new payment system was equally effective for all drugs. For example, a system that might work for generic drugs might not be appropriate for single source innovative drugs. Or as Jack reported earlier, it could

be that infusible drugs might require a different system than injectable drugs that might be more like a commodity.

The alternatives that I described in the paper come from Congressional testimony and from reports by sources like the GAO, CB0 and OIG. The list is not exhaustive, but it does seem to capture most of the ideas that are out there in the world. In most cases, policymakers described a list of alternatives rather than making a specific recommendation.

Most of the suggested alternatives really consist of two parts. First, they choose a price measure like AWP to use as a benchmark for the system. We'll pay AWP minus 5 percent, as Medicare does now. So once you have chosen what your benchmark is, then the second part of the system is to decide what you're going to do with the benchmark. If it's AWP, you usually make some reduction. For some of the other benchmarks that I described in the text, for example the federal supply schedule, that's a price that's below what most providers if not all providers could actually acquire the drug for. So you need to add something to make sure that providers can actually purchase the drug.

A number of recommendations have been made to continue using AWP AS a benchmark but reduce Medicare's costs either by changing the way it's calculated, by increasing the discount from AWP, or using CMS's inherent reasonableness authority to pick out some drugs that we pay for it that are very much above market price and reduce those prices.

Any of these methods that would be used AWP would still not correspond to any transaction price and could not be audited.

A second set of recommendation -- and I would say that these are the most common recommendations -- seek to look for a new benchmark instead of AWP, a benchmark that would be based on an actual transaction cost and therefore could be audited Medicare would pay providers based on that benchmark. Some of these examples would be the average manufacturer price, which is the press that's used for Medicaid reimbursement, the average sales price, and the average acquisition price. These measures represent the weighted average of all final sales charged for a product by -- what a manufacturer in the United States gets for a product after all transactions, all rebates, and all discounts, except for purchases who would be not counted for Medicaid's best price transaction.

In each of these cases, providers would be paid a percentage above the benchmark and most of the alternatives that are out there that use one of these methods, the main place they differ is how much above the benchmark Medicare should pay.

You've heard about a number of the additional alternatives that are vaguely related to competitive bidding from Jack a little earlier. You also heard about the Medicare competitive bidding demonstration this morning. If we attempted to use a system like this for physician administered drugs, there are several additional issues that would have to be addressed.

For example, who would do the bidding? Would it be wholesalers, GPOs, pharmacies, PBMs? Would the bidders bid for all drugs or for certain therapeutic classes or for certain

conditions? Would the bids be national or regional? How many bidders would be accepted? Who would be paid, the suppliers or the physicians as they are now? Until decisions like these are made it's very hard to evaluate how a system like that would work in terms of the potential savings for Medicare.

Some people have suggested that Medicare pay based on actual invoices submitted to Medicare. One can imagine this being a tremendous administrative issue where each claim has to be handled separately.

George Grob from the IG's office, one of his proposed recommendations was to empower a commission to recommend payment updates in the same way that MedPAC recommends updates for other payment systems. But again, there's so little detail here that I really can't even analyze that.

The lesson that I learned from going through this year-long process is essentially every approach has its advantages and disadvantages. We can't get a perfect approach, but pretty much all of them would result in a significant improvement over the current system.

Also, in any system, it might be appropriate to vary the payment method by drug type because there are differences. For example, generic versus single source drugs.

Thirdly, payments for drug administration and dispensing also need to be addressed and they should be addressed through the proper payment systems.

And that's it.

DR. WAKEFIELD: You probably mentioned this before or I can imagine I would have asked this question before, but I can't remember what the answer was.

Just taking a step back, in the text you mention that local carriers determine the specific drug products that are eligible for reimbursement. And that there are differences in coverage for specific drugs by regional carriers.

To your point about local carriers making decisions, would you remind me of why that's a good thing? Why that decision is being made by a regional carrier, for example, and so you're getting variation in what's covered, so that that variation is impacting what Medicare beneficiaries region by region might have by way of coverage? Can you tell me why it is that way?

DR. SOKOLOVSKY: In some issues it is a medical necessity decision that couldn't be -- they're not determining specific classes of drugs that should be covered. But it's more a case of is this drug appropriate here? Does this relate to this condition? Is it medically necessary?

DR. WAKEFIELD: So that decision could fall out differently, the medical necessity decision could fall out differently in one region of the country, and people in another region could come to a different conclusion about the medical necessity of a drug to be used for a particular health care problem?

DR. SOKOLOVSKY: For a particular person. That's one thing. The other part, which is more of an issue, I would say, is the self-administered issue. What does it mean under the law now to say a drug that is not usually self-administered? There are differences in interpretation there.

MR. HACKBARTH: Other questions or comments?

DR. STOWERS: This is probably a question. It's silly, but when we were talking about growth in variation in physician service and then we had total and then we separated out evaluation and managing, and imaging. I know in the SGR these are in that under physicians services. When we were talking about variation in physician services before, are we leaving that in? Are these drugs in all of that?

DR. SOKOLOVSKY: No.

DR. STOWERS: So we took it out. It's just in the SGR?

DR. SOKOLOVSKY: Yes.

MR. HACKBARTH: Others? I think that this is --

DR. STOWERS: The most decisive statement of the year.

MR. HACKBARTH: Most are better than the current.

I think this is a really excellent chapter in terms of A, describing the problem; and then B, laying out what the conceptual alternatives are. As you say, each of them has significant advantages and disadvantages.

What do you see as the next steps from here? We basically have framed questions here. That's the good news. The bad news is that once you frame them, somebody might expect you to answer them. And we've not done that yet. So where do we go from here?

DR. SOKOLOVSKY: That's a very good question. There are additional analyses that can be done of these various alternatives but once again -- and I can, for example, the issue of the spread. If you take a different benchmark what would be the reasonable difference between the benchmark that would ensure the providers could, in fact, afford the drugs? That's an area of research that can be done.

In many of these cases, unless you get really close to specific proposals, it's hard to evaluate them, to put a number on what they do because it varies so much those details really matter.

In terms of additional work that could be done, you know, I'm really not sure. I have been working since September, going in every possible direction, and beyond that I'm not quite sure where to take this.

DR. MILLER: I think we could do two things here.

First of all, Joan has been doing all of this work and probably hasn't been able to lift her head up and ask what next. And in all of our discussions, we felt that there was enough of, at least for the June report, of a public service to lay this out all in one place and make people understand how this works and what the problems are, and at least conceptually talk about. And a lot of our thinking has only gone that far.

You could potentially stop here and say okay, let the issue mature a little bit on the Hill and see if there's more to say about specific directions they seem to be picking, because at this point it's not clear there's a horse that people seem to be coalescing around. I'm sure I've just mixed a couple of metaphors there. You could do that.

There's a couple of more narrow issues in terms of drugs and drug payment generally that we can look at. We can do some more work on the administrative cost side and start to look over on

the physician side, issues of formularies and some of the directions the private sector is going to, again to see if perhaps that helps inform the debate. But beyond that, I'm not sure I've got any great ideas.

DR. SOKOLOVSKY: I thought of something.

DR. MILLER: Excellent. See, I was just supposed to cover Joan while she was thinking of something.

DR. SOKOLOVSKY: One of the issues that is pretty clear now with the changes in the outpatient system is that we now have payment systems in place between dialysis, where we have statutory rate for Epo which is number one everywhere and growing really fast. We pay one rate there. We pay a different rate in the outpatient department. And we pay still a different rate under the Part B system.

I think there's some work to be done in terms of looking at the differences across payment systems and what that's doing. How is it or is it not driving care?

DR. WOLTER: Just two things. I think one direction, I think it is essential if we could get people in the same ballpark on the administrative costs of giving these drugs. I mean, it's so linked to the cost of the drug issue that that has to happen, I think.

And then secondly, Joan, I was just going to make the point you just did. I went over with our oncology staff just before coming out here how our chemo drug costs are covered under APCs because in our particular killer organizational setting, physicians are employed and it's a provider-based clinic.

It's so incredibly confusing and it's so incredibly different from what happens in the Part B system. I hesitate to raise this because I don't know how one would work through a comparison of the two settings. But there's something very different now going on in those two settings. And yet, the patients are the same. In many cases the settings are even equivalent, in terms of where the chemo is being given.

So that would be other work, I think, that could have value over time.

DR. WOLTER: Just somewhat tangentially related. I think at least some anecdotal evidence in the private sector side or employment-based sector side is really calling out the specialty pharmacy management, particularly from our PBMs is something that I think we are looking increasingly at.

Having said that, I think -- and this deals more with the general outpatient as supposed to Medicare's payment here -- there's such a fundamental distrust of all parties, in terms of what we are getting, what we are paying for, what the margins are and what's the most of cost-effective way of doing it, that I worry about that.

Certainly, the second thing, I think, within the employment-based purchasing is really moving much more rapidly to a much more prescribed narrow formulary, perhaps even customized.

Those are sort of two things from the employment-based side.

One question that we might frame, and it might be a little early if Congress is not even picking, as Mark said, which horses in terms of changing the current system . And I think I've

mentioned this before. But I asked many of our benefit managers what kinds of benefit designs and how do we pay for what are going to be increasingly therapeutic agents that, in fact, are going to be customized or tailored genetically for individuals? And how do we deal with that? I get a Coast Guard salute from everybody on that?

I don't know whether we want to raise a question that I think we're going to have to be dealing with pretty soon.

MR. HACKBARTH: As if this wasn't complicated enough already, you want to add still another dimension to it.

DR. WOLTER: Again you've heard me say it, my alma mater treated a Pennsylvania state retired employee and it was something like $200,000 a day was the blood supplement costs on a $5.2 million cost and a 35-day stay. And most of it was drug. That really said, and it was a drug supplement, as I recall, it was being manufactured in London or Belgium or something, and shipped over every night.

We are at that point and we had better start framing the question. So maybe just simply -- and all I can do is think through it and, like I said, I asked a lot of my high paid consultants and I get this vacant look that no, they haven't really thought about that. And how do you ration that? How do you deal with the moral and ethical issues?

MR. HACKBARTH: As I understand the current situation, this issue has been around for a while. There is widespread, if not unanimous, agreement that there's some major issues here. The problem is that the solutions are complicated and there are multiple moving parts that need to work together in tandem in order to address the problems.

That situation seems like a difficult one for Congress to generate the solution to because of its complexity and the multiple moving parts. I think ordinarily they would look to their experts in the Medicare program, namely CMS, to propose a solution to this.

What are CMS's immediate plans? I know they've dealt with one very small piece of this by standardizing the calculation of the AWP. And I've seen reference to Tom Scully saying well, something needs to be done. It sounds almost like he wants Congress to act. I'm not sure who's got the lead right now.

DR. SOKOLOVSKY: He's talked about using the single drug price carrier to conduct a market survey to get an AWP that more closely tracks what the average wholesale price is. He talked about not doing it before May in order to give Congress a chance to act. And I believe that CMS would prefer that Congress act. I suspect May will slip somewhat.

MR. HACKBARTH: The likelihood that they're going to act by May seems small at this point.

Is there enough there in terms of a proposal that that would be the next logical step for us, to evaluate that path? Obviously not now, for June we're just doing this current analysis. But as is always, I like to know where we're going from here, so far as I can.

DR. MILLER: I think I'd really, to be completely honest, I'd really have to think about whether there's enough

infrastructure that we could start to say there are specific directions to go in. Because at least a couple of things that Joan is pointing out here is different distributions make change. You might handle different drugs differently. And then, of course, there's the administrative side of things.

I wouldn't want to sit in this setting and say no problem, our next move should be to put together our next best step. I think that this is something we can certainly think about and maybe bring something to the retreat to try and talk through, if that was your question.

MR. HACKBARTH: I don't think that our comparative advantage in this is trying to formulate a proposal, especially in an area like this. I don't think we have enough face-to-face time with commissioners. It's a very complicated thing. I think our comparative advantage is in doing this sort of analysis, of framing the issue, and then commenting on somebody else's proposed solution.

MR. MULLER: One of our comparative strengths is the analytical capacity. When you think about whether it's the growth curve going up 35 percent or whatever, among the many problems here, both looking at Joan's presentation or the one before, is the big problem, the "paying too much" for drugs, in terms of purchasing function. It's a big problem, the kind of proliferation of the kind of drugs, with all the biotech coming up and Alan's point to that.

So when we're looking at something that's at $6.4 billion and moving to $8.5 billion, and so forth -- and that $6.5 billion was a lot more than the year before -- just starting to put some rough measures on that in terms of what this is costing us. If they're "overpaying" in the purchasing function, if I can classify it that crudely, what is that worth? If we think AWP minus five is higher than it should be, what are the cost savings of going to a better system?

If the question is really one of proliferation of these drugs and more and more biotech and designer-type drugs, what is the cost of that? How much of the cost acceleration will come from that?

There's also the kind of ethical, moral concern about the administration fee vis-a-vis the payment and how those things overlap, and what it would cost to clean that one up and so forth. So I think perhaps getting some costs estimate in there as to -- I agree, several presentations have convinced me this is an incredibly complicated area at least I don't want much about. But I think to try to get some sense now of what kind of dollars we're talking about around these various issues in some kind of broad way, to the nearest billion almost or the nearest $500 million as to what -- because when you start having something with a curve of 35 percent
you want to start asking yourself what's the big driver of that? I'm assuming -- I may be wrong -- that it's the real proliferation of the kinds of drugs that we're putting in there, but I may be totally wrong on that.

DR. SOKOLOVSKY: In the mailing materials or in the chapter you have a list of the 20 top drugs for Medicare, seven of them

just came on the market in 1996 or later. The new drugs clearly are a very important part of what's happening the now.

MR. HACKBARTH: It sounds like there are going to be proportionally more biologicals, more single source, which will, all other things being equal, tend to maybe accelerate the rate of growth.

We need to leave this for now. Joan, this is really excellent work in terms of framing the issues. Thank you very much.