MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building
International Trade Center
Horizon Ballroom
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9:15 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
ROBERT D. REISCHAUER, Ph.D., Vice Chair
AUTRY O.V. "PETE" DeBUSK
NANCY-ANN DePARLE
DAVID F. DURENBERGER
ALLEN FEEZOR
ALAN R. NELSON, M.D.
JOSEPH P. NEWHOUSE, Ph.D.
CAROL RAPHAEL
ALICE ROSENBLATT
JOHN W. ROWE, M.D.
DAVID A. SMITH
RAY A. STOWERS, D.O.
MARY K. WAKEFIELD, Ph.D.
NICHOLAS J. WOLTER, M.D.

AGENDA ITEM:

Ambulatory surgical center services: assessing payment adequacy and updating payments -- Ariel Winter

MR. WINTER: Good morning.

I'll be reviewing our assessment of payment adequacy for ASC services and our draft recommendation for updating payment rates for 2005.

I'll also be discussing draft recommendations on revising the ASC payment system and the process by CMS decides which procedures to pay for in an ASC.

I will quickly review our analysis of payment adequacy based on the following four factors: it appears that beneficiaries have good access to ambulatory surgical services. The number of ASCs has significantly expanded over the last several years. In addition, the number of beneficiaries receiving ASC services grew by 14.5 percent per year on average between 1998 and 2002.

Next, we'll look at the increase in the supply of providers and some new data that we've been working on to characterize ASCs. We're going to move on to a couple of other slides and come back to the framework in a couple of minutes.

So as of June 2003 there were over 3,700 Medicare certified facilities, an increase of 50 percent from 1997. Most of the new and older ASCs are for-profit freestanding providers located in urban areas.

At the Commission's, request we attempted to identify ASCs by the types of services they provide. We based our analysis on Medicare claims from 2002. We encountered some data problems that limited the scope of our study, but I'll present what we were able to find. To ensure that we had an adequate number of claims to characterize each ASC, we selected ASCs with about 1,000 total claims. About 1,150 ASCs met this threshold, which is about one-third of all ASCs. These high-volume centers accounted for two-thirds of Medicare volume and payments to ASCs. We defined an ASC as single specialty if at least 90 percent of its Medicare payments were related to one physician specialty, such as ophthalmology or gastroenterology. We found that over half the centers met this definition of single specialty.

This table shows the number of ASCs in each specialty category as well as each categories' share of high-volume centers and Medicare payments. There's an error in the bottom row under the column percent of high-volume ASCs. those numbers should sum to 99 rather than 95, as shown.

Over 40 percent of high volume ASCs were in the general category which means that fewer than 90 percent of their payments were related to one specialty. However, most of the general ASCs received a majority of their Medicare revenue from ophthalmology or GI procedures. One-third of ASCs specialized in eye procedures and almost 20 percent in gastroenterology procedures. Although we are unable to identify the age of each ASC, 90 percent of these facilities submitted Medicare claims in the previous year.

The next question is whether Medicare's share of an ASC's volume or revenue varies by its specialty type. Unfortunately, the most recent source of data on Medicare share of overall volume by service is from CMS's 1994 survey of ASCs. This reinforces the importance of collecting more recent ASC data.

The survey data show that Medicare accounted for 40 percent of all services covered by Medicare in an and ASC. Medicare's share of ophthalmology procedures was about 75 percent and its share of GI procedures was about 40 percent.

Now we're going to go back to our update framework on slide two. We're now going to be on the third bullet. We found rapid growth in the volume of services provided by ASCs to beneficiaries. Between 1998 and 2002 annual growth of ASC services averaged 15 percent. By comparison, there was about 2 percent average annual growth of ambulatory surgical services in outpatient departments over the same period.

Finally, we found that ASCs have sufficient access to capital. These factors suggest that Medicare's payments to ASCs are more than adequate to cover current costs.

In the next part of the update framework we look at changes in the unit cost of ASC services for fiscal year 2005. The ASC payment system uses the consumer price index for urban consumers to approximate changes in input prices. The CPI-U is currently projected to increase by 2.4 percent in FY 2005. This is a more recent number than appears in your mailing materials. As with other provider sectors, MedPAC sets a policy goal for productivity growth of 0.9 percent. Subtracting productivity growth from input price inflation results in an increase of 1.5 percent in the unit cost of ASC services. We believe that current base payments are at least adequate to cover this increase in cost.

Thus, our draft update recommendation is that there should be no update to payment rates for ASC services for fiscal year 2005. It is based on our conclusion that current Medicare payments to ASCs are more than adequate to cover current costs and are at least adequate to cover a 1.5 percent increase in next year's costs. Because this would reflect current law, they would be no spending implications. And we do not believe that this would affect ASCs' ability to provide services to beneficiaries.

The next question we'll look at is how to revise the ASC payment system. The new Medicare law requires the General Accounting Office to study the appropriateness of using the outpatient PPS procedure categories and relative weights for the ASC system. The law requires the Secretary to implement a revised ASC payment system no earlier than 2006, fix taking into account the GAO report. I will quickly review the main issues involved in basing the ASC payment system on the outpatient system.

Using the outpatient procedure groups would expand the number of payment groups for ASC services, which could enhance the accuracy of ASC payments. There are significant variation among rates in ASCs and outpatient departments for some surgical services which could create financial incentives for providers to shift services to the profitable setting. Using the same

grouping of services and weights in the ASC and outpatient payment systems would likely make the weights more comparable, thus minimizing these financial incentives.

Due to competing agency priorities and Congressional action, CMS has not implemented revisions to the ASC system since 1990. Linking the two systems would allow CMS to update ASC procedure groups and weights each year, along with its annual revisions to the outpatient PPS. This should reduce the long delays between revisions to the ASC system.

However, this approach does raise some concerns. The outpatient weights may not reflect the relative costs of individual services which could have a large impact on ASCs that specialize in a narrow range of procedures. Given data limitations, however, it doesn't seem practical to set separate rates for each individual procedure.

Another concern is that currently base rates in each payment system sometimes cover different bundles of services. For example, outpatient departments may receive additional pass-through payments for new devices which ASCs do not receive. On the other hand, ASCs can bill separately for prosthetic devices used in surgical procedures unlike outpatient departments. When CMS revises the ASC payment system, it should address these variations.

If we use the outpatient weights for the ASC payment system, how should we set the conversion factor or average payment amount? The new Medicare law requires that total payments under the new system be equal to total projected payments under the old system. Thus, the conversion factor would be based on the level of payments under the old system, which may not reflect ASCs' costs.

One of the Commission's principles is that Medicare payment rates should reflect the costs incurred by efficient providers. If the conversion factor is to reflect costs of efficient ASCs, then CMS will have to collect recent ASC cost data.

This leads us to our next draft recommendation, which has three parts. First, the Secretary should revise the ASC payment system so that its relative weights and procedure groups are consistent with those in the outpatient prospective payment system.

Second, the Congress should require the Secretary to periodically collect ASC cost data to monitor the adequacy of ASC rates and develop a conversion factor the reflects the cost of ASC services.

Third, the Congress should ensure that payment rates for ASC procedures do not exceed outpatient PPS procedures for the same procedures, accounting for differences in the bundle of services. Thus, outpatient rates would be the ceiling for ASC rates, even if we find that ASCs incur higher costs.

We are unable to estimate the spending implications of this recommendation. ASC rates that are currently higher than outpatient rates would decline, while ASC rates that are significantly lower than outpatient rates would probably increase and it's unclear how these changes would offset each other.

We also cannot predict the net impact on beneficiaries cost

sharing. Our recommendation assumes that co-insurance would remain at 20 percent of the total ASC payment rates. The co-insurance amount would increase for services where the rates increase and decline for services where the rates decline.

In terms of provider implications, ASCs that focus on services that are currently paid more in ASCs than outpatient departments would experience payment reductions. However, ASCs that provide services currently reimbursed at much lower levels, such as some orthopedic procedures, might receive higher payments.

The next issue is how CMS decides what procedures to pay for in an ASC. CMS is required by statute to maintain a list of services that are payable by Medicare in an ASC. Procedures must meet several criteria to be placed on the list. They must be performed in inpatient settings at least 20 percent of the time but cannot be performed in physician offices more than 50 percent of the time. They cannot exceed certain time limits for surgery, anesthesia, and recovery, and they also have to meet certain clinical safety criteria. For example, a procedure is excluded if it results in expensive blood loss.

Although CMS is required to update the list every two years, it was not updated between 1995 and March 2003. Long gaps between updates make it difficult for the list to keep pace with technological changes that enable ASCs to safely provide additional services. Some of the criteria, such as the volume of a service in inpatient settings, may no longer be relevant for determining what services are clinically appropriate to perform in an ASC.

Instead of maintaining a list of services that are eligible for payments, it might make sense for CMS to create a list of services that are specifically excluded from payment. For example, CMS maintains a list of inpatient only services that are excluded from payment in hospital outpatient departments. When considering what ASC services to exclude from payment, CMS should continue to apply clinical safety standards. It should also exclude services that are likely to require an overnight stay to ensure that ASCs only perform ambulatory procedures.

To avoid creating financial incentives for services to shift from physician offices to ASCs, CMS should exclude procedures that are routinely performed in physician offices and would be paid significantly more in an ASC.

We propose recommending that after the ASC payment system is revised, the Congress should direct the Secretary to replace the current list of approved ASC procedures with a list of procedures that are excluded from payment based on clinical safety standards, whether the service requires an overnight stay, and payment differences between ASCs and physician offices. We propose that this changes occur only after CMS has revised the ASC payment system and reduced payment disparities between ASCs and hospital departments.

There are two main goals of this recommendation, to give physicians greater discretion over where to provide a service, and to make it easier for ASCs to keep up with changes in clinical practice and technology that allow more services to be

safely provided in ambulatory settings. There is a risk that if the list is not kept up to date, this change might encourage the migration of some procedures to ASCs that are inappropriate for beneficiaries in that setting. However, ASCs have to meet minimal safety and quality standards to obtain accreditation and Medicare certification, which should mitigate this risk.

This recommendation could increase Medicare spending if more surgical services over all are performed beyond the shift of services from other settings to ASCs. Of the other hand, if ASCs are paid less than outpatient departments under a revised system, Medicare spending could decline if services shift from outpatient departments to ASCs.

ASCs would likely be able to provide a broader range of services, thus offering beneficiaries an additional choice of setting. Beneficiaries who could obtain services in an ASC instead of an outpatient department would also likely have lower cost sharing.

This concludes my presentation and I look forward to your feedback.

DR. NEWHOUSE: Do you want to take the recommendations in order or do you want to just -- my comment is on recommendation two.

MR. HACKBARTH: For purposes of the discussion, we'll just treat them as a group.

DR. NEWHOUSE: Could you go back to slide nine, Ariel? So what is being proposed here is that, in effect, we take the outpatient PPS payment system with a different conversion factor. What I'm concerned about is that the weights is the first concern there, the weights may not be right. The reason I'm concerned about it is that we have all of these single specialty ASCs. In the outpatient side, the joint costs that go across different procedures get spread around into the weights. Those may not be appropriate for the ASC.

I don't have a problem with going with the recommendation but I would like to, although given the administrative load on CMS I'm reluctant to say this, but I think at some point we need to have some data on what the right weights are for the ASCs, at least to back up our assumption here that the outpatient weights are approximately right.

What I'm concerned about actually is advantage number two up on this slide is actually only an advantage if the relative weights are correct. If the relative costs in the ASC is different relatives than in the outpatient department we could potentially be enhancing financial incentives to shift services. I don't think CMS can do it now given the load it has, but at some point we need to say that there needs to be some real data in the system on what actually are the weights that are appropriate for ASCs.

DR. MILLER: I think that's the second element of the recommendation number two.

DR. NEWHOUSE: It doesn't say anything about weights. I got this to get to the conversion factor advocacy and not the weights.

DR. MILLER: That's fair but I think in some of our

discussions it seems to be we've gone around this true a little bit. Once you get the cost data you could actually go through the process of running it through the OPD categories and determine how the weights actually compare to the OPD weights.

MR. WINTER: Right. You could think of this as sort of a starting place. They start off using the outpatient weights in groups. And then once you get ASC cost data, you could adjust, calibrate, those weights based on what the data show. And the GAO study is supposed to consider data submitted by the ASC industry and that might also shed light on adjustments that you might want to make in the weights and the procedure groups.

DR. NEWHOUSE: Depends on what you mean by ASC cost data. Obviously you need more than total cost. You need some way of allocating those costs down to procedures. It's not clear just from saying -- I mean, you can put this in the text, but collecting cost data is going to get to there. It's a puzzle. The question is what kind of cost data would you collect that let you set the weights?

DR. MILLER: For example, the GAO report that mandated in the legislation to collect cost information on ASCs.

MR. WINTER: It's supposed to consider data submitted by the industry. So I guess you could do it that way.

DR. MILLER: It's not clear that would come in by procedure, for example?

MR. WINTER: The legislation does not specify that level of details for cost data. And it did repeal, eliminate the requirement on CMS to do a survey every five years of ASCs' costs, which is why this part of the recommendation is very important. And maybe we could specify that, the Secretary should periodically collect ASC cost data at the procedure level to address Joe's concern.

DR. ROWE: Ariel, I'd like to have a little more discussion about recommendation number three, particularly some of the issues about excluding from payment based on payment differences and some of the other requirements, and the issue of what can get done in a physician's office versus what can get done in an ASC and what can get done in an outpatient department.

My experience is a little different. You write about the fact that ASCs are more costly, more specialized, they may be. My experience this was always about a bargaining unit issue, this was a labor relations issue. That, in hospitals that were unionized, which is the setting that I worked in, the ASC was not unionized. That the ASC was owned more than 50 percent by somebody else, and therefore the salaries and the benefits or whatever else was associated with that were very different, the input prices were lower.

And the doctors offices were on the medical campus. And therefore the people who worked in the doctor's offices were in the unit. I'm not saying that's good or bad. I'm just giving you an experience.

So things were actually quite a bit in a different direction than we maybe assuming here, in terms of the cost of doing something. And I'm not sure that influences the recommendation. It's one of the issues here and we might want to think it

through.

But what I want to make sure is that the physicians actually really have more discretion and the patients have more discretion about where to do a given procedure because my feelings are that the patients who get colonoscopies vary a lot, and some of them are really healthy 50-year-olds who get one for their 50th birthday as a screening procedures. And others are frail people with a lot of diseases and comorbidities and medications and you just take one look at this patient and say I don't want to do this in my office. But they look the same to Medicare from the point of view of the charge or whatever.

So just explain to me that we're not excluding paying for a procedure to be done in an ASC just because it could be done in a doctor's office and the doctor prefers to do it in an ASC because of the condition of the patient. Just assure me we're not doing that because that's the way I interpreted this.

MR. WINTER: The concern here is that if you allow more procedures to be done on particularly more basic procedures that may not require the specialized setting of an ASC, such as a dedicated operating room and recovery room, that you might encourage physicians to open up an ASC next door to capture the higher facility payments for an ASC for that procedural when the additional infrastructure of an ASC may not be needed for an average patient.

Now I understand what you're saying for a sicker patient.

DR. ROWE: I'm looking at it from the doctor's point of view and the Medicare beneficiaries. We want to make sure that clinically we get this done in the safest, most appropriate environment. Now it may be that that environment is going to be replete with other resources that aren't needed to do a safe colonoscopy in an 87-year-old frail patient. But as a doctor or the son of the patient or whatever, I don't care about that. Just don't tell me that this guy's got to do it in his office where there's no anesthesiologist around and where he does two a week or something because he can't get paid if he does it in the ASC. That's the way I was interpreting this recommendation. Maybe I'm wrong.

MR. WINTER: That physician could still do the procedure in the hospital outpatient department if the ASC were not available.

DR. ROWE: Not everybody can do that. That's not ubiquitously available to every practicing physician. Or maybe an ASC. It varies, I guess is my point.

I'm just trying to look at this clinically rather than the financial incentives. I don't know that there's a solution here. I'm just concerned about it.

What if the hospital outpatient department stopped doing these things because they owned the ASC? They just say we're not going to have this duplicative redundant infrastructure and the only such-and-suches we're going to do are inpatient. And if they're outpatient, they're going to get done in our ASC which is around the corner? Then the guy is stick, right?

DR. STOWERS: This may be an obvious question but when you say replace it with the outpatient procedure list, are you limiting that to surgical procedures or are we going to throw in

CAT scans with contract or all the other things that are done in the outpatient departments?

MR. WINTER: In terms of allowing them to be done in ASCs?

DR. STOWERS: Right.

MR. WINTER: That's not our intention. Our intention is to continue to limit the ASC procedures to ambulatory surgical services and not include radiology and other services.

DR. STOWERS: We may need to make that clear because that outpatient procedure list has all sorts of things on there that would really open Pandora's box because there's a tremendous price difference between getting a CT scan done in the outpatient department or getting it done in a community x-ray center by three-to-one in costs. So if we were to throw all of those into this procedure list, it would totally change the complexion of all of this. So we may want to make it clear we're still talking just surgical outpatient procedures.

MS. DePARLE: Generally, I think the recommendations are moving in the right direction and I just had a couple of comments.

On number three, I think I said this the last time but I'll just say it again. I'm really glad that I think we've come up with something that makes a lot more sense than what CMS has been trying to do, and not very successfully. I think this area has really been neglected by CMS, for lots of reasons including the ones that Joe and others have pointed out, which is that they simply don't have the resources given everything else on their plate to keep up with this.

I think what we're doing is moving this where it should be, which is more towards a clinician making a clinical judgment in the way that Jack described. You could also make the argument, subject to Ray's caveat, that anything that isn't on the inpatient-only list should be open here, that is should be a matter clinical judgment.

But in any event, I think this definitely moves in the right direction.

Our second recommendation, I will support it but I just would note that I have a slight misgiving even as you've modified it in that Congress stated a month ago, I guess, that this new payment system should be budget neutral. My experience, from having implemented a number of new payment systems, is that when they are budget neutral it is far easier to get it done, to work with the industry to get it done.

Now, you may have lots of changes underneath the overall baseline spending so that some things will move in one direction and some things will in another. But that it's far easier to implement. And then in the end you actually do get behavioral changes that move in the direction that you want.

So while I'm not going to vote against this, I do caution that that may have been why Congress chose to say this thing should be budget neutral. And what we're trying to do, I think, may make it more difficult to achieve our objective.

MR. SMITH: Ariel, thank you. This was a very good job.

I want to return to the question Jack raised about recommendation three from a slightly different angle. His

discussion about whether or not things are organized or not, I'm going to avoid.

But I did wonder, Ariel, why we didn't apply the same principle of ceiling price that we thought about with respect to OPDs and ASCs, why we didn't apply the same principles to the issue of physicians' offices? If we use the physician office payment as a ceiling, why wouldn't we want to have the option of having the procedure performed in an ASC, as well, with that caveat? Partly addressing Jack's clinical concerns, but also trying to establish neutrality in site of service here. So we both open up the possibility of a more sophisticated setting, but we don't introduce the possibility of site shifting simply on the basis of payment rates.

So unless I'm missing something, it would seem to me that we ought to see if we can deal with the third bullet there, the payment difference between ASCs and physicians offices to apply the same ceiling principle we used in the earlier recommendation with respect to ASCs and OPDs.

MR. HACKBARTH: Ariel, do you have any reaction to that idea?

MR. WINTER: I'm trying to think about whether to add it to this recommendation or have it as a separate free-standing recommendation. I guess we could eliminate the third bullet under this recommendation and say procedures that are routinely and safely performed in physician offices can be performed in ASCs, but would be paid at the physician office practice expense rate if it's commonly done in the office setting.

MS. DePARLE: Then what would you do to -- there probably is some set of procedures that could be performed in a hospital outpatient department, an ASC, or a physician office. I think we all support the idea of a level playing field here, but I don't have any sense of what the impact of that would be in terms of payment, do you?

MR. WINTER: We'd only do it for services where -- one thing you could do is only set that rule for services where 50 percent or more of the ambulatory volume is in a physician office, but then you would still have a big gap between the physician office -- probably a big gap between the practice expense rate in the physician office and the outpatient facility rate.

MS. DePARLE: Right, but then are we suggesting that we should lower the hospital outpatient payment, if a lot of these things could be performed safely in a physician office? I think that seems like we're introducing a whole new, perhaps very interesting, but a whole new element to this.

MR. WINTER: I think before we consider doing that, we'd have to look at the patient mix in each setting and the regulatory burdens and quality in outcomes. This is part of our longer-term agenda for payment differences across settings for the same service. So we may want to wait and think some more about that before heading into this area.

DR. ROWE: I think that there are the same issues about what the payment scales are and the benefits, and all kinds of different things.

MS. RAPHAEL: Ariel, just a clarifying question. Why are we

saying that this has to occur after the ASC payment system is revised? Because I look at this as a very separate set of activities that are clinically driven. So I don't understand the bridge between the two.

MR. WINTER: One of the concerns about opening up the ASC list or allowing more procedures to be done in ASCs that are currently being done in outpatient departments is that under the current ASC payment systems there are big disparities in payments in both directions.

But we're more concerned about cases where the ASC payment rate is higher than the outpatient rate. So if you allowed more procedures to be done and those rates ended up being higher than the outpatient rate, then you might encourage the migration of procedures to the ASC setting for financial rather than clinical reasons. But it depends on what -- what payment group would you put the new procedures in? That's the big question.

And CMS struggled with that when they expanded the list in March of last year and they ended up not including new procedures on the list for that reason, because they didn't know what group to put them in. Even in the lowest paid ASC payment group, they would still be paid significantly higher than the outpatient rate. That was the issue. So based on the current architecture of the ASC payment system, it could create problems when you try to allow new procedures to be done in the ASC setting.

DR. WOLTER: I also thought it was an excellent chapter and the recommendation is in the right direction. I have two concerns.

One is we state again that we would like in both the ASC and the hospital outpatient setting for costs of efficient providers to be covered. In one case we don't have any cost data. And in the other case we either don't believe it or aren't sure how to interpret it.

And I can't help but point out once again that we need to decide are we going to wrestle with that issue on the outpatient hospital side as well as the ASC side or not, because it leaves us in a position of making decisions year-to-year based on a framework that we can't really use because we don't have the data that we believe.

My second concern, which I haven't really seen raised but it concerns me. And that has to do with self-referral and utilization patterns over time when physicians are significant owners of a facility. I don't know whether that should become part of our agenda ever or whether it's being looked at by someone else. But I think it's an inevitable question that's going to be raised as this movement continues over time.

DR. ROWE: [off microphone.] These are the safe harbor, the Stark privileges.

MR. HACKBARTH: In fact, it might be useful Ariel for you to just quickly summarize what the rules of the game are right now.

MR. WINTER: Sure. The Stark legislation prohibits physician self-referral, prohibits Medicare and Medicaid payments -- it prevents a physician from self-referring to an entity in which they have a financial stake. And there are nine health services that are excluded from physician ownership but ASCs are

not on that list.

The other relevant legislation is the anti-kickback law, which is much broader and covers all health care services and prohibits remuneration or any kind of incentive for physicians to perform a service. And there are safe harbors that allow physician ownership of ASCs under the anti-kickback law.

DR. MILLER: So the punchline is right now there is an exemption in the Stark rule for the whole hospital exemption, and essentially, once you troll through all of this, for ASC; is that right?

MR. WINTER: That's right.

MR. HACKBARTH: That's the piece I don't understand. I understand the logic of the whole hospital exemption being that an individual's decisions about where to send a patient are small in the context of a large institution. That doesn't seem to apply to ASCs which can be much smaller and very specialized. So the risk that the Stark law is directed at seems to exist in the case of ASCs and why are they not covered?

MR. WINTER: I think the logic initially was that when the Stark law was enacted in the early 1990s, actually the first one was 1989, the government was trying to encourage the growth of ASCs because they were seen as a less costly alternative to outpatient departments and inpatient hospital settings. And most ASCs at the time were owned by physicians. They were the main source of capital for ASC development. So if you prohibited physician ownership of ASCs, you limit the growth of ASCs. And that was the concern in the late '80s. And the market has obviously changed a lot since then so it might be worth revisiting.

MR. HACKBARTH: I'm with Nick on this. I have some concerns about that issue as well and whether the current rules make sense in the world as we now know it.

DR. ROWE: I think practically, it's quite striking when you read the legislation. It's been sitting out there a long time. This didn't just happen. And it specifically exempts ASCs. And I think the issues were clearly that if a hospital -- the way these are usually done, they are owned by physicians but not to get the capital. There's generally a business partner who makes a capital contribution and who manages the facility and there are a number of these very effective, highly ethical, very productive organizations around the country that do this.

And what they'll do is go to a hospital or community and identify a group of physicians who are heavy utilizers of these kinds of services. And say you guys are doing this in your office, you're doing it in the hospital outpatient, and the hospital doesn't have the money to update its outpatient department and you've been complaining for 10 years that the suite is archaic and unsafe and it's more and more expensive for you to do this in your office. And we'll give you the capital if you guys come together as a group.

But of course, you realize that the patients that are going to get treated here are the patients who you treat. They're your patients. But we need you to set up the clinical rules and the oversight and the quality committee and the infectious control

and all the rest.

So because of that kind of built-in conflict, these were exempted from the Stark anti-referral rules because if they weren't ASC growth would have been eliminated. And so that was the concern.

I served on the New York state committee that oversaw the CONs or whatever for facilities. Remember that, Carol. And this came up all the time.

And I would have to say my experience was that the physician input was vital to the quality and to running the thing in a clinically appropriate way. I can't imagine how it could be done otherwise. So I know it does give you the self-referral thing, but in fact, they were referring these patients to themselves before. In other words, they were doing it in their own office. The patient would come and get a colonoscopy. That's what they were doing.

MR. HACKBARTH: You've clearly explained the historical rationale. Would you leave it that way?

DR. ROWE: Let's say I'm a gastroenterologist and you sent a patient to me and the patient is pretty sick and frail. And there's an ASC where I could do the procedure or I could do it in my office. And I can't send the patient to the ASC because I'm on the board, or I'm an part-owner of the ASC, and all my partners are, and all the gastroenterologists in town are.

So then I tell the referring doctor, Dr. Nelson, I have to send your patient to Pittsburgh to get a colonoscopy because all the doctors in town -- I mean it's just stupid.

So sure, I'm sensitive to Nick's concern. And we saw that with imaging centers. Doctors owned imaging centers and patients would come in and then a lot of people were getting CAT scans and there were questions about whether or not the right clinical criteria were being applied. I remember those bad old days.

But in this particular case, unless there's evidence to the contrary, I think it seems to work. Nick?

DR. WOLTER: I think you've explained well the positive side of the story. I do think that in recent years we're seeing an explosion of these. I'll tell you in Billings we have about four of them now, or a fourth one was just announced. I think, especially when there's a high volume of single specialty ASCs, at least the question of utilization should be raised.

I think that now that this has become a much bigger movement and we're seeing a lot of dollars being invested in duplicate infrastructure, and in fact, many of these patients maybe come from what was previously in the office but many are also coming out of what was previously done in hospital outpatient. And I don't know the sustainability of this over time, quite frankly. It's become a major economic movement. And I think there are pros and cons to this, and you've outlined those well.

I do think we're going to need to monitor this.

DR. REISCHAUER: Jack gave us the example of some procedures that could be done in a physician's office as well as an ASC or an outpatient. But there's a lot of procedures that can't be done in a physician's office and the choice is simply between hospital outpatient and an ASC. And that's a different trade-

off.

DR. ROWE: Yes, that would be significantly different and I view those differently.

MR. HACKBARTH: Jack, your description has been helpful. What I'd like to do is learn more about this and think about it some more. There will be other opportunities, I think, to take up the self-referral on a piece of this, either in a discussion of ASCs in particular or maybe in some other context as well. So let's hold off on that for now, Nick, if that's okay with you, and focus on the three recommendations before us.

Any other questions or comments?

Why don't you put up number one. All opposed to recommendation number one? All in favor? Abstentions?

Now help me out on number two. I know we had some discussion about this. Are there any modifications we want to make?

DR. MILLER: I think in response to Joe's comment, the modification is in the second bullet point. It would read something along the lines of the Congress should require the Secretary to periodically collect ASC cost data at the procedure level to monitor adequacy, et cetera.

MR. WINTER: Can I suggest one other change based on comments? To continue on from where Mark left off, to monitor the adequacy of ASC rates, calibrate the relative weights, or monitor the relative weights, and develop a conversion factor that reflects the cost of ASC services.

MR. HACKBARTH: We can tinker with the language but I think the intent is pretty clear. Do people understand what we're trying to get at?

So let's vote on number two with that modification in mind. All opposed to number two? All in favor? Abstentions?

Okay, number three. Any modifications on this one based on the discussion?

MR. WINTER: One suggestion from David, I believe, was to take out the third bullet and add a sentence that says payment for services that are routinely provided in physician offices should be no higher than the physician practice expense office rate.

MS. DePARLE: I don't feel prepared to vote on that today. I don't think I have any idea what the implications of that might be.

MS. RAPHAEL: I was just going to suggest we pull out the last one, payment differences, because we're trying to do this in a clinically -- to me -- defined way having to do with safety and overnight stay. And then all of a sudden we drop in there payment differences.

So I just think that one has to come out for this to make sense in terms of trying to figure out what procedures should be approved or excluded. And then whatever we do on this, I think we should do separately.

I was persuaded by what Ariel said that there were some really compelling reasons not to go forth with this because of payment implications.

MR. HACKBARTH: The proposal on the table is to delete

payment differences between ASCs and physician offices.

MR. SMITH: That would accomplish, I think, what Jack and I were trying to get at, that the exclusion list here ought not to be based on a payment consideration. And simply removing that would take care of it and it would allow the clinically appropriate decision to be made without having excluded the ASC option on the basis of a payment difference. That would accomplish what I think I wanted to do.

DR. REISCHAUER: But do we want the text to reflect that this is an area of interest and further analysis by us? Because I would think we would.

DR. ROWE: Also, really you can't have it the way it's written because if you use the example I gave of the pretty frail, multiply impaired, functionally marginal patient then the clinical safety standard indicates yes and the payment difference indicates no. So then you have to have some mechanism to say well, if one of these says yes and the other says no, how do you determine which is subordinate to the other?

MR. HACKBARTH: I think that makes sense to delete that third item and focus on the clinical considerations in the note in the text that we'll come back and think about the other issue.

With that modification, all opposed to recommendation three? All into favor? Abstentions?

Okay.

MR. FEEZOR: Glen, just to underscore your comment, the issue on Stark or other incentives or disincentives, I'd like to put that as a potential issue that we might plow into a little more somewhere offsite, potentially.

MR. WINTER: Allen, we do plan to address this issue as part of our study of specialty hospitals, which is a Congressionally mandated study under the new Medicare law. So we'll be looking at it in that context and we can certainly think about it for the June retreat, as well.

MS. DePARLE: But Glen, when we're looking at it, and Allen and I had a chance to talk about this some yesterday, we also want to make sure we're looking at it in the context of the things that we're trying to do on quality because we both think that until you allow physicians' interest to be aligned with those of hospitals and other providers that it will be hard to achieve some of the things we're trying to achieve. Even in the two areas where we made those recommendations yesterday there are those issues. So it's multifaceted.

MR. SMITH: Glen, on the same subject, as Nick was raising his concerns a minute ago, I think there are two issues here and they're not entirely covered by the self-dealing, self-referral Stark provisions.

The other one is the cannibalization question and whether or not that has an impact on the viability of the hospital setting which needs to be viable for a variety of other functions. Does the development of this additional infrastructure have implications for the architecture of the rest of the system that we ought to pay attention to?

I don't have a view about the answer to that, but I think that question is as important as the potential conflict, self-

dealing, kick-back questions.

MR. HACKBARTH: Mark was just saying that one is a significant part, I think, of the specialty hospital.

DR. STOWERS: [off microphone.] I don't know if we need to get into service that requires an overnight stay. We could just say based on clinical safety. We've already voted on it, but I'm just saying you don't need the bullets under it.