Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws

Transcript
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Vicki Robinson: Good afternoon everybody and welcome to those of you here in the auditorium as well as those joining us by phone. I am Vicki Robinson, senior advisor for healthcare reform for the Office of Inspector General for the Department Health and Human Services. I'm actually until recently I served in a different position where I spent many years working on this exclusively on Stark's kickback and civil money penalty matters. Joining me as co-moderator for today's panel is Troy Barsky, director of CMS' Division of Technical Payment Policy where he leads the CMS team that addresses Stark law issues.

We are also joined today in the auditorium by colleagues from our offices, the Department Of Justice, the Internal Revenue Service, and the Federal Trade Commission. We are delighted to have with us today distinguished panelists to discuss the intersection of Stark's Anti-kickback and the Civil Money Penalty Law with Accountable Care Organizations and similar integrated models. During the next 70 minutes or so, our panel will bring their various perspectives to this topic. During the listening session that will follow, we invite all of you in the room and on the phones to offer your views on these subjects as well.

So, let me introduce our panelists. To my right is Ivy Baer who is director and regulatory counsel for the American Association of Medical Colleges (inaudible) it is the Association of American Medical Colleges, I apologize. Seated next to her is Jonathan Diesenhaus who is the Fraud and Abuse Counsel for the American Hospital Association, and then and next to him is Jeffrey Micklos, the E

Next, we have Robert Saner, Washington Counsel for the Medical Group Management Association. Next to him, Chester "Chet" Speed, Vice President for Public Policy of the American Medical Group Association followed by Nora Super, Director of Government Relations for AARP, and then we have joining us Jan Towers who is Health Policy Director for the American Academy of Nurse Practitioners. And seated next to her is Tom Wilder who is Senior Regulatory Counsel for America's Health Insurance Plans, and finally, at the end of the table, we have Marcie Zakheim who is Counsel for the National Association of Community Health Centers. And we thank you all for being with us today.

Before we get started, we wanted to take a few minutes to provide some context for this afternoon's discussion and for the listening session for the benefit of our audience here and on the phone. As was described this morning, Accountable Care Organization are, very broadly speaking, groups of providers and practitioners that work together to manage and coordinate patient care, and are accountable for the quality and cost that care. As we have been discussing today, the Affordable Care Act contains several provisions that incorporate ACOs into the Medicare and Medicaid programs.

The focus of our panel this afternoon is how ACOs will interact with the Stark Law, the kickback statute, and Civil Money Penalties Law. Many have observed that these laws create potential barriers to innovation and development of Accountable Care Organizations and similar models. As the Inspector General said this morning, as Medicare and Medicaid programs move to incorporate and test payment and delivery models, there is a need for fresh thinking about program integrity and the types of risks for programs and patients.

Now, as most of you know, the Stark Law prohibits physicians from referring Medicare patients for certain designated health services, including hospital services, to entities with which they have a prohibited financial relationship. The entities cannot bill Medicare for improperly referred services and fitting in one of the many of exceptions as mandatory. The anti-kickback statute is an intent-based criminal law that, very broadly speaking, prohibits the purposeful buying and selling of any federal health care program business.

Now, there are number of voluntary safe harbors to protect some arrangements. These two referral laws seek to prevent over-utilization, increased costs, and improper steering of patients motivated by financial interest.

Now, the Civil Money Penalty Law is a little different. It arises in the context of the hospital prospective payment system and it prohibits hospitals from paying physicians to reduce or limit services to hospital patients under the physician's care. It addresses the risk that hospitals will pay physicians to reduce costs by limiting the care that patients receive.

These fraud and abuse laws operate on the general principle that programs and patients can best be protected by prohibiting or limiting financial relationships between referral sources and referral recipients.

Troy Barsky: the challenge for today. As Vicki said, these laws constrain financial relationships between parties in a position to generate federal health care referrals. Therefore, models that integrate providers in the system with shared financial interests and referrals such as Accountable Care Organizations potentially implicate these statutes.

Now, Congress provided the Secretary of Health and Human Services with a tool to address these impediments that are created by the statutes,

assembled here. For the second session, we will be opening up the microphones on the floor and then also listening to folks on the phone and receiving comments from them. We're asking all the speakers both from the panel and then also on the phone to please limit your comments to no more than two minutes also that we can work to get so we can work to listen to all the varied views amongst our panelists, and with that, I'm going to turn it over to Vicki for our first question and we can get started.

Vicki Robinson: Great. And just we're going to adopt a method that was used this morning to identify when people want to get in the conversation, if you will tip your name card up if you want get in, we will also be calling on certain folks during this panel.

So, we're going to start by talking about waivers and the waiver authority might look like and what might what we might need to be considering when we're thinking about this waiver authority. And so the first question is this, it has been suggested that waiving that application of Stark, the kickback, and CMP to the distribution of shared savings will positively impact the development of ACOs. We'd like to know if you agree or disagree with that statement and if the HHS agencies decide to exercise the waiver authority in this direction, do you have any recommendations on what needs to be stated in the waiver to accomplish these goals? And I'm going to start with Bob Saner representing MGMA and then we will move onto other panelists who are interested in this question.

Robert Saner: Thank you, Vicki, and good afternoon. I don't think it will surprise the audience or my fellow panelist that I am a strong advocate for waivers. I think they are necessary if your agency wants to get this program off the ground quickly and expand it rapidly beyond the very large integrated systems that are already in it.

In terms of what you should say in connection with the waiver authority, I think you should say, "As little as possible." I think you should I think you should provide a one-sentence waiver of the three authorities that we're talking about this afternoon and I say that for several reasons. One, I think you really need flexibility. Somebody on the panel late this morning said we

process. And as you know under the APA, there's a process where any kind of regulations or guidance to get public comment and then consider that first. I will just very quickly as you know there's been a lot of regulation that has come out so far under the Affordable Care Act on a very fast basis and then subsequently the regulators has had to issue all sorts of guidance and enforcement safe harbors because the rules came out so quickly that they icipate all of the issues. So, I think it's important that the regulators get it right from the starting point and really whatever you're thinking about doing, push it out and what people react to that and say, "OK, these are the rules going forward."

Vicki Robinson: Great. Thank you. I'm seeing a forest of tents (inaudible) I'm going to call people as I saw them come up. Jeff Micklos.

Jeffrey Micklos: Thank you, Vicki, and thank you to you and Troy and all of your colleagues for having us this important session for us and I think would agree with Bob. I think that history with regards to gainsharing has several years and all the debate about that shows that clearly there's a need for some relief under the fraud and abuse laws to be able to make the shared savings arrangement work.

problem that's been out there for a while that probably needs to dealt with. So, I clearly clearly, I think that would enhance innovation.

But

waiving requirements that are going to foster the growth of ACOs that should be done in a uniform way to create level playing field.

Vicki Robinson: Ivy Baer.

Ivy Baer: I'm Ivy Baer, Association of American Medical Colleges. We represent the teaching hospitals and physicians, and so we little integration around ourselves. And I want to say I was glad that Troy mentioned that the waiver authority is in two sections, 3021 and 3022, 22 being ACOs, but 3021 includes the ability to waive for a variety of models including health care innovation zone which will be formed around teaching hospital. We support Bob Saner and that I think waiver should be very broad and they should be quick, but I think that were in a few sentences more than the one that Bob suggested that if an ACO or a model that's approved under 3021 has CMS approval so that it has in it the safeguards and the monitoring that we think will protect the program and patient then the waiver should follow. Speed and flexibility are really essential in this whole process and we don't think a long regulatory process would be beneficial.

Vicki Robinson: Thank you. Jonathan Diesenhaus.

Jonathan Diesenhaus: Hi, Jonathan Diesenhaus here for the American Hospital Association. I think a half step back actually and think about the question of waiver versus safe harbor in terms of what Stark, the safe harbor, the CMP statutes, what their focus is. Their focus is on risks presented by an older model of health care and what Congress has said is, "Throw those away. Break down the silos," as folks at AHA want to say and develop an integrated approach to

subject to those pena

certain class of providers. And so, one of the cautions that we would have is, in order to maintain that level playing field and allow patients to have the choice of the patient of the providers that they want to see, that indeed you need to keep this in back of your mind that you're looking at waivers so that those groups are protected and the other non-physician provider groups probably have a very similar kind of framework.

Vicki Robinson: Great. Thank you.

Troy Barsky: So, moving on to the question and Marcie we'll definitely get to next time. And I think a lot of the panelists have already started to delve into this question, but I want to drill down a little deeper. Let us (inaudible) in for a second that HHS does exercise the a waiver authority with regards to shared savings. We've heard in various comments we received and discussions that we've had that that perhaps the waiver may need to apply to other type of financial arrangements, business arrangements that that may need to be created in order to facilitate Accountable Care Organizations. This is one example in something that was discussed at length this morning is electronic health records and the use of electronic health records.

So, I want to explore of what else HHS might want to consider as we think about exercising the waiver authority and sort of moving beyond this, the distribution of shared savings, what other financial arrangements might want to think about. And we can leave it open to anyone who might want to to jump in and then to start calling on people as well.

Sir.

Robert Saner: I guess this is I guess this is the old thing about age before beauty. I think this is a tougher question. I think this a considerably tougher question for you as policy makers. I would think at a minimum you should extend waiver protection to the upfront capitalization of whatever the ACO organizational entity is. EHR, other IT expenditures, initial staffing, there would be no protections for most of those things if one participant in an ACO would contribute more staff in another participant, there would be no protection for

If we don't if we're not flexible in the development portion of it as opposed to just on the outcome, then I think we go right back to the fact that it's a chilling effect and it's just not going to be a workable program.

Vicki Robinson: OK. Let's shift to a new topic or a related topic. We've talked a little bit about sort of the scope of the waiver and what arrangements it might cover. But I'd like to explore for a moment the types of providers that a waiver might cover, that a waiver might apply to many different types of providers and different types of arrangements.

And so I'd like to talk for a moment about the different types of business arrangements that may need a waiver in order to function and the different types of providers and whether there are differences that need to be recognized.

So different kinds of business arrangements may include the hospital, physician, group practice, joint ventures or other affiliation, and then, maybe differences related to small versus large group practices, rural versus non-rural providers; physician practitioners versus other kinds of physician practitioners and whether those differences there are things we need to be considering about those differences.

Marcie, you have your tent up first, so we'll oh, no, it was a false alarm.

Marcie Zakheim: Sorry.

Vicki Robinson: Does anybody, would like to jump in or I can certainly ask, Jan, do you want to talk for a moment about the practitioner's issue?

Jan Towers: Well, bottom line is a nurse I will use, since I'm representing nurse practitioners I'm going to use this is the example. But for nurse practitioners, when we have our own practices, they are very similar to the structure of a physician's practice. So we have the same problems that a small physician practice would have.

And we certainly have had discussions with some of the family physicians and the rural physicians who worry about the same thing in terms of what happens to the little guy. And of course, we sort of, I guess, fit into that little-guy framework because we are a small business, but the problems would be the same.

We have another framework of practice that we call nurse-managed centers. These function a lot like federally qualified health centers. They are tied many times to academic health centers. And there possibly could be other

have it assigned to them and whether or not that will be transparent to the patient.

And I think from AARP's perspective, we think that the ACOs should demonstrate to the patient that there are benefits to seeking care within the ACO. I think from the Medicare perspective, this can be difficult. We were sort of grappling with this. I think quality measurement of course will be critical in making sure that people know what these performance measurements are and understanding how they vary by the performance measurement.

Looking at the cost equation though is more difficult for Medicare patients since the vast majority of them have Medicare supplemental coverage. So cost isn't going to be something that will be that they'll compete as much on.

So I think patient centeredness really has to be the core of how ACOs demonstrate why they may be better choices from others and looking at patient centeredness in a different way that many different demonstrations or other quality organizations have begun to do in terms of how patients actually receive care if it's, you know, measured based on patient experience which I think will be really important to be demonstrated by the Accountable Care Organizations if it's going to be a meaningful way for them to make choices and determine how the seek care. udd-5(c)4(or)3(e)4(2 8f2bs)-2(tra)353.81 Tm 8A som70.f

Robert Saner: I disagree just so slightly on a couple of points. I don't disagree that it should be transparent to the patients. I think if the patients are going to be assigned to an ACO, they should know they've been assigned to an ACO.

But I don't view it in the same way you would view marketing considerations in a competing health maintenance organization or other highly structured managed-care environment. As I understand it, these patients are already there. When you take the primary care base that you need for any one of these organizations to work, the patients are essentially already there.

And at least in the short run I don't think you can impose an obligation on the ACO or the primary care base of the ACO to go out and sort of market the advantages of its approach. This is an effort to take existing care systems and better organize them to achieve better quality and a slower rate of growth in cost.

More than it is, I think, to move patients from one care setting to another. In the long run, ACOs if they're successful will be competing with everybody and they'll be competing to move patients from the from the ACO next door to their ACO. But in the short run, I don't think that's the primary issue.

Troy Barsky: Chet Speed.

Chester Speed: Sure. On the potential, the patient safeguard question, I think, I can't speak for all of the AMG members but I think the vast majority would certainly support the idea of transparency particularly on the quality improvement side of things.

If we think about the PGP demo and I apologize if we keep going back to the PGP demo

Nora's point about

efficiency, whether that should be self-monitoring, whether it should be government monitoring.

And then in connection with this, although this is a topic that cross-cuts I think across a number of issues for today's panel, what role might health-IT and electronic health records play in these systems. And I see Tom Wilder has his tent up so we'll start there.

Tom Wilder: Oh, sure. I'll pitch this one out. I think there's really three components. I do think self-monitoring is an important function and I think one of the requirements for ACOs is they have a compliance plan in place. And I think one of the things that you as regulators can do to help out is maybe put some structure around a model, what that would look like. Again, I recognize there's not, you know, one-size fits all but I think helping ACOs that are starting up understanding kind of what the compliance expectations are and how that would look.

I think it'll be interesting to see what role accreditation might play in some of these groups like NCQA and others in terms of providing standards for ACOs. And finally, I do think the government needs to, you know, keep an eye on the development of ACOs and see how they're working in the context of Stark and anti-kickback and CMP.

And I just think it's useful in any kind of exercise like this to build in a feedback loop so that at some point down the road, everybody just takes a step back and says, "OK, is this working to promote, you know, quality healthcare? Is this working to help deal with some of the cost issues? Are there some things that we're seeing that, you know, unintended or not, you know, we think are causing problems from a Stark standpoint?"

So I think I think again, I think there's kind of three components to this and I think just at the end of the day kind of taking a look to say, "OK, is this really working the way we intended?"

Vicki Robinson: OK, thank you. I think we'll just work our way down the table. Nora?

Nora Super: Yes, thank you. I just wanted to go back to, you know, something I said earlier, again, they're Accountable Care Organizations. So I think that the expectation is that they will be held accountable. I think self-monitoring is important. I don't think it necessarily has to be the government. I think Tom raised an excellent point that we should go to a lot of the, you know, we don't need to reinvent the wheel here. There are a lot of very good performance measurement tools that are already in place that should be relied upon.

And I think people always generally think of that as over-utilization but I know that, you know, most of us in the room are certainly old enough to remember the managed care backlash of the '80. And so I just really fear that if we don't take this seriously and think about how patients may think about doctors not talking to them and showing to them why this is value for them to actually be lowering cost and higher quality that we'll see that all over again unless we really think about this carefully.

Robert Saner: I think I think the accountability for clinical metrics has been an essential part of the group practice demonstration project that receives this. And I would just presume that both self-monitoring and some degree of reporting with respect to clinical metrics would be a part of it going forward.

And that gets you to the subject of EHRs and other IT expenditures. I don't know how a large Accountable Care Organization responsible for a large primary care base of Medicare patients is going to be able to either self-monitor or report without pretty sophisticated systems.

At the same time, I would urge you not to make full implementation of those sophisticated systems a sort of front-end requirement for getting in to the

ACO business. MGMA's most recent data suggest that it cost about $33,000 per doctor to put an EHR in and that's just capital and installation. That's not ongoing training and operating cost and the things that go with that.

I also think I have read somewhere that something like 20 percent of

which is good because that means there will be different types of organizations.

But rather than the organization just being accountable to someone outside of itself that the self-monitoring to me seems just a logical extension of what in my head the picture of an organization that's committed to meeting the goals laid out and the statute is doing, because the organization comes together to rethink on a day-to-day basis how it delivers care.

The example that Dr. Berwick used this morning of the patient transitioning through the Harvard clinic in that context was it took each of those players to rethink how to communicate with respect to a particular case and then to implement it. Tracking that, whether it requires EHR or massive computer systems or not depends on the size of the entity, but thinking about communicating either on paper or through email or through a medical record, about those changes creates information that should studied for the function of the organization and then can become the basis for tracking and monitoring, self-policing, all the way to compliance end.

I think it would be difficult at this stage to develop a model compliance plan like we have for other industry sectors, just like it would be difficult to come up with a safe-harbor because the elements are going to be different from organization to organization. But that said, it shouldn't be that difficult to require that there be something and that it be that there be a test to see that it is effective and working and there be improvement and discipline if necessary when something doesn't work out right.

Vicki Robinson: And we will work our way to the end of the table with Ivy Baer.

Ivy Baer: Ivy Baer, AMC. I really just want to echo what other people have said. But I remind you there's a discussion this morning about the fact that part of what will be built in to the ACOs is looking at continuous improvement. So even if you have monitoring, you don't want it to be just against (inaudible) what

And there needs to be reporting because we need to disseminate the information so that when people learn something that others should do or not

do, there's a way to get the information out there so everyone can benefit from it.

And in terms of Jeff's remark about HIT, I certainly agree with that and just want to remind you that the stimulus bill is giving, on the Medicare side until 2015 to become some form of meaningful user and on the Medicaid side until 2021. So it really is a long process and should just have to occur in a reasonable timeframe.

Vicki Robinson: Great, thank you.

Troy Barsky: So switching gears slightly and, Jan, we'll work to get to you. I wanted to discuss briefly governance structure or governance issues and formal legal structures of Accountable Care Organizations and how that might help achieve success.

One thing that we've heard or questions we've received is specifically around Section 3022 which discusses governance, discusses formal legal structure is that would it be helpful for CMS to dictate specific terms with regard to what a formal legal structure should look like because it creates certainty or would instead, specific terms chill innovation and also increase transaction cost.

So I wanted to focus on that for a few minutes and talk specifically about that. That's something that I know CMS is very interested in sort of picking about these issues and trying to figure out the best way forward with regard to these, I think, important questions.

So I'll actually start with Chet Speed to lead us off and then if other folks want to jump in, please raise your card.

Chester Speed: Yes, I volunteered for this question yesterday morning and that's the real problem. It was early. But when I think about governance, well, actually, take a step back when I think about ACOs in general I tend to think of our members there's probably some of you here are doctors of ACO (inaudible) in 2012. And when I think about I remember is a lot of them had a fairly sophisticated governance structure. And when I think about they're having

executives, administrators, clinical quality, legal/compliance and of course the financing function.

And then depending on whether they're you know 501(c)(3)s or professional corporations, they may even have a you know community Board of Governors or position ownership that manages the whole enterprise.

So there are a lot of commonalities in the government structure and a lot of our members at the same time there's a saying once you've seen a group practice you've seen a group practice. So within each of our members the government structure is actually probably radically different from you know folks in Minnesota to Wisconsin et ceteraa to Wisconsim[ )]TJET EMC /P <</MCIyou know

Vicki Robinson: I think, Jan.

Troy Barsky: Yes, Jan.

Jan Towers: Well with the comment that I was going to make before has to do with including all players. I would hate to see flexibility be turned into a framework of not being inclusive and instead trying to maintain the status quo, and so, I would make that appeal.

Troy Barsky: OK, thank you.

Vicki Robinson: I think at this point we're going to move to the final topic for our panel which is (inaudible) future, looking towards the future, looking beyond the waiver authority, looking at else maybe needed and what other considerations that we should be bearing in mind.

And this is (inaudible) questions to the panel. But a couple of points here that we've been sitting and hearing your thoughts about one of the for existing ACOs and innovative delivery systems I'd like to know what is working now under the fraud and abuse laws. I mean how might we build on this? And then moving beyond one of the shared savings program and demonstrations that we've been talking about.

What exceptions, safe harbors, or other accommodations may be necessary to encourage innovations? What other what else should we be thinking about as we look more broadly towards the future? If anybody would like to jump in here or I can just...

Male: I'd like to, I think what's interesting to me is how much focus ACOs have gotten since the health reform law which put in if you're in the conference management business it seems like a great topic to have; I'm not sure anyone said anything about them but I really think that you know from a hospital perspective and everyone around the table (inaudible) has other provisions that they are looking in the law but you know we're looking at value-based purchasing coming down the pike, we're looking at readmissions policies, we're looking at bundling.

Nora Super: Hi, thanks. I just wanted to say that you know you are maybe going through a lot of conferences about Accountable Care Organizations but I wanted to show you at ARP we've not had one number of calls anyone asking us when am I going to get my Accountable Care Organizations.

So it's really not on the mind of a lot of Medicare patients. And I think that's one of the critical components that people need to focus on is this should be about transforming the delivery of care. And one thing that and making that something that patients want. It really can't be just about saving money. And if that's what it's about it's going to fail in my opinion.

And that we really need to I know that's a critical thing that we need to do in the Medicare progra
think that this is better value and that this is the better way to receive care. And that needs to be something that this focuses on. And so I think some of it needs to get out of just talking to the industry and I guess focusing more on what it is that makes patients understand this is better care.

Vicki Robinson: Great, thank you.

Jonathan.

Jonathan Diesenhaus: I would actually agree with that; part of what was interesting about (inaudible) story this morning was the role that the patient's mother played in the health care process and as a member of the integrated team. That was a particular case but it's patients are going to h9.h-7(e)4(li)-3(ve)4(r)-16(y)20(a)4(no j(a)4(i(

back to the question you know what is there now and what's the problem going on?

Helping people sort their way through how to organize the (PHO) or you know something short of an ACO with the alphabet (inaudible) arrangements that we have out there. The current structure is based on not just the fee-for-service risk but also the decision that we all made whenever we made it that we would focus on paying people by the hour for the work they do.

And yet even that isn't fully protected by existing safe harbors. Yet they're sort of getting a tortuous way to that final position under the kick-

statutes and making sure that their provider and that these comply with Stark kick-back and CMP et cetera.

And I think you know they view that through the use of in-house counsel, outside counsel et cetera. And so there's a fairly intense scrutiny internally. But then again it is sort of like flying a plane or getting into a plane. You know you are safe but at the first time you hit turbulence and you really sort of wonder. That's why I think that's why there's a lot of discussion amongst our members about sort of the broad waiver just to give them the comfort to let them move forward.

And as far as the second question which is what to think about the future I think Dr. Wilson mentioned that this morning that shared savings over time will get to zero. And that's why there's a partial capitation payment mechanism in the statute as well.

And so the CMS (inaudible) should start thinking what the range of issues, capitation brings to the ACO field in the next few years.

Vicki Robinson: All right, thank you.

Tom Wilder is just going to have the last comment this afternoon.

Tom Wilder: Thank you. I just want to react very briefly that though a couple of comments were made and while the fraud and abuse laws you know may have been designed in a fee-for-service world they're really intended to promote you know patient's safety and the independence of the physician decision making and to safeguard medical funding.

And I would just suggest that those goals which I think are part of the Affordable Care Act that are still valid today regardless of the type of payment model. So I think we should just keep that in mind as well as we're looking at you know how these laws interact with Accountable Care Organizations and what other kinds of waivers or exceptions maybe need.

Vicki Robinson: Good, well, thank you. I just want to thank our panel very much. This was very informative and we thank you.

And so we appreciate everyone's participation. We will take a break until about 3:10 and then we will start with our listening session. And we hope those on the phone as well as those in the auditorium and our panel will stick around to offer more views on these subjects. Thank you.

Troy Barsky: Thank you.

Operator: Ladies and gentlemen, this is the conference operator and it is recommended that you (inaudible) lines for this short 10-minute break. Thank you very much.

Vicki Robinson: Everyone could please take their seats. We're going to start in a minute.

Troy Barsky: Again, I am Troy Barsky, the Director of the Division of Technical Payment Policy in the Center for Medicare at CMS. And I wanted to introduce the folks who are up here with me.

This is not a panel discussion but instead this is simply a listening session for CMS and for HHS and also our partners at the Federal Trade Commission to hear your feedbacks with regard to many of the discussions that we've had today.

First I'd also like to thank our panelists from the last session for the very informative discussion they had. I think it will lead us into the discussion this afternoon. It will focus on a lot of the same themes that we covered previously.

I'd like to introduce the people who are sitting up here. First Jonathan Blum to my right who is the Deputy Administrator and Center Director for the Center for Medicare; next to him is Greg Demske, the Assistant Inspector General for Legal Affairs at the Inspector General's office. To my far left is with the director who is the deputy center director for the Center for Medicare and then also Vicki Robinson I'm sort of bouncing around here, sorry.

Vicki Robinson who is the Senior Advisor for Health Care Reform at the Inspector General's office; also for those of you who are here for the morning

session we have two of our moderators from this morning. One is on the Federal Trade Commission, Susan DeSanti who is the Director of Policy Planning at the Federal Trade Commission and to my left is Michael Wroblewski, the Deputy Director for the Office of Policy Planning.

And with that I just wanted to lay a few ground rules for this afternoon's listening session. This is our time for us to hear from all participants regarding their thoughts, regarding the things that we've discussed. We plan to take questions from both those folks who are in the room and then also from folks on the phone line.

We will start our process by taking three comments from the floor and then go into our operator to take three calls or take three messages or comments from the folks on the phone line. If we ran out of comments in the room or on the phone line then of course we'll just continue with the people either on the room or on the phone.

So our standing rule for the day we are going to ask all commenters to keep your thoughts to approximately no longer than two minutes in length, shorter is fine. Also we will be accepting written comments that we had been accepting before this conference, before this workshop and we'll be happy to continue to accept written comments at the same email mailbox that was in the federal register notice.

We're encouraging you to submit those comments within the next two weeks. But we will of course we will continue to discuss these issues with all of you. So with that I think before I actually turn things over to the folks on the floor I just wanted turn things over to our operator, Andrea, to give instructions to those folks on the phone as to how they can queue.

So Andrea, are you there?

Operator: Yes. I am. So ladies and gentlemen if you'd like to ask a question on the telephone line please press star then the number one on your telephone keypad. Again star one on your telephone keypad.

Troy Barsky: Thank you. So as folks are queuing up on the phone we're going to take comments from the room and we'll start. There are two microphones in the room and please ask that you walk up to the microphone if you are going to make a comment.

So we'll start with the front microphone and work our way back from there. So go ahead.

Danielle Lloyd: Good afternoon, my name is Danielle Lloyd, I'm with the Premier Health Care Alliance. We have over 2,000 hospitals that share information together to improve quality and reduce cost. And we as part of this have a collaborative with over 75 hospital systems participating in an effort to become Accountable Care Organizations. In fact 25 of them have the goal of having (inaudible) sector ACOs by April of this coming year.

So we're very interested in this topic and thanks for the forum. In particular we're going to ask about if the agencies conform with exercising their waiver with the (authority) or expansion of safe harbors. Obviously you've heard some preference towards waivers there. But certainly not to think just about sharing of the bonuses but to think about also the other financial arrangements as you started to get at in one of those panels.

It was mentioned about capital investments but there are also other types of payments for primary care physicians, for instance in coordinating or achieving certain levels of efficiencies and such. And so we urge you to look at that, broader than just the bonuses.

There wasn't a lot of talk about the provision of free or discounted care items or services to beneficiaries. That's something that we have some constraints on right now in terms of for instance paying for transportation cost, paying for in-home assistance technology and that sort of thing.

That's certainly something where we think we can really help the patients become more engaged and improve our ability to increase quality. And so it's something that we think you all need to be certain to give us some guidance around what circumstances that we might have to do that within the ACO model.

patient notification well in advance of each ACO encounter. The rules have changed and both beneficiaries and other patients should know it.

Second with respect to the antitrust law considerations and market stability, AdvaMed is concerned about the overall market power that an ACO may wield to the exclusion of competitive forces in the health care marketplace. And the ACO that come to us in every hospital, in every physician and every (inaudible) provider in a given geographic area would permit no competition and skew the market power to the detriment of health care providers.

They may also be anti-competitive if an ACO has a super majority or a majority of even the largest minority share. AdvaMed is most concerned about the impact on patients of having little or no choice in the health care services and items available to them. We're pleased the FTC is considering ways to foster the formation of multiple ACOs to encourage competition in a given market. And this consideration will require an analysis of each relative market. Such analysis is critical to protect and preserve health care marketplace competition, patients' employers and payers.

With respect to the Secretary's broad waiver authority the law states that the waivers to be used only to get "as may be necessary to carry out" programs. And with this consideration AdvaMed recommends that the scope of the arrangements covered by the waiver should be tailored so that only those ACOs arrangements that coordinate care, improve quality and protect beneficiaries should be eligible.

Arrangement between ACOs and third parties, between providers or parties, subsumed within the ACOs that are either existing or new but unrelated to

Troy Barsky: Thank you. We'll take one more comment from the room, the back microphone please.

Larry Martinelli: Good afternoon. My name is Larry Martinelli. I'm an infectious disease physician in private practice in Lubbock, Texas. And I'm here today for the Infectious Disease Society of America.

I have one comment briefly on this morning's session in terms of outcome measurement. We are in desperate need of inpatient measurements at the physician level particularly for those physicians who are either hospital-dominant or hospital-based.

In terms of this afternoon's session, I'd like to make a brief comment on system type measures which maybe within or without an ACO. There is the possibility now and in many most hospitals, there are programs in place for patient protection such as infection control and prevention and antibiotic stewardship.

And these programs have the potential to have an extraordinary impact both on patient safety and cost savings by preventing hospital acquired infections, readmissions for complications by decreasing antimicrobial use and preventing the emergence of infections and resistant organisms.

At this point, as the payment system evolves, if the regulatory system does not evolve then physicians who are not directly employed by hospitals are unable to gainshare what may be literally millions of dollars of savings to hospital systems when they design and implement monitor accountable for these types of programs. And we'd appreciate your consideration as we move forward to allow these types of arrangements so that the credit can accrue where it has been gained.

Thank you for your attention.

Troy Barsky: Thank you.

At this point, we'll turn to the phone line.

And so we would have great interest in seeing that there is some sort of equivalent when it comes to standards of accuracy and clarity in marketing materials and similar communications that ACO they're essentially held to the same standards that MA Plans currently are. Thank you very much.

Troy Barsky: Thank you for that comment. And we'll take one more call from the phone.

Operator: And your final question from the phone lines comes from the line of (Nicole Palin) with (Marsh and Allen).

Your line is open.

(Nicole Plain): Thanks for the opportunity to participate during this session.

What is the anticipated timeline for the release of the final rules or guidelines from the (FTC) and/or (HHS)?

Jon Blum: I think the best we can say is this (fall).

Liz Richter: They're the proposed rule.

Jon Blum: Proposed rule (this fall). Thank you for the clarification.

Male: Thank you. I think we're working on the similar timeframe.

Troy Barsky: OK. So we will now go back to the room and we'll start with the person at the front microphone.

(Elizabeth Keith):

Number one is the focus on the civil monetary penalty statute with respect to its prohibition on reducing services as opposed to reducing medically-necessary services as well as examining even further options to allow incentives for preventive care. I think that would be good for beneficiaries and would be good for providers.

Number two, I would like the government to strongly consider finalizing the exceptions for the shared services and the incentive payments under Stark that is needed, those have been out for a few years, and I think that would be a big thing for the provider community.

And number three, reexamine the electronic health record subsidy, exception and safe harbor in light of the new health reform and look at ways that it could become more contemporary and more permanent. Thank you for your time.

Troy Barsky: Thank you. We'll go to the front microphone.

Jim Kaufman: Good afternoon. Thank you Jim Kaufman with the National Association of Children's Hospitals.

There are three issues I wanted to touch on. First on there's a lot of great discussion about commercial ACOs and Medicare. One payer that I noticed was missing was Medicaid. So I'd be curious with (CMS's) view on Medicaid and pediatric ACOs.

With Medicaid covering one in four children, it is the largest payer of children's healthcare services. So how do you envision incorporating children's healthcare in the ACO model?

Jon Blum: So I think we're very conscious with the fact that this is not just a program for the Medicare program but also for all payers and to the extent possible we'll be coordina

Jim Kaufman: The second issue I have is related to exclusivity, when you were talking before about providers whether it should be exclusive ACOs or open to multiple providers.

The one thing with children's hospitals is usually you have one or two children's hospital in a given market. If you are required to be exclusive with a ACO and you will have four or five ACOs in a market, you may actually be creating barriers to accessing care at a children's hospital.

This last issue I want to mention was regarding measurement. There was a lot of talk about measurements and how to include appropriate national measures. The only request that we have is you included appropriate pediatric measure nationally in the development of the commercial and Medicaid ACOs. Thank you.

Troy Barsky: Thank you. And we'll now turn back to the phone line, so, (Andrea), if you could give us our next caller.

Operator: So again, ladies and gentlemen, if you'd like to ask a question, please press star then the number one on your telephone keypad.

Your next question comes from the line of (Albert Weinstein) with (Precision). Your line is open.

(Albert Weinstein): Hi there. My name is Dr. (Weinstein). I'm a vascular surgeon here in Atlanta and I think the effort today was excellent.

I think though that you need to consider one of your main challenges and it came up both in the morning session and again in the afternoon session. And that challenge is how do you put in place these ACOs in a way that it's pro competitive and doesn't allow the large academic centers within a particular market to dominate by purchasing and employing physicians.

I'm in private practice. Our group which has the clinical integration model in Atlanta is one of those that I think is an excellent model for that 60 to 70 percent of patients who get their care through private practice. And I'm wondering if you have any comments about that.

Female: No. We don't have any comments, but we appreciate your observation.

(Albert Weinstein): Thank you.

Troy Barsky: (Andrea), we'll take the next caller.

Operator: Well, there are no further people in queue.

So again, if you would like to ask a question, please press star then the number one on your telephone keypad.

Troy Barsky: Hey, (Andrea), we do have someone in the room here. So I think we'll go to the person in the room and then we'll turn to you in a few minutes.

So that person on the front microphone.

Julia Hesse: Hi. My name is Julia Hesse and I am an inside counsel for Tufts Medical Center and our affiliated physician organization, New England Quality Care Alliance. And we're located in the People's Republic of Massachusetts.

And one of the many things that's great about that is that our state has implanted a number of ways in which quality and efficiency data and cost data is being reported. And I would encourage you to the extent that you can collaborate with the regulators of the state level because I think that a theme we've heard in both the morning and afternoon sessions was that consistent reporting of quality data in costs and efficiency data is going to help all of us achieve our I think generally recognized in mutual goals of improving quality and reducing cost and having the provider community have a gazillion different quality metrics that we're complying with that are often payer-specific as well as specialty-specific impedes our ability to do this.

And so we see at the state level that because there is becoming standardization required by the state that's advancing the ball at least a little bit and so I'd

Troy Barsky: OK. Thank you very much for that comment the next person at the microphone.

Ross Stromberg: Yes. I'm Ross Stromberg with (inaudible) in the People's Republic of San Francisco and Berkeley.

If by chance, one or more of your agencies happen to grant a waiver, will that at to an ACO that is a certified as meeting all the standards under the 30-22, will that waiver be broad enough to also apply to the commercial side of the business?

In other words, if you're doing business in a certain way with Medicare, you almost start going to have to do the same kind of business with the same kind of arrangement, the same kind of sharing of interest on the commercial side. Have you given any thought to that?

Troy Barsky: I guess I'll start at least from the Stark perspective and then Vicki would want to comment on the (OIG) and that kickback in (CMP) perspective. But (and at least) from our sort of authorities, we're really only able to focus on referrals for (claims) that are submitted to Medicare sort of from the federal perspective.

And obviously, I think a lot of our thinking with regard to sort of ACO and sort of the beyond the Stark and legal issues that we've talking about today, I think we'll get to a lot of the issues between the federal payers and private payers. But at least from our perspective, the Stark perspective, that's not really something that we will be focusing on.

Vicki Robinson: And I think similar ways from the for the (OIG) authorities, (that these) authorities affect Medicare and Medicaid federal healthcare program business and referrals of federal healthcare program business.

There are some types of arrangements and some situations in which payment on the commercial side or payment on the private side may spill over onto the federal business and its intersections where we look we have to look at those (cases).

So we are still considering how this will impact more broadly across payment arrangements on the commercial and private side. I'm looking at how we can provide guidance or a waiver or whatever it needs to be done here that is appropriate, then we'll take into account the issue (raised) which is the desire to have consistent payment arrangements across the commercial and federal side.

Ross Stromberg: How about the (FTC)?

Susan DeSanti: Yes. We are thinking about that. And we recognized and one of the reasons we're participating in this (inaudible), we recognized that many ACOs are going to want to participate in a private marketplace.

And so what we're looking at is the potential to have safe harbors that would apply for Medicare and then also in the private marketplace conditioned on your operations being the same in the private marketplaces as the received approval from CMS.

Ross Stromberg: Right, right. OK. Thank you.

Troy Barsky: OK next commenter from the room.

(Tina Irving): Well, my name is (Tina Irving). I'm with DecisionHealth in Gaithersburg. And I was wondering if you could provide comment or insight on what role independently owned, long-term providers such as home health agencies might play in an ACO framework.

Male: Well, I think I think that's the question for ACOs to you know to determine themselves and I don't envision that CMS's proposed regulations would dictate precisely how such precisely post-acute) care type of (inaudible) might work. But I think that would be something for an ACO to bring to CMS, but they're on proposal.

(Tina Irving): Thank you.

Troy Barsky: OK. And we'll just turn back to the phone line and see if anyone is queued up on the phone line.

Operator: Yes. Your next question comes from the line of (Howell) (inaudible) with Crystal Run Healthcare.

Your line is open.

(Howell): Hi. This is (Howell) (inaudible) from Crystal Run Healthcare in New York.

I'm just hoping that in considering waivers and/or safe harbors that both the (FTC) and (HHS) take into consideration (inaudible) to put function over form and I think this issue has been raised previously.

But for example, a Geisinger like structure operating as it does in a relatively rural area in Pennsylvania works in a fully integrated system but would be much more difficult from anti-trust perspective if we were talking about a joint venture clearly with much more than 20 or 30 percent of the market.

And when you look at an area like the one of which our practice operates we're a multi-specialty group you have a situation where because of the demographics, we're not urban, we're not densely suburban.

One group could easily or a ACO could easily extend beyond 30 percent market share. It could be providing improved quality and lowered cost and yet violate technically some of the restrictions that currently exist for joint ventures in healthcare practice.

A second comment would be that, again, looking at the New York market where physician owned practices are virtually excuse me, physician owned hospitals are virtually nonexistent.

Again, much contracting between hospitals and physicians outside of academic centers is going to be exactly that through contracting and with hope that particularly when we look at Stark and the civil monetary penalties and anti-kickback statute that we take into consideration, the specific differences in market places throughout the country including New York where a lot of these arrangements do have to be done contractually and not through an employment model as it might be possible elsewhere.

Troy Barsky: Yes. Thank you for that comment and perspective the next caller on the phone line.

Operator: Your next question comes from the line of (Michael Cook) with (inaudible) Parker.

Your line is open.

(Michael Cook): Hi. Thank you very much. I have a question to extend on Ross Stromberg's and the counsel from Tufts and that is have has any thought been given to trying to expand or encourage a demonstration to encourage ACOs to look at an all-payer type of a demonstration.

Maryland does something like that with their hospital system. Obviously, this would be a lot broader.

Male: I think there are two ways to answer that question from a CMS perspective. First, is that under the statute, we have to create a shared savings program for the Medicare program.

But I think as Dr. Berwick and others had said that our goal is to ensure that we're well coordinated with other payers to ensure that we're not that we're complementing not undermining other private sector efforts.

There is authority within the statute in the centered for innovation that has to be stood up by January 1, 2011. I think Congress had contemplated at that innovation authority as being a possible vehicle to work with other payers.

(Michael Cook): Thank you.

Troy Barsky: Thank you next caller on the phone.

Operator: Your next question comes from the line of David Klatsky with McDermott Will and Emery. Your line is open.

David Klatsky: Good afternoon. It's David Klatsky, partner with McDermott Will and Emery in Los Angeles.

Two points that I would want to touch on that haven't really been addressed to this point are incentives for patient access to care and then also expansion of protections for incentives for efficiency within ACOs.

On the first item, in our work as outside counsel to the premier ACO collaboratives, we've heard a lot of anecdotal evidence of a you know access issues that impede the ability to ensure that patients will be compliant with their treatments and would certainly encourage consideration of further liberalization of the ability of healthcare providers to provide appropriate incentives to patients to accomplish those goals, be it free transportation and you know other type of assistance.

You know, in an economy such as this one and even in good times, it's amazing sometimes how very trivial amounts of money are the real difference between a patient you know with chronic diabetes being able to you know attend regular doctor visits and comply with their meds.

The failure of which ends them up in the emergency room at great cost to Medicare program. Particularly in an environment in which patients are assigned to an ACO based on their preexisting relationship, you know we certainly feel that there are sufficient protections in the system that the traditional concerns about program integrity would be safeguarded in this area.

Secondly, I think the point was made in an earlier in the earlier panel discussion that achieving Triple Aim Outcomes is going to be difficult if ACOs do not have protection with respect to the process by which the Triple Aim Outcomes are achieved. And certainly, finalization of the shared savings or incentive payments' exception to Stark and a kickback safe harbor would be a step in that direction.

But I think you know in large measure, the lack of progress made on that effort over the past years has been a result of a lot of pushback regarding the highly complex and very restrictive nature of the proposed exception in the safe harbor, and that you know in the spirit of promoting innovation and

experimentation, that has been cited consistently throughout today's session that, perhaps, a more liberalized approach in that regard would be appropriate.

And I think it is particularly appropriate from the regulator standpoint in the context of ACOs where you have two factors that are not typically present. One, you know under the Medicare Shared Savings Program, you are committing yourselves to a finite three-year agreement.

And so, you're not in the position of having to blindly bless arrangements for all time, but rather, you will have organizations applying for Medicare contracts and have the ability to you know approve or disapprove those arrangements. While these obviously also affect the commercial market you know, again, as was mentioned, the structures put in place for the Medicare side will also apply in the commercial venue as well.

And you know so basically, you have that protection of finite period. And secondly, you have reporting of information as outlined in the statute, which would provide regulators with all of the information they would need to determine if there were undesired outcomes resulting from from these relationships.

So you know for those reasons, I would certainly encourage you to consider taking a much broader approach to protecting incentives paid to providers within an ACO that are aimed at incentivizing achievements of those goals.

So you know whether it'd be you know gain-sharing type arrangements between hospitals and physicians or what not that unless folks have certainty with respect to those arrangements, it's going to be very difficult to get ACOs off the ground. Thank you.

Troy Barsky: Well, thank you very much for that comment. And I do want to, for the rest of our time period, just have speakers and commenters be mindful of the two-minute requirement. I have not been enforcing that yet, but I'm about as the time gets shorter, I will become more strict from here on out.

So, with that, we'll turn back to the to folks in the room and start with the front microphone.

practicing in the rural areas where we have a hard time getting physicians and other practitioners to go.

So and there needs to be some thought about you know, one, training more providers; and two, how do you support them and encourage them to go into the underserved areas. You can't form ACOs if there m an ACO with, ultimately. So that's one of the things I'd like to see happen.

Troy Barsky: Yes. Thank you very much for that comment. We'll next go back to the phone lines and see if there are anymore folks in the queue.

Operator: Your next question comes from the line of (Gerald Connolly), a private practice physiotherapist. Your line is open.

(Gerald Connolly): Thank you very much, and thank you for having this session today. I represent the private practice section of the American Physical Therapy Association and I think that membership is about 4,000 independent practicing physical therapists who are small independent businesses, community based.

And I'd like to express the appreciation of the difficult path that the agencies must walk in trying to lay out the framework for ACOs, particularly as it relates to the issue of exclusivity.

The while, of course, you desire to promote collaboration at the same time allowing providers to negotiate in and among themselves could create an opportunity for collusion.

The by virtue of forming an ACO, individual practitioners or the ACO professionals, as defined by the statute, will need to determine who is included in the ACO and who is not included in the ACO.

But independent community based providers, such as private practicing physical therapists, are by nature in competition with not only the services that are provided in the hospital, but also in some cases in competition currently with some of the services that are provided by physicians.

So, this is a difficult, indeed, path to walk because exclusion from an ACO could mean an impact on privately practicing physical therapists or the non-physician providers. It could mean a lack of freedom of choice to the patient.

So, the way you set up the framework and the model and the waivers of this particular entity are going to be extremely important to this particular this particular cohort.

how else do you determine whether an ACO is being successful in terms of outcomes, controlling cost, et cetera, there also needs to be sufficient transparency to patients and payers, et cetera.

My concern would be, and just something to keep in mind is that we also have the Patient Safety Act with the development of Patient Safety Organizations, which allows for the treatment of all of that information as (inaudible) confidential. And so, it's taking a while to get hospitals and the physicians excited about that and truly understand it.

And our my hope would be that as you think about monitoring what has to be reported out that we don't inadvertently undercut the protections and the goals of fostering open communication of fostering physicians and others to come forward, acknowledge issues, problems so that it can be a healthy discussion about those kinds of problems so that you know quality can improve. So, you know keep that in mind if you can.

it in the rural areas where the benefits of having connectivity and (inaudible) ability are and the opportunities for telemedicine and so forth are so great.

And second, as we face the physician shortage and the continued difficulty in recruiting and retaining physicians both primary care physicians and specialists in rural areas, I would encourage re-examination of the physician recruitment and retention restrictions and exceptions and also some consideration of how hospitals can help specialists do outreach without the hospital (inaudible) physicians. That's it. Thank you.

Troy Barsky: OK. Thank you. If there's no one else in the room here, I'll turn it back to the phone line.

Operator: At this point, there are no questions on the phone line neither.

Troy Barsky: OK. So, any last chance for comments in the room or comments on the phone? Or if not, we will conclude the session for today.

Operator: So, on a telephone line, if you'd like to ask a question, please press star then the number one on your telephone keypad.

Troy Barsky: OK. I will take that as a no. I wanted to thank you all for your participation today and I appreciate all of the thoughtful comments and the work of all the panelists in both the morning session and the afternoon session.

As I said, a few times, we encourage you all to submit further written comments that we will consider very carefully. We have already considered all the comments we received previously, and we will carefully consider all further comments you submitted.

So thanks again to everyone, and this was a great session. Thank you.

Female: Thank you.

Operator: This concludes today's teleconference. You may now disconnect.

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