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 Executive Vice President for Management, Compliance and General Counsel for the Federation of American Hospitals.

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: So, I'd like to just focus on 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, which is waiver authority. Specifically, section 3021 of the Affordable Care Act, dealing with demonstrations and pilots, and section 3022 of the Affordable Care Act, dealing with the Medicare Shared Savings Program. We are expressly authorized to waive the fraud and abuse laws as necessary to carry out these important statutory provisions. In addition, CMS and the OIG have the authority to create additional exceptions or safe harbors as necessary.

What we are considering now is how to best use these various authorities separately or in combination in the context of ACOs and other integrated care delivery models. And by way of background in 2008, CMS proposed just such an exception for shared savings and incentive payment programs. CMS received significant public comment but we did not finalize the proposal. Given the more recent development including passage of the Affordable Care

Act, CMS is engaged in new thinking about the best way to address shared savings and other performance-based programs. Furthermore, CMS has begun work in crafting a proposed regulation for the 3022 shared savings program and we expect to issue proposed regulations shortly.

Now, turning to the panel discussion today, we've organized our discussion into basically three main broad categories. We first wanted to talk about how the secretary may exercise waiver authority with regards to fraud and abuse laws as Vicki mentioned a moment ago. Next, we want to focus on safeguards that may need to implement to protect patients and also protect the integrity of federal programs that should be included in the design of any Accountable Care Organization. And then finally, we want to conclude by discussion of the future and moving beyond our explicit waiver authority, what other possible safe harbors and exceptions should be considering in order to facilitate the creation of Accountable Care Organizations?

Further as we move forward with our discussion today, for those of you who joined us in the morning, we would just like to remind all of our participants both on the panel and in our second listening session about Dr. Berwick's Triple Aim goals which are: to focus on better care, better health for populations and lower cost per capita, and how we might work to fulfill those goals. We're interested in exploring how we at HHS can most effectively insure that the fraud and abuse laws are not a barrier to improving quality and reducing cost through Accountable Care Organizations.

Now, in reading some of the comments that we received before the, this panel or before this workshop over the past week or two, we noted that there are a range of views on the exercise of our waiver authority and other mechanisms as needed and what conditions may be applied and we're looking forward to exploring that further today. Those comments are now posted on the Federal Trade Commission's website and they will be posted on or linked to from the OIG's website as well as CMS' website in the coming days.

Now, just a few ground rules for today. Similar to this morning, we – you know, we will be asking the questions organized around these certain themes. For this first session, we'll be focused on listening to our panelists that we've

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

need the permission to experiment and I think that applies in spades to Accountable Care Organizations and I think it is as important with respect to the fraud and abuse authorities as it is with respect to the anti-trust authorities.

Speed helps you get up and running, reduces the costs, the sort of transactional costs for the people who want to participate and put these Accountable Care Organizations together and I think it levels the playing field to some degree. Clearly the very large integrated systems have a head start in this game and they have certain advantages under the fraud and abuse laws as they large non-profit integrated systems. We – we view ACOs as an opportunity to bring small groups and contractual arrangements or perhaps many smaller groups into the ACO field and I think if you go down the path of many safe harbors and new Stark exceptions we will get mired in detail. Therefore, I'm a strong advocate for waivers.

Vicki Robinson: Great. Tom.

Tom Wilder: So, thank you. I guess I take a bit of a contrary view and I would not automatically start with the assumption that Stark and the anti-kickback laws and CMP are somehow this great impediment to ACOs. We heard from the panel discussion this morning that there are a lot of these kinds of organizations or ACO-like entities that have been in operation for a while and numbers that are forming. And so, I think as a regulator, I would start with no assumption one way or other and what I would say to those groups that are have either operating ACO-like entities now or looking to form them, I would say, "OK, what are the five or six or 10 things that you really want to accomplish that think improve patient care that you think you know will address some of the cost issues that you believe the current structure doesn't permit?" And the let's build safe harbors or exceptions around that.

And again, I'm not – I'm not saying yes or no, I'm saying instead of – instead of giving this kind of blanket – there are problems, let's do away with them. Let's focus on the specific question that people are struggling with. And the second point I would raise is I think to some extent, to me, the process of developing those exceptions or waivers are as important as what they actually say and I credit both the FTC and CMS and OIG for starting that discussion

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 didn't really anticipate 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. And so, I think we're seeing it in the context of an ACO now but only 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 the one point I think the context that everyone has answered the question I think is the right context but I want to make sure we put on the table that the waiver authority is something – it's a little bit different really in a real live program. We've seen waivers in the past with regards to demonstration projects, but with regard to pilot programs and clearly the three – 3022 shared savings, this is real.

And so the question that we've had some debate about is really is the waiver appropriately applied in the context of giving everybody a level playing field or will the government be looking to potentially provide waivers to individual ACOs who may come in and present a particular type of arrangement and we think the former is the right way to go. We think to the extent that you are

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 delivering care so we can meet the goals that were discussed this morning.

The anti-kickback statutes and Stark and the CMP look at that old model and impose very significant penalties made even worse by (inaudible) law enforcement world you know by (inaudible) whistleblowers the False Claims Act really supping up the penalties. So, safe harbors and exceptions are designed within a statutory framework that – that doesn't favor innovation, that doesn't favor flexibility, that prescribes the type of transactions that will be protected from these penalties, and if you're half inch outside, you're

subject to those penalties. So, the consequence is twofold. It discourages innovation because it's very narrow, very focused and very upfront structurally limiting in what the transaction can be.

But the penalties, the existence of the penalties also discourages risk of those participants from engaging in the process of innovation. And I think that's you know in this reform environment, that's the worst case. And so, if – if the choice is between designing Stark exceptions and safe harbors the way we've come to understand them with the old check list of what the documents need to look like on the front-end or waiver, then I choose waiver. I don't think waiver means an unlevel playing field's like if you can do it as Jeff said that it can be across the board and I also think it can be structured in a way where it needs to qualify for the waiver.

I guess I disagree with Ivy. I don't think that case by case approval of an ACO to qualify for the waiver would (lend) and it will – it will just put a lot of paper in people's desks and it wouldn't more very fast. But some set of safeguards, and I'm going to go all the way to (inaudible) now I'm taking more than two minutes. But you know in the fraud and abuse world, we received guidance from the Inspector General and from CMS about the need to have effective auditing, monitoring, and compliance, and what we're talking about in the big picture is Accountable Care Organizations.

So, if the organizations have a minimum criteria internal self-policing, accountability, and a real measure of integration that takes into account accountability so that the entity is taking action on this information it's gathering, that it's actually moving forward, not a sham integration to pass money back and forth, but a real integration through which reform of the practice of medicine and reduction of cost occurs, and that can be monitored on the back-end. That would be a way to qualify for waiver have a structure that allows for output and measures outcome.

Vicki Robinson: OK. Thank you. Chet Speed you've had your card up for quite a while so will (inaudible) recognize you.

Chester Speed: Hi guys. Chet Speed with the American Medical Group Association. I think we would favor a waiver, that rhymes, and I come from a – from an ACO development standpoint. As many of you know the ACO statute was largely based or in part on the experiences of the Physician Group Practice Demonstration participants, nine of which were AMGA members. Thankfully for us, one of the things that we've learned from them was that startup costs for the PGP Demonstration were about $1 million and much of that was fixed for personnel and the maintenance cost to continue these care management processes in place which are necessary to tightly manage our (currently) all patient population.

We are also in the seven figure mark. And so when you think about those participants were fairly sophisticated on the integration scale and they had a lot of things already in place structure wise, (EMR) is being one. But when you think about you know seven figure investment figures to even begin in the process of being an ACO, I think a lot of potential ACOs (inaudible) some type of clarity from OIG and CMS regarding you know that they are indeed – there is a waiver authority in the statutes because it's difficult for them to put them in that type of investment and not know what some – to be in certainty that they are within fraud and abuse statutes.

Vicki Robinson: OK, thank you. I think we'll take one more for this very popular question and then – and then Jan Towers.

Jan Towers: One of the things that people in my framework are concerned about is unintended consequences. Nurse practitioners are generally thought to be employees but six percent of 140,000 of them had their own practices and one of the things we're very concerned about is making sure that we get included in whatever developed here as full partners so that we can continue to provide care to our patients.

One of the things that can happen -- and so we're just cautioning and saying please keep an eye out for this sort of thing -- is that you can find when our groups get together to negotiate the things with waivers that there is an opportunity sometimes for collusion that needs to be protected in a way that there cannot be a leaving out or an exclusions, a delivered exclusion from a

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

those kinds of financial transfers under the kickback law or the Stark law as they now (exist).

So – and I think it will be almost impossible to start ACOs quickly if each potential collaboration among otherwise independent providers has to come up with the same formula for sharing those upfront costs. I wouldn't begin to know how to do it. You know, what share should the hospital pay if the hospital is part of it? If it's a primary care base and 10 specially practices, how do you allocate the share of those costs so that no regulator could ever say there was an imbalance there that must have reflected a kind of underhanded subsidy of a referee for a referral or…?

So, I think you will need that kind of upfront protection under the waiver. I think when you go beyond that, it gets more difficult and I don't know that there are easy answers to what you do to other financial relationships that might predate the formation of the ACO or that might come into being after the ACO is already operating. It may not have anything really to do with the ACO but they are entering into relationships between these other participants. Presumably, if they're preexisting, they're already protected in some fashion at least to say, have Stark implications presumably they're already protected in some fashion. So, they may not need the waiver to the same degree as the distribution of the saving and startup capitalization.

Troy Barsky: Ivy Baer.

Ivy Baer: I'm Ivy Baer, AAMC. I can't have specifics, but the question is sort of a follow-up to Jonathan's remarks. It's again starting to think the paradigm that we used to thinking in because Stark is all about financial relationships. So, let's think about those that need to be protected and maybe the thing to do is – we originally talked about waiver and being broad and being flexible, and maybe we need the protections come elsewhere as I suggested earlier and it's not that we should be setting out every relationship that needs the protection because we'll never get them all because they were staying in the same boxes if we do that.

Troy Barsky: Chet.

Chester Speed: Sorry. And so I was thinking – we're – for OIG and CMS, it is a difficult question, where do you draw the line even if there is a waiver? But I think about some of the relationships that may occur as the ACOs are developed. If you're a physician practice for instance and you want to develop an ACO, presumably you may want to partner with a hospital so that obviously brings in a range of Stark and kickback and CMP concerns.

You may want to also look at teaming up with a SNF or a Home Health Agency. I mean, if ACOs are going to be integrated and provide a comprehensive level of services, the arrangements would span the gamut from, you know, Part-A, B, oh, yes, that's pretty much it. So I guess there's going to be a fairly – if you're all considering a fairly broad waiver I think it's important to keep all those potential arrangements in mind.

And we can talk about what the idea of – there's obviously going to be some sort of tradeoff with that protection as – because the public will be – the program is going to be protected as well.

Troy Brasky: Great. We'll just go to Marcie and then I think we'll move on to our next question.

Marcie Zakheim: You know, it's a very interesting question as far as whether to waive the other elements of the ACO development. And I think if you don't do that – if you don't – either waive or protect the other types of arrangements within the ACO, the waiver of the shared savings is protecting the outcome of the ACO.

It's not protecting the inner workings of how you get to that. It's not protecting the development of the ACO and without doing that, whether it's through a waiver or through the use of existing safe-harbors or something to that effect, although, you know, if the goal is to try and get up as quickly as possible, the most effective way would be using waivers as opposed to trying to rely on a combination of the waivers and the safe-harbors and exceptions currently.

It's, you know, one of the – you know, we keep going back to – the idea of the waiver is so that we're not – so that we're chilling the innovation and we're not chilling the ability of providers to develop these integrated systems.

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 kinds of issues related to that because we already know that because they are tied to academic health centers and don't have their own community boards that make them free-standing that they don't qualify for federally qualified funds – health clinic funds at this point in time.

So those are the kinds of things that we would have. We do have nurse practitioners who have arrangements with hospitals and so those – the same kind of problems that any physician would have with that – would fit into our business framework as well.

Vicki Robinson: All right. Thank you. Jeff Micklos.

Jeffrey Micklos: Excuse me. Yes, I think that obviously from a hospital perspective, just in our own world you see so many different types whether it's, you know, a physician hospital organization or whether it's just hospitals that have employed physicians which are probably a little bit easier to analyze currently.

But if you have hospitals with, you know, community-based hospitals with a predominantly voluntary medical staff, the issue get a little bit thornier. And so just in our space you see a bunch of different models and you think about kind of what you pose in the question as far as rural versus urban and different provider type. I just think you really begin to complicate matters significantly.

And you're going to really have to tread lightly without creating I think an undue impact on the market. I really do think that there needs to be at a level playing field. If you're an ACO and you're achieving the policy objectives of the ACO, really, what your characteristics or your demographics are really

shouldn't be that big of an impact in my view. I think you really probably create more complexities than necessary.

Vicki Robinson: Right. Tom Wilder.

Tom Wilder: I think, you know, I think there's a lot of different types of arrangements that may form as ACOs and I think you need to give them the flexibility to flourish. I would look at – I would think about it in terms of two issues. The first is, "Are there certain types of arrangements that raise a heightened risk of some kind of improper relationship, some, you know, some kind of improper referral or a financial relationship?"

So that's one piece of the puzzle you'd look at. And the other one quite frankly is regulatory burden. Obviously, a smaller physician practice, they don't need a lot of kind of regulatory requirements layered on top of whatever they do now. So I think size to me matters in that particular perspective as well.

Vicki Robinson: All right. Nora Super.

Nora Super: Yes, hi. I'm Nora Super with AARP. I just wanted to go back to if these people are going, you know, around this question of, "Do we want to provide these waivers so we can have as many as possible and everyone flourish?" And – or get to the outcome of what the policy objective is of the Accountable Care Organizations.

And I think that I'd fall on the side of making sure that we stick to what the policy objective is. I mean, they are called Accountable Care Organizations and we want to make sure that they're accountable to the patients. I know that people want to have this market opportunity and see the ability to improve the delivery system which we certainly support. But I think there is a risk that the patients will be going to systems that aren't fully able to achieve the objectives that are laid out in the statute.

And so we need to make sure that criteria are clearly set and I think the types of organizations that are able to achieve that are different and you can't just have a blanket waiver for all organizations because they want to participate.

Vicki Robinson: Great. Thank you. I think with that, we may move on. I know tents are popping up and we have more questions in this area but we want to be sure to cover the major topics. So if I can ask, maybe we will move on and then hopefully you can work your thoughts into other questions.

So we're going to I think now turn to the question that Troy mentioned at the beginning about safeguards and what kinds of safeguards we might need to consider in connection with waivers, exceptions and safe-harbors and these various issues.

Troy Barsky: And I think at this point or these series of questions sort of gets to what some of you have raised as sort of the larger policy questions and policy issues sort of underlying the exercise of the waiver. And so at this part of the discussion I think what we really want to focus on is moving away from the waiver itself, thinking about either the regulations that CMS will put out with regard to the 3022 program or other models or demonstrations that we may be exploring over the coming months and years.

What type of issues or concept should we be making sure that we incorporate into the programs themselves to serve as a safeguard to really get at the policy goals which we've all been discussing?

And specifically, I wanted to start with something that was discussed this morning about patient-centeredness and how we create Accountable Care Organizations. Assuming that we will exercise some waiver authority, how we will focus on the protection of patients that we're focusing on patients and focusing on giving the best quality care to individuals?

So Nora, I'm going to actually ask you to pick up and start again and maybe sort of continue it with some of the comments that you gave a few moments ago to really address this issue about patients and patient-centeredness.

Nora Super: OK, thank you very much. Yes, that's a very interesting question and several of us were discussing it over lunch as well and have been discussing it as we think about ways of course that people will either be assigned to an ACO or

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.

Troy Brasky: Anyone else on the panel before I move on to the next question. Jan?

Jan Towers: One of the things that I think does happen when you hear discussions about assigning patients to an ACO, and a lot of that discussion centers around the patients that nobody wants and that's the high-risk patients, the poor, the socially disadvantaged. It does send a bit of a chill up our backs in relation to really allowing everybody to have a choice of provider and getting the kind of care that they deserve and want.

And so if we're really truly being patient-centered we really need to think about that whole concept.

Troy Barsky: Robert?

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 – but that's where a lot of our feedback from; they had 32 measures that they reported on all focusing on high cost, high-volume disease conditions and they were publicly reported.

Their cost savings were also publicly reported by CMS. That's a – I think someone mentioned it, a thornier issue. But I think ACOs would certainly largely agree to be transparent on the quality improvement side. And to

Nora's point about patients should know that they're on ACO, we would fully support that also.

The problem I think is actually a CMS challenge and that's one of attribution. I think a lot of patients may not know they're in ACO and the ACO won't find out who their patients are either. Perhaps, 12 months after a performance year.

So I think ACOs would certainly support their patients knowing they're in ACO. And perhaps, perspective (inaudible) is a way to get at that very issue.

Troy Barsky: Thank you. Marcie, we'll finish with you and then I think we'll turn to our next question.

Marcie Zakheim: I just want to reiterate something and add a little more to something that was already mentioned and that's having to do with the patients who are the underserved patients who are currently patients of participants within these ACOs. I think one of the things we have to keep in mind is really focusing not just on quality improvement but evidence-based or outcome-based criteria measurements.

I think if we get too lost in the cost savings side of this equation, what we'll end up seeing is a negative impact on the safety net and potentially a negative impact on safety net providers participating in these ACOs.

So I think it's very important to keep that in mind when we're talking about measurements or patient protections to ensure that we're going down the path of really looking at that evidence-based, outcome-based types of measurements so that we can ensure that we don't end up with the safety-net folks kind of falling through a gap.

Troy Barsky: Great, thank you.

Vicki Robinson: All right, thank you. I think we'll shift to another topic now, one that was touched on I think in an earlier response. I'd like to talk about what types of monitoring the government should perhaps require in order to best serve patients and to ensure that ACOs are improving healthcare quality and

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.

But we also need to make sure that there meaningful ways for the patients to know how these organizations are being held accountable in ways that they can look at the shared savings. It should be transparent to people, again, when you started your comments and talked about Stark and anti-kickback, you talked about how it's improper steering of patients motivated by financial interest.

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.

Vicki Robinson: OK, thank you. Bob.

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 American physicians have what they think of a functioning EHR system in place would suggest that 80 percent of them don't. I think if you want to encourage the rapid development of ACOs, you will be encouraging at the same time a more rapid implementation of IT and EHR investments. But I would strongly encourage you not to make it sort of a day-one requirement.

Vicki Robinson: Jeff?

Jeffrey Micklos: Sure. You know, I would agree with that. And I think just quickly, yes, self-monitoring with some reporting I think is an inadequate way to kind of get at this. I think on the EHR question, I found the discussion in this morning's panel kind of fascinating that we have some real cutting edge programs out there that have come up at few different ways.

So kind of stepping back from the two sections that we're talking about that (law) today, I think that with the stimulus package from a few years ago, we certainly have a policy driver that's getting healthcare to electronic health records. I don't necessarily think you need to use this authority to kind of further drive that.

I think at the end of the day, it's the objective measures that are out there saying the program is being – is meeting its goals, it's serving its patients well. You know, we're eventually going to get to that electronic health records, but I think that you then curtail kind of innovation and uptake of these programs if you were to require electronic health records.

Vicki Robinson: Jonathan.

Jonathan Diesenhaus: OK, again, I come at it from a slightly different angle and maybe ending up in the same place. But part of the way questions are being answered is that everyone has a slightly different view of what they organizations will do

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 it's monitoring against may change as folks learn things.

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 cetera.

So as far as – that the question is, is it would it make sense for CMS to impose some type of you know governance. Stretchers I think all of you would be – we'd like and this mentioned this morning. We'd like some sort of flexibility because the governance structures are so (inaudible) and at the same time so different. Amongst the members I think many of them just follow the dictates of the statute which is fairly broad. It's probably the best way of going about the issue of governance at least from our point of view.

Troy Barsky: Jeff Micklos.

Jeffrey Micklos: Yes, I know I agree with that I think that you know if we pick again what's the theme and the goals we're trying to achieve here, it's innovation and look at a variety of different care models and kind of test them and see how they're doing. It would seem counter-productive to me to get prescriptive in the way that these organizations really would be governed.

I think that you know the statute is probably more than enough really; you have a separate legal structure so it can get you know basically the payment and the arrangement. And then there's shared governance. And clearly the statute talks about who can participate and to the extent that you have some or all of those people in your ACO and they should be part of the governance.

But I think to go much further than that is really going to be – you know a stifling innovation in a way that it would be the opposite of what we're really trying to achieve.

Troy Barsky: OK, thank you, Tom Wilder.

Tom Wilder: Thank you. I would agree to some extent on the – I think I would come from a standpoint that I think any waiver (inaudible) where it needs to be fairly specific, I think kind of dictate the governance or legal structure. At this point we'll cycle from innovation. You know it's been discussed some of the component that I think are very helpful such as the compliance function, administrative function.

And I think it might be helpful to discuss that to some extent and to help those who want to form ACOs and understand what those functions are and how best to carry them out. But to dictate the (inaudible) they need to put those together in a formal corporate or legal structure I think is not necessary.

Troy Barsky: And let's conclude with Marcie.

Marcie Zakheim: I fully agree with that. We don't want to be dictating terms on a legal structure because from the perspective of somebody who works with a lot of – (inaudible) works with individual providers that form a lot of different joint ventures, networks and so forth if you've seen one, you've seen one.

It's very difficult to dictate and it would chill the innovation, I think it would you know impact – it would potentially impact the ability of certain folks to come together and to form an ACO. I think the one thing that will obviously (inaudible) folks would agree the one thing we want to be clear is that whatever government structures are chosen they don't impact – they're not going to impact the existing governance structures of the participants.

But short of that I think we really need to leave it up to the individual participants..

Troy Barsky: Great, thank you.

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.

And I think that you know the discussion that was started with regards to the 2008 rule making, looking at a payment incentive exception and a shared savings exception and safe harbors I think that really should continue. Because what I feared here is that because of the workload I understand that this is clear and present and it's now and we've got to figure it out. But the waiver authority really just goes through those two sections.

It's not really helping – you know even if you were to put something after that thought it's not necessarily helping you in other contexts where the waived payment is being done, the way that care is being coordinated in different ways than it has been historically are being helped. And I think the payment incentive one is the key one from my perspective. And if you're doing value based purchasing and you want to be able to tie the positions in there has to be some level of incentive that's permissible there.

So I do think that we need to kind of think about this and the barrier question to the extent that the fraud and abuse laws are barriers you know in a broader context because the waiver is very narrow and I think you all should continue to think about policy making.

Vicki Robinson: OK, thank you. Ivy Baer.

Ivy Baer: I guess we (inaudible) we need to go back to Congress but at this point the fraud and abuse laws are written to apply to a system that's based on fee-for-service where the incentives are to increase volume. But as we move to new payment systems the fraud and abuse risks become different. And you can't easily fit the current laws into different payment systems. We just keep on having square boxes and round systems and they're not working.

And so I think we need to rethink what do we really need to protect the programs, protect the beneficiaries but to allow these new payment systems to function freely and so I think that this is a discussion beyond something that CMS can do but perhaps if you think it's true you'll be supportive of really considering major changes in the laws that are out there.

Vicki Robinson: Nora Super.

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 program. Don't get me wrong but I think that patients need to 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 have to join in the process and engage in the process.

With respect to the question I'm still back at the exception to safe harbor approach were overly prescribed. The result of this reinventing you know reformation of health care that needs to happen, should happen in order to get that experience to more patients in more locations across the country's large cities and small towns.

Innovation is dynamic and it seems to me that the expectation in the statute is that we're going to not let it loose and let it run wild but let it loose and let it roll down the track. And so, if you have – what's the problem and tying it

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 the difficulty that we've had over time embracing gainsharing, shared savings you know that – the fraud and abuse paradigm that we live in now just can't really get all the way around what incentives would be, not just financial for cost savings but incentives for doing it right or improving the delivery of care or making it faster or you know reducing the readmission rate or whatever it is; so that the measure of success that results in payment to the nurse practitioner who is involved in the delivery of care or a physician you know that the home – the visiting nurse that was discussed this morning. All of that needs to be you know reinvented.

And the existing exceptions won't work. You have to get an advisory opinion and that could take, depending on how many advisory opinions come in on this new ACO wave you know 10 to 12 years to get one. It's a little joke.

But you know it's just that the current structure is allowing people to do some of what's desired here but not to continue to grow it and that's why they – another reason the existing structure just doesn't work.

Vicki Robinson: Thank you. And yes, in your case, that yours will definitely take 10 or 12 years (laughter).

I think we're going to recognize the (inaudible) and then take a break before our listening session.

Robert Saner: Yes. I just want to comment briefly on your question of what's working now under the existing fraud and abuse laws. And what's working – what's working now are highly integrated systems with employed positions and no physician ownership of anything anywhere in the picture.

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-back law and sometimes under the CMP law. So I think you have moved well beyond some of what your existing safe harbors protect through your advisory opinions and through things you say publicly. And maybe it's time to bring a couple of safe harbors to where your thinking is – I'll give you one example in this fully integrated system, there's no safe harbor to protect transfers of money between components of the fully integrated system.

I don't think that would be a huge leap for you all to fix that. You said in 1999 you weren't quite comfortable with that and you weren't ready to fix it. Maybe times have changed enough that you could.

You have existing policy in several places for example in physician incentive plans. There's a nice little physician incentive plan piece in the Stark regulation, maybe that has applicability in the ACO context and beyond the ACO context as a piece that protects the beneficiary from undue physician incentives, the control and cut care.

So I think you – I mean, I think there are things you can do to build on what is working now and move that out. That's particularly important to the smaller medical groups that MGMA represents because almost all of them have physician ownership somewhere in the picture. And under existing Stark exceptions and safe harbors that ownership complicates everything even if they are compensated exactly the way they would be compensated in a big non-profit employment-based model. And in fact many of them are compensated essentially in that same way.

So I think there are things you can do to make this a little more user friendly to a larger spectrum of organizations than the very large highly integrated physician employment models for whom it now works best.

Vicki Robinson: Chet Speed.

Chester Speed: OK, thank you. I think you know for existing ACOs and innovative delivery systems I think what's working now is the fairly intense focus on fraud abuse

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.

And then one of the – in terms of reward sharing within the ACO one option might be to allow the ACOs to put the compensation plan within their application. And if it's approved and they adhere to it then they would be free from the scrutiny of the Stark anti-kickback and CMPs.

And so it's something to think about and certainly we'll follow up with some additional written comments but thanks for the opportunity.

Troy Barsky: Thank you. The next person at the front microphone.

(Ann-Marie Lynch): Good afternoon, my name is (Anne-Marie Lynch) and I'm with the Advanced Medical Technology Association or AdvaMed and I thank you very much for the workshop today.

We did submit more details and comments including a brief legal analysis on September 27th and so I encourage you to use the (inaudible) document. But I'd like to make a few key points here today. First is concerning the quality of care and patient access. AdvaMed strongly supports initiatives to improve the quality of care and to ensure patient access to high quality care.

We are active participants in the national quality forum and other quality organizations. We are concerned however that the new ACO provisions in the law provide little detail about how to ensure protection for beneficiaries and their access to appropriate care including critical lifesaving medical innovations. Safeguards and protections can and should be built into the program to protect beneficiaries. And they should include – but shouldn't be limited to the following.

Explicit protection for Medicare beneficiary access to medically appropriate care including advances in medical technology, development of robust quality measures for the care provided by ACOs to offset the financial incentives to reduce the volume and intensity of care. The development of quality measures that monitor utilization in order to detect under-utilization of services and technology to ensure that patient care is not compromised; independent monitoring of beneficiary access to appropriate care including access to innovative technologies and importantly providing meaningful

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 – coordinated care should not be covered by the waiver. AdvaMed received information about a number of arrangements between hospitals and physicians that are not meant to improve quality and coordination care.

Here are two examples: hospitals subsidizing physician office leases or administrative support staff expenses in exchange for the physician’s using the lowest cost device without regard to the quality or the individual patient need or hospitals and physicians entering into co-management agreements or other

joint venture arrangements that enable profit sharing in exchange for, again, physician use of the lowest cost device without regard to the quality or the individual patient need.

The key concern here is that many health care and even physicians could potentially structure their financial arrangements to enhance profit margins without regard to the quality improvement and coordination care. So expanding the waiver authority would open the door to this activity and present a significant risk for patients.

Finally the fourth issue I'd like to mention is the creation of a Stark exception section to the anti – I think that's safe harbor. Even after considering today's input about ACOs that are likely to be created and included in the Medicare shared savings program without experience and an independent evaluation of the impact that these ACOs may have it's simply impossible to ensure that there will be adequate Medicare beneficiary protection to safeguard quality of care and access to care.

We recognize that the Secretary may grant waivers as may be necessary to carry out provisions of this section. However for purposes of determining whether to create a permanent regulatory exception to the physician self-referral law AdvaMed recommends that the Secretary provide a clear explanation of why any risk of program or patient abuse might be appropriate within the shared savings program.

While today's workshop is focused on consideration of the antitrust laws, Stark self-referral law and the federal anti-kickback statute and civil monetary penalty laws, there are many other legal considerations that will be important for ACOs. These include but aren't limited to federal income tax law and various state laws such as the state fraud and abuse laws and the state corporate practice in medicine laws.

AdvaMed recommends that the secretary also take into consideration these legal requirements as she implements Section 18-99 of the Act.

Thank you for the opportunity to comment.

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.

(Andrea), if you can queue up our first person in line.

Operator: Your first question comes from the line of David Stein with Drexel.

Your line is open.

David Stein: Hi. My name is David Stein. I'm actually a colon and rectal surgeon at Drexel University College of Medicine in Philadelphia.

One of the issues that tend to come up is monitoring outcomes and whether it's different Patient Safety Organizations, the National Surgical Quality Improvement program—getting objective measures and using these outcomes to be able to compare how you're doing versus equivalent groups or equivalent ACOs is going to be very important.

Also, figuring out the outpatient outcomes versus inpatient outcomes for large medical groups that are affiliated with different hospitals is also something that needs to be considered strongly. It's going to save you time. And that's all I wanted to say. Thank you again for the opportunity to participate.

Troy Barsky: Thank you – (Andrea), the next caller.

Operator: Your next question comes from the line of (Seemin Pasha) with (Families Health). Your line is open.

(Seemin Pasha): Hi. Good afternoon. My name is (Seemin Pasha) and I'm with Families USA. Thank you for very much for the opportunity to participate in this listening session, it's such a timely and relevant topic.

I'd like to echo some of the earlier comments that we heard about consumer protection. We have some questions about how beneficiaries will be assigned to an ACO—what that assignment will look like and whether it will have either a real or perceived effect on consumer choice around their ability to select a provider.

The other thing, and this is looking a little further down the road at possible scenarios, our own experience with MA Plans demonstrates the need for rigorous consumer protection.

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): Good afternoon. Thank you. My name is (Elizabeth Keith), I'm representing the California Hospital Association.

I just want to thank all the staff and the panelists for an exceptionally informative conversation today and we really appreciate – excuse me – the opportunity to provide comments.

(We talked) a lot today about the need for flexibility and (a line) for experimentation and to achieve this goal, it'll be critical to create a level playing field from which experimentation can take its many forms. I think

many of you know that most California hospitals are not permitted to employ physicians due to the existing prohibition against (corporate) practice of medicine.

California law only authorizes county hospitals and the University of California health systems to employ physicians and therefore, as a result, those hospitals aren't able to access both the state exemptions to the corporate ban and the employment exemptions or exceptions to federal fraud abuse and self-referral prohibitions.

This complicates our ability to take leadership roles in ACOs throughout the state and we'd welcome an opportunity to further dialogue with you about this issue as we look for innovative ways to bring physicians, hospitals and other care providers into ACOs.

Second and on a larger point, as we are now embarking on ACOs and other payment mechanisms that help drive quality, we also – at the same time, (HHS) currently has its national plan or national strategy for quality improvement that is due to release to Congress in January.

That hopefully will step forward some goals towards achieving quality improvement. I think the challenge here is alignment and focus. As we're looking at cost and quality measures for ACOs, we're looking at them for value-based purchasing (book) on the hospital and physician side. Aligning them with this national strategy will be critical for focusing at the ground level and improving care at the bedside. Thank you for the opportunity.

Troy Barsky: Yes. Thank you. We'll go to the back microphone there.

Greg Wallander: Thank you. My name is Greg Wallander. I'm an attorney in Indianapolis with Hall Render. Thank you for having this presentation and panel today. It's been very helpful. I appreciate it.

I'd like to make a couple of comments with respect to the provider's side. There are so many areas which the government could focus our time on. I would like to urge it to focus on a few that I think would alleviate a lot of the issues.

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 coordinating with our colleagues in state on the Medicaid side, so that is a CMS priority to ensure that what we're building for the Medicare program also has a close tie-in and collaboration for states as well.

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 encourage you to work with the state or to demand that people implement of a single system of quality measures.

Thank you.

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.

(Thomas Bartrum): Thank you. (Thomas Bartrum) with Baker Donelson in Nashville, Tennessee. I'm speaking on my own behalf, but we have a number of clients that are looking at developing ACOs. And despite the fact that I'm a lawyer, I will stay within two minutes.

First of all, I think it's important that you consider allowing ACOs to make financial payments to patients for financial decision-making, cost-effective decision-making. I think that would really allow ability to get patients involved in the process.

I would also say that you know unlike when we built integrated delivery systems in the '90s, today is very ugly. Meaning that you know one hospital might have a pay-for-performance arrangement with its (IPA). It might have a medical co-management agreement with its cardiology department and has employed physicians.

I think if you're building a waiver or a safe harbor, it's important that you take into account that there's a lot of preexisting arrangements that have incentive compensation and are those arrangement be accepted.

And then the final issue is really just for your awareness. It's more of a legislative issue and that is you know we have a lot of providers that operate in several states. Remember the '90s, a lot of states adopted anti-managed care. Well, I mean, it would be nice if Congress would have given pre-emption here so we had a level plain field as opposed to dealing with these issues on a state-by-state basis. So that's it.

Jon Blum: So, can you clarify your first point about ACOs being permitted to provide financial payments to patients? Are you referring to differences in co-pays and cost-share? Or what more precise did you mean by that?

(Thomas Bartrum): Well, I think the ACO could actually say we're going to allocate a portion of the cost savings of total care that will go back to beneficiaries for effective you know decision-making based upon cost data. If you put that transparent information out there, they can see different sites of care, different costs for those sites of care, and they can make a decision that way.

And if you can track that through your system, then you can take that pool of funds and distribute it back to patients, which I think would get patients more involved in the process than simple data transparency. And that's it.

Troy Barsky: All right. Thank you. We'll go to the back microphone next.

(Randy Fenninger): Thank you. (Randy Fenninger), Holland & Knight. Just an observation, we've spoken mostly about physicians and hospitals in the arrangements for ACOs. There are many health systems that incorporate health plans which are interested in this and to the extent that that health plan may become a simple part of the operation of the ACO, may have a bearing on your considerations both to the FTC as well as looking at the other statutory interaction between the private sector and the public sector.

So, just wanted to raise that for your awareness and information. Thank you.

Troy Barsky: Oh, thank you. The next commenter at the front of the room.

Male: I thank Dr. Curtis Lowery, chairman of the OB-GYN Department and the director of the Center for Distance Health at the University of Arkansas for Medical Sciences. And one thing I've learned at this meeting is that attorneys talk a lot more than doctors.

So, Arkansas is a very rural state where we have a huge population of underserved individuals in the rural areas. The director of the OB-GYN department, where we train more physicians and as you know CMS has not dramatically increased the money for training our physicians for quite a few years.

We had to pick up a fifth resident in our department and we did that as department revenues because it's very important that we increase the number of OB-GYN physicians we train in that area.

And the second thing is, is that we have one of the largest telemedicine programs around the nation with the idea that we're going to try to support for the primary care physicians and nurse practitioners and other individuals

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 – isn't anybody to form 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.

For that reason, I would really appreciate any comments the members of the panel have, but also I would like to encourage CMS to convene one or more listening sessions for non-physician providers to talk about things like this and talk about governance and also talk about the Electronic Health Record, which as you know there are no funds or no stimulation for private entities other than physicians at hospitals to become funded and up – up and running on (HIT).

So, there are a number of inherent issues here – some legal, some implied – but I would appreciate your consideration of those – of those points. Thank you very much.

Male: And thank you for those comments. Just to let folks know on the phone, our panelists have been dismissed, so I think you won't get any further independent analysis from them for today.

We do encourage you – and as I said at the outset of this afternoon's listening – if you have further comments, written comments, we do encourage you to submit those and CMS will consider those as we work through the regulatory process.

And so, the next question on the phone.

Operator: Your next question comes from the line of (Michael Callahan) with (inaudible). Your line is open.

(Michael Callahan): Thank you very much. That was close enough. Just a couple of comments. I know you're going to end up here. One of the comments made on the question dealt with the issue of monitoring both the internal and external, I don't think there's any question that there needs to be both. And

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.

And then secondly, because I have technical difficulties in trying to connect this morning, I don't know if there was any comment about when you look at the ACO certification requirements and taking on some of the indicia of what we would call clinical integration, whether those are developed in consort you know with the FTC with the idea that if one becomes certified, I don't know that there is a determination that you have now achieved sufficient clinical integration or maybe a presumption of integration. Maybe that's something (inaudible) talked about.

But you know that would – some guidance along those lines would be very helpful, recognizing that we're really talking about the private payer side and not the public payer. So, thank you.

Male: For your comment, that second issue is something that we are actively considering. So thank you.

Operator: Your next question comes from the line of (Jeffrey Brinier) with the (Compton Collision). Your line is open.

(Jeffrey Brinier): Hi. Thank you for taking my question. I'm the executive director of a non-profit city wide coalition focused on improving the safety net in Camden, New Jersey. It's one of the poorest cities in the country.

We have multi-hospital involvement, so two hospitals, three emergency rooms, all of the local FQHCs and private practices, we have found that the high-cost, complex patients who are often (inaudible) move from hospital to hospital and are quite mobile and it would not work to have three competing ACOs in this market place that the intervention really requires collaboration across multiple domains, multiple providers, multiple hospitals, which obviously creates anti-trust issues.

Will there be much like the rural issue, urban communities have many of the same problems? If a state where the design or legislative model for Medicaid urban underserved ACO in which Medicare could participate as well, would you imagine the federal government delegating some of the responsibilities for oversight to the state in order to ensure and prevent monopoly and steering of patients?

Male: I'm not – I'm not sure that there is so much we can say at this point from a CMS perspective. I think as Jon Blum stated earlier, especially with regard to Section 3021 and the Center for Innovation in some of the models that they will be exploring over the coming months and years, I think that that – that could definitely an area that – that they – that they could and we'll explore in the future.

So, I encourage you to submit those comments around that area and we can – those folks are not up here on the (dais) today, but we will definitely pass along those comments to them.

(Jeffrey Brinier): Thank you.

Troy Barsky: And we will now turn back to the room and to the back microphone.

(Elizabeth Mills): Hi, I'm (Elizabeth Mills) with Proskauer Rose, the law firm. I just had a couple of comments on the rural issue. First, if you're going to give relief anywhere on the 15-85 percent cost allocation for EHR installation, please do

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.

END