MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

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9:40 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
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MARY K. WAKEFIELD, Ph.D.
NICHOLAS J. WOLTER, M.D.

AGENDA ITEM:

Private insurer methods of paying for outpatient drugs
-- Jack Hoadley, NORC; Joan Sokolovsky

MR. HACKBARTH: Joan, I think you're next up, along with Jack. The next item on the agenda is private insurer methods for paying for outpatient drugs. Welcome, Jack.

DR. SOKOLOVSKY: I'll just introduce them and step aside for a while.

In January, I presented survey results that indicated that the private sector, in general, was paying for physician administered drugs in a manner and at a rate that was really quite similar to the Medicare payment system. But We also found that some payers were beginning to implement new systems, new payment methods for at least some physician administered drugs.

Unfortunately, there was very little work available that had been done describing or cataloging these systems in the research literature. We commissioned a research team from NORC at the University of Chicago and Georgetown University's Health Policy Institute to conduct a series of structured interviews to examine the way physician administered drugs are purchased, distributed, and paid for both under the traditional system and through some of the newly developed methods.

We wanted to learn how these system worked and the advantages and disadvantages of them.

The leaders of that research team -- and boy, they had to work fast, as you can understand here. They're here today to present the results to you.

I'm pleased to introduce Jack Hoadley and Michael Gluck from Georgetown University, and Dan Gaylin from NORC.

I should mention that this team also completed the study of drugs in the pipeline and their impact on Part B spending that was included in your mailing materials, and I'm sure will be happy to answer any questions on that project, as well. I'm going to turn it over to Jack.

DR. HOADLEY: Thank you, I'm glad to be here.

Basically we're going to talk about several things here and give you a little bit of background just on the context, talk very briefly about the methods that we're using to do our little study. We'll talk about the traditional distribution channels that physicians have been using to date in the distribution of physician administered drugs, a little bit about how payment works in the private sector, and then talk about some of the innovations that have been attempted in the private sector recently and reactions of the different stakeholders to those innovations.

Background I'll be very brief on because Joan has certainly brought you up-to-date in recent meetings on how this works. Obviously we're talking about the physician administered drugs that Medicare typically covers under Part B.

The private sector situation is somewhat parallel and somewhat different. You often hear the term specialty drugs used, which is not precise equivalent. First of all, there's no precise definition of that term that's used consistently. And it's not precisely equivalent to what Medicare uses. But generally, we're talking about the same set of drugs.

The big difference in the private sector is these tend to be covered under the medical benefit as opposed to their drug benefit, which again is somewhat parallel to Medicare's situation of covering them under Part B as opposed to Medicare's outpatient drug benefit; i.e. no benefit.

And so the claims, therefore, in the private sector are typically not run through a PBM. Cost-sharing would be based on however the medical benefit is structured. And generally,

they've had less scrutiny. This is not an area that the private sector has looked at very much.

Very simply, our study was a set of structured interviews, or we could almost say semi-structured interviews, conversations with a number of stakeholders from different parts of the distribution chain. We had a special focus on oncology, since that's the biggest area, probably that's involved with this Medicare Part B drug reimbursement. So we talked to a number of oncologists, insurers, PBM, specialty pharmacy companies, group purchasing organizations, wholesalers and some consultants who worked with different parts of the field.

Obviously, our numbers were limited by the amount of time we had to do this and there's no sense of a random sample. But we tried to pick representative people from different parts of the industry, different parts of the country, and so forth.

We used a general protocol to set up our questions that we would talk to them about. But mostly it was a relatively open-ended conversation of just trying to understand how things worked.

The traditional acquisition methods that are used in the system, physicians acquire their drugs in a number of different ways for the drugs that they're going to administer in their office. In some cases they may go directly to the manufactures and purchase the drugs directly through a contract with the manufacturer. That's probably not the most common method that's used, but it is used to some degree if they can get a good deal by working directly with the manufacturers. We get a sense that that's more common for some of the ancillary drugs rather than some of the chemotherapy agents.

A major method that physicians use is to work directly with wholesalers. They may work with large national wholesalers or with local or regional wholesalers that operate in a particular part of the country or in a particular market, or with specialty oncology wholesalers. And there's a number of those that operate that really specialize in the oncology drugs and help to obtain the drugs from the manufactures and move them on to the physicians.

Typically a physician will be under a system where they're getting a regular delivery of drugs. Maybe it's a couple of times a month. Maybe it's as often as a couple of times a week, depending on the volume of their practice.

In some cases they may have an ongoing contract with a wholesaler. In other cases they be looking around and doing almost kind of a spot market and getting different drugs, depending both on their needs and where they can get a good price.

In other cases, physicians use group purchasing organizations to provide them some leverage. This is both in the cases of some large practices who may contract with a GPO to overall take care of purchasing and perhaps some other services, as well, for the practice. It may also be for some small practitioners who really don't have the time or the resources to work their own deals out with wholesalers or manufacturers.

In these cases, typically the GPO does the negotiating with the manufacturers and the wholesalers, tries to get discounts, and so forth. The GPO tends to arrange the delivery of the drugs but tends not to handle the drugs directly. They'll have a wholesaler who will actually take care of shipping the drugs to the doctor. So the GPO really is playing kind of the middleman operation.

In some cases, the doctors may work directly with a retail pharmacy. And of course, they be doing several of these at once. They may use a retail pharmacy for some special drugs, special circumstances. And this tends to be not so much the CVS, the big chains, but perhaps a pharmacy that's located in the medical building and tends to work directly with the physicians in

these situations.

So these may be also used for special orders, for very specific patient situations. Generally, if a pharmacy is providing a drug, those are done under a pharmacy license where the drug may be labeled specifically for an individual patient's use.

So what are some of the issues that come up under the distribution system as it has traditionally existed? One question we asked was how much do they shop for price? How much is there really a process of going around and trying to get the best prices?

We kind of heard some different stories on this. Some told us that they do only a modest amount of price shopping, that they tend to get settled with a particular GPO or a wholesaler and work on bigger contracts, and may occasionally look for better deals or maybe for certain drugs.

Others told us that there was really a fair amount of shopping going on. So we're not getting a clear signal picture on this particular question. But there clearly are deals out there and there is a market out there. There may be situations where a wholesaler has some drugs that are getting fairly close to their expiration date and a large volume practice may say we'll take those for a discount because we know we can use them while they're still good, before their date has been met. So you get those kinds of deal situations that get created.

In terms of inventory, typically the oncologists are keeping a fair amount of inventory in their offices. We think probably a typical inventory might be a weeks worth of drugs. And maybe for a modest sized practice that's $300,000 to $500,000 worth of drugs involved. Of course, these are pretty expensive drugs.

They need to have enough drugs in their inventory because when a patient comes in they may look at the patient's blood work and say what I thought we were going to give you isn't right anymore, we've got to switch. And they need to have the drugs in stock to make those changes, or else they're going to have to ask that patient to come back again a couple days later after they get a new delivery.

There are certain drugs not so commonly used where they need to keep them in stock because when they do need them they need them immediately for a particular patient situation.

Then of course, they have to have an inventory system and a lot of them have used these commercial systems like the PCSIS system where you're keying in a particular use of a drug and then there are drawers that are opened up to provide those particular drugs.

A lot of these drugs also have to be kept under refrigeration so the storage considerations are not insubstantial.

The physician may or may not be at risk for -- they're obviously at risk for carrying their inventory, the carrying costs of maintaining that inventory. Drugs that get spoiled or out of date, they may have prior arrangements with the wholesaler or the manufacturer to be able to return those, either for full price or for a discounted price. Obviously, if there's spoilage in drugs, typically we were told that the physicians are at risk for that. So there are costs to maintaining this inventory.

Quality concerns are, of course, a major part of this as well. I mentioned before, a lot of these drugs require refrigeration. Some of them do have relatively short shelf lives. So they have to really have an active effort to make sure the quality of the drugs are maintained.

We also asked whether some of the other services, patient support services, working with insurers for prior authorization tend to be things that are provided alongside the actual purchase of the drugs. And we were told in most cases that's not the case. The wholesalers typically are not providing those other services. Those are either handled in the doctor's office or they may

have a staff person whose job it is full-time to work to get prior authorizations and to do all these other kind of support service. And of course, a large practice will have perhaps specialized staff to do patient counseling and so forth that goes along with the use of these drugs.

Payment I think you've heard more about from Joan in past meetings, and you're aware that there really are a variety of "prices." And I put that in quotes because some of the prices are not necessarily real prices. You've got things ranging from the actual acquisition price that the physician obtained the drug for. You've got the AWP or the average wholesale price, which as I think you know is sort of a list price that's provided by the manufacturers. And even on AWP, we found that because there's at least two major keepers of the list of AWP, sometimes the AWP itself varies substantially between the two keepers of the AWP list. And so even though it's not a real price in the sense of a transaction price, even the listed price tends to vary sometimes.

There's the WAC, the wholesale acquisition price, which is another sort of nominal price that's listed in some of the books. Then there's the Medicare price.

All these prices sort of are out there. As your previous work has shown you, the private insurers do tend to use an AWP-based price, but those levels -- and we didn't specifically go out to survey levels of price because you've had that already. But we heard prices ranging from AWP plus 10 percent, AWP minus 20 percent. So again, there's a huge variation out there.

A couple of the doctors also reminded us that even though that's the nominal payment price that's established by the payer, that they still have to collect the co-insurance from the patient, so they're not getting that entire amount from the payer. They're still responsible for collecting some of that. And sometimes that's a problem, they don't always find themselves able to collect that. So they may only get 80 percent of the AWP base price.

The spread is the term that we heard a lot, is the difference between the payment price that the payer provides and the acquisition price. We really heard sort of two stories about the spread, and they were very different stories. When it was told by the insurers, the payers, we heard that the spreads were very large, that there's a lot of money sitting there in the gap between what the physicians are able to acquire the drugs for and what they get paid by the insurer.

When the physicians told the story, the gap wasn't so large. In fact, in some cases it was non-existent. We didn't try to resolve the difference between those two stories, but I do want to emphasize that really it sounds like you're talking about totally different things when you have these conversations on the one hand with the physicians and on the other hand with some of the payers.

There clearly are some substantial differences in some of the administrations costs that that's spread tends to cover, because as you know the physician administration fee is generally viewed as below the actual cost of administering the drug. But how much of that is really appropriate costs and therefore how much spread is left for just excess income is not so clear.

Moving on to talk about what we've heard about innovations in acquisition and payment, we asked all the people we interviewed where they had experience with some of these new approaches, what they'd heard about if they hadn't had direct experience, and then what they thought about them. We grouped these into five areas and I'll go through each of them separately and then come back after that and describe some of the stakeholder reactions to them.

What I would emphasize that while we grouped these in these five areas, they are used in combinations. They're not mutually exclusive categories. They're also generally, we're told, in a lot of cases being done as pilots. These are still very new. A lot of the people that are trying these are still experimenting and adjusting what they're doing.

The first of these is what we called the prescribed distribution channels. This takes on a number of variations. But basically it's a system where the insurer, in some sense, takes charge of the system. And rather than just being the passive payer of the bills that come in from the physicians, they are now trying to take over the process, get more involved with the negotiation for price. In an extreme case they may arrange for a single vendor, a single GPO or wholesaler, to take charge of all of the purchase of these drugs for the physicians and for the patients that they're responsible for and then really try to manage the use of these drugs more like a PBM would. In some cases, it is a PBM who then takes over.

Otherwise, we were told that the PBMs had not traditionally been involved in this part of the process. But here's a situation where the insurers may bring the PBMs into this set of drugs. In other cases it's a specialty pharmacy company. And as I say, try to manage this benefit.

In other cases, they may have a choice of vendors. It may not be a single designated vendors but several vendors that are involved. But again, they are taking some charge and trying to negotiate a good price.

It typically is more of a just in time delivery system where in some cases again, the drugs may be obtained with particular patients in mind. So the physician may tell the insurer that we've got these three patients coming for chemotherapy in the first half of this week and we need the appropriate drugs delivered and they're provided.

In other cases it operates more as sort of an inventory replacement system. The physician, either in advance or after the fact, says here's the drugs I used for this insurer's patients and I need to get my inventory replaced to cover the drugs that I used. In some cases the insurer may give the physician a choice between those two approaches. In others, they may try to mandate a particular way that they want to do it.

Typically, they were combining this with some kind of utilization management. Again, that's part of taking charge both of the price side and of the utilization side. And probably also revising the fees that they pay based on the price that they're contracting with, as well as making adjustments to the physician administration.

Another method is what we called patient purchase. In this case, really we've turned the responsibility over to the patient and it operates more like an outpatient drug benefit would operate. This doesn't always involve the patient actually going and obtaining the drugs. In some cases, the patient actually has to go to the pharmacy and then carry that drug with them to the physicians office for the injection. In other cases, there may be an arrangement where it's delivered directly to the physician's offices. But payment now is handled not through the doctor's office but through the patient. So it's more like your typical outpatient drug benefit. The patient is responsible for their copay and the insurer pays directly for the drug and doesn't involve the physician in that part of the process of all.

We think this is probably more common for some of the standard injections like for MS or arthritis than in some of the infused cancer drugs, but there are some that are trying to do it on the cancer side as well.

Another approach is what we called revised payment levels. This is a simpler kind of change where you basically are trying to make some adjustment in your payment, going from AWP minus 5 percent down to AWP minus 15 percent or some other kind of shift like this. Generally, this is accompanied by a higher physician fee for administration.

In some cases the insurers will come in and say to the doctors we're going to maintain the same spread you've been getting. We're just going to negotiate a better price and we're going to

pay less for the drug. But we'll make sure that your markup is maintained. And obviously they do that to try to get more acceptance from the physicians for making a shift. In other cases this is viewed as an opportunity to really reduce that spread and get both a lower price for the drug itself and then reduce some of the spread and how that's handled with and without the physician fee is maybe done in somewhat different ways.

Then the two other approaches we heard about were just sort of straight out utilization management. This is trying to do the same kinds of things that are done in so many other areas, they try to really manage what goes on, review treatment choices, perhaps make a judgment whether the oncologist is maintaining chemotherapy treatment longer than is appropriate or with a different kind of therapy than appropriate. But we think this is probably more commonly used in the non-oncology settings than it is on the oncology settings, for a variety of reasons.

And then formularies have been very uncommon in this field until recently. Some movement to going for formularies, partly because a lot of drugs in this area are not multiple source drugs so there may not be a possibility of picking a formulary drug. But in some of the ancillary drugs, some of the anemia treatments, or some of the non-cancer situations, formularies are getting to be possible.

Then turning to how the stakeholders are reacting to these, when you look at the perspective of an insurer or PBM or the specialty pharmacies that are coming from the payers side, their big goal here is to save money. They're trying to reduce what they're paying to get both better discounts and better management. And so they're really trying to influence both price savings and influence utilization of the drugs.

But there are some barriers they're facing. One is data and coding issues. Typically these claims have been paid through J-codes which are aggregated potentially across some different forms and strengths of drugs rather than the NBC codes which identifies each individual product, form or strength and manufacturer. So with the J-codes, it's harder to do that kind of management because you don't have the detailed information that you sometimes need. Plus a lot of drugs, apparently it takes a long time to get J-codes assigned. So there's a lot of billing done under the miscellaneous J-code. And then again, you're getting less information.

Also, of course, the insurers that have tried to implement these systems have had to address physician resistance. There's a lot of push-back from the physicians on these. In some cases it's been quite dramatic. Physicians said we'll stop providing these treatments in the office, we'll move them to the hospital outpatient department and that's going to cost everybody more money but that's the only choice we have. In one case, there was a couple of months period where that happened and then some negotiating was done and a modification of their original system was implemented.

But the insurers do try to do some outreach. They try to work with the physicians. As I mentioned before they may try to maintain the spread so that they're not taking money directly out of the physicians.

They also have to address a number of distribution issues. If you're taking more charge of the system but there's change in orders, as I mentioned, at the time of treatment, do you have a system that makes it hard to do that? Or do you have enough flexibility to try to maintain that?

From the patient point of view, there may be quality issues. Those can cut in both directions. If there's overutilization of some of the treatments or incorrect treatments, perhaps there's some improved quality if there's more management of this benefit.

On the other hand, as we'll talk about when we talk about the physicians perspective,

there's concerns that the physicians raise about the changing distribution channels and implications for whether they're getting good drugs and whether proper storage is being maintained, and so forth.

There's a potential for lower cost for the patient. If the prices are reduced and the patient is paying 20 percent of the cost, obviously the patient is going to benefit from a lower price. If these are shifted to the outpatient drug benefit, potentially there's some savings there, too, depending on how the cost sharing structure is on their outpatient drug benefit side.

There's also convenience issues or inconvenience issues. If the patient has to go to the pharmacy and pick up their injectable drug, and if this is an arthritis patient or an MS patient for whom that extra trip may be a burden, that can be pretty serious. If sometimes this means the patient has to come back for a present visit to the office because the original treatment got changed and the proper drugs weren't available, again there may be convenience concerns.

From the physician perspective, I think the biggest things we heard about on the negative side were quality concerns and complexity concerns. Physicians told us a lot about their concerns about quality. That there have been some scandals recently with counterfeit drugs or diluted drugs. And what they tell us is that they really are concerned when they're losing control of the system. They don't know their distributors anymore, when the insurers are mandating a particular distributor and they no longer feel they can vouch for the quality.

Some even raised issues about drugs being delivered in pre-mixed forms. They said this is not a good situation for us. We'd like to be the ones mixing the drugs and knowing that they're mixed safety and on a timely basis. Most of the people putting these new systems in tell us that it's very rare to see a situation where things are being sent out in an already mixed form. So that perhaps is not much of a real issue, but it is certainly something we heard raised.

Then the complicity, the multiple distribution channels. If you're working with five insurers in your practice and each one's got a different designated vendor, how are you keeping track of everything? Have you got five separate refrigerators and storage systems? Okay, that's partly dealt with if you have an inventory replacement system. But even then, there's probably more tracking that you're doing than in the past. At least that's what the physicians would tell us. They feel like they're really losing a lot of control over the system.

On the other hand, it may be that at some point physicians will be happy to be out of the drug sale business. They do have carrying cost for the inventory. And perhaps if the drugs are reimbursed directly by the insurers to the wholesalers, this could turn out in some cases to be an advantage. We don't hear this much yet from the physicians, but people are saying that perhaps physicians will see this. And a lot of it is probably going to come down to the adequacy of payment.

Some of the physicians did tell us that if they felt like the current payment was done on the physician administration side, they wouldn't necessarily have a problem with getting out of being the ones who are handling the direct payment for the drugs, but then that is the big question. How do you make sure there is adequate payment? I know you've talked about the issues around that in the past.

What are the potential for savings? Because these are new pilot projects, for the most part, it's pretty early to know what the savings are. But we did have two of the people that we talked to give us a sense of the potential savings. One told us that they think on the price side they can get savings in the range of 10 to 25 percent of the cost of this category of drugs. One had done a particular study on their system and felt like they got a 14 percent savings on price, so

in the range.

They definitely also felt like there were savings to be had on the utilization side, but those are a lot harder to quantify. They know they can get the direct payback for the added marginal costs of doing the prior authorization or other kind of management steps. But what they're getting in terms of an overall savings on utilization they weren't sure of. In fact, we heard different opinions on whether the utilization side savings would be greater than the price side savings. I'd say we heard no consensus on which had the greater potential.

And finally, I just wanted to mention three lessons I think we learned from what we did. One is it's going to be difficult to make changes. There's a lot of factors. This is a very different market than just purchasing a pill that's going to be used for all consumption. There are a lot of complexity, as I've mentioned, with how these drugs are distributed and stored. And anything you do to change it is going to be complex.

But we also heard two other interesting perspectives. One is that it really may be a different story in oncology versus some of the other specialties, where there are physician administered drugs. And the clinical complexity of oncology treatment is a lot of higher than the complexity of some of the treatments for MS and hemophilia and arthritis and some of the other areas where you have physician administered drugs. It may be worth thinking about how to divide up, and think differently or at least think sequentially, about how to handle things in oncology versus other specialties.

Then we also heard a similar distinction made, and obviously it's correlated, between infused drugs and injected drugs, injected, inhaled, and other forms that may get involved on this side of the drugs. But typically the injections tend to be more straightforward. There's a given quantity and a fairly known thing. Whereas the infused drugs, it's a more complex clinical situation than doing infusion. It's more common in these oncology infusion situations to have a lot of clinical decisions being made at the point of treatment. So all these methods that try to separate how the drugs are obtained and provided may just be more complex in that area.

So that's the last point I want to leave you with, and I'd be happy to take your questions.

MR. HACKBARTH: Thank you, Jack, Mike, Dan.

MS. ROSENBLATT: I just have one question. Thank you, that was very well done.

You brought up something that I mentioned at our last meeting which was the J-code issue versus the NDC issue. Wellpoint has looked at this and I've talked to some of our people.

I'm also hearing that HIPAA, which is standardizing the J-codes, is making that issue more complex than it would have been before because of the difficulty of changing the J-codes. Do you agree with that?

DR. HOADLEY: I can't really speak directly to that. We didn't get very much into the HIPAA issue. I know we looked at a little bit, as we were writing up our final report, and I know that there are issues around that but I can't speak more specifically to that.

MR. HACKBARTH: Any other questions?

Okay. Thank you very much.