FEDERAL TRADE COMMISSION

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FEDERAL TRADE COMMISSION	)
ROUNDTABLE ON:	)
ANOTHER DOSE OF COMPETITION:	) Matter No.
ACCOUNTABLE CARE	) P111205
ORGANIZATIONS AND ANTITRUST	)

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MONDAY, MAY 9, 2011

Conference Center
Federal Trade Commission
601 New Jersey Avenue, N.W.
Washington, D.C. 20580

The above-entitled hearing was held, pursuant to notice, at 10:00 a.m.

PANEL 1:

PARTICIPANTS AND AGENCY STAFF:

HENRY ALLEN, American Medical Association

CHRISTI BRAUN, Mintz, Levin, Cohen, Ferris, Glovsky & Popeo, P.C.

DR. LAWRENCE CASALINO, Weil Cornell Medical College

DR. ROBERT GALVIN, Equity Healthcare, Blackstone Group

ELIZABETH GILBERTSON, Unite Here Health

THOMAS GREANEY, St. Louis University of Law

MELINDA REID HATTON, American Hospital Association

STEPHEN KATINAS, BlueCross/BlueShield of Massachusetts

ROBERT LEIBENLUFT, Hogan Lovells

JOSEPH MILLER, America's Health Insurance Plans

DR. LEE SACKS, Advocate Physician Partners & Advocate Health Care

TOBY SINGER, Jones Day

TRUDI TRYSLA, Fairview Health Services

PATRICIA WAGNER, Epstein Becker Green

MODERATORS/QUESTIONERS:

SUSAN DESANTI, FTC, Office of Policy Planning

SARALISA BRAU, FTC, Health Care Division

CHRISTINE WHITE, FTC, Northeast Regional Office

JOSHUA SOVEN, U.S. Department of Justice

P R O C E E D I N G S

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MS. DESANTI: Good morning. This is the first time in my experience of running workshops that we've been ready to go two minutes early, so I'm definitely going to take advantage of that. Bob Galvin, who is sitting at the end there, was on the 8:30 shuttle from New York so he will be joining us at some point no doubt.

I want to welcome you all to the second FTC workshop on antitrust and Accountable Care Organizations, otherwise known to multitudes as ACOs. My name is Susan DeSanti. I'm the Director of Policy Planning at the Federal Trade Commission.

This is our second workshop on antitrust and ACOs. We had one in the fall to discuss what issues our panelists thought that antitrust enforcers should take into account in developing a policy for ACOs. We had payers, providers, and many others on the panel in October, and I'm happy to report that many of these people have been able to come back and have agreed to give us thoughts now on the joint proposed statement of antitrust enforcement for ACOs in the Medicare Shared Savings Program, and we really appreciate the willingness for you to come and share your thoughts with

us, and I also want to welcome our newcomers.

I want to emphasize at the beginning that we know that we can only have a relatively limited discussion today, so we want to encourage all of you who have thoughts about the policy statement that you would like us to take into account, to please provide written comments. There are instructions for how to do that in the Federal Registry notice at the FTC website on Accountable Care Organizations, and those comments are due on May 31.

Now, here's how we're going to proceed. First I'm going to read the required security briefing. This always happens. It's not related to Osama Bin Laden. Anyone that goes outside the building without an FTC badge will be required to go through the magnetometer or x-ray machine prior to re-entry into the conference center.

In the event of a fire or evacuation of the building, please leave the building in an orderly fashion. Once outside of the building, you need to orient yourself to New Jersey Avenue. Across from the FTC is the Georgetown Law Center. Look to the right front sidewalk. That is our rallying point. Everyone will rally by floors.

You need to check in with the person accounting

for everyone in the conference center. In the event that it is safer to remain inside, you will be told where to go inside the building. If you spot suspicious activity, please alert security.

Now, we're going to begin with a brief overview of the Medicare Shared Savings Program and the context in which all of this arises, and we're going to be led through that by Lynn Shapiro Snyder from Epstein Becker who will take my place.

MS. SHAPIRO SNYDER: Thank you, Susan. Hello, everyone. I'm Lynn Shapiro Snyder with the law firm Epstein, Becker and Green. I'm a Medicare Medicaid managed care lawyer, been there 32 years, and the title is very brief overview of the Medicare Shared Savings Program and how this particular workshop fits into the broader scheme.

So this is a page I wanted to spend a moment on. I think people talk about the baby boomers, but they don't really know what it looks like, so the last five years, we've added approximately 500,000 new 65 year olds to the Medicare program, and this particular year it is going to be 1.3 million. So it's a three times increase in one year, and then it goes up at a 45 degree angle for about 20 years.

I try to be bipartisan inside the Beltway, so I

have both of our former President Bush and former President Clinton because as you know, we had World War II, and then when they came back, we had babies, and they both turn 65 this summer, and we have to become prepared, and part of what the Medicare Shared Savings Program is a piece of a bigger puzzle to try and figure out how to make the most out of every entitlement dollar.

This is a page that is a summary of the Medicare programs, and historically before the Accountable Care Act, we only had two real Medicare programs. On the left was original Medicare, which is ala carte, fee for service, freedom of choice, and the government's role is as a public plan, and therefore what you worry about from an enforcement and an accountability standpoint is primarily over utilization.

On the other hand, we had Part C of Medicare Medicaid advantage where the government was outsourcing all the Part A and B benefits, and when you outsource on a bundled payment, the government's role is much more consumer protection, because there's an outsourcing, and the concern is underutilization.

Then the only other thing we had before Accountable Care Act were demonstration projects and what we call one offs. The accountable care statute and

the Medicare Shared Savings Program in particular creates what's supposed to be a permanent program option for providers to access the Medicare program and to offer new types of products and new payment schemes, and that's why I call it the hybrid, and one of those hybrids is the Medicare Shared Savings Program.

This is just a very quick summary. As I go around the country, I've been keeping a listing of all the different ways we can control costs. I hear all the speakers, and shifts in health status, I'm sure you've heard if you lose five pounds, each of us, we could really save a lot of money in the healthcare system, changing the way healthcare is delivered away from the hospital and more towards primary care, bundling the savings, pay for savings, advances in medical technology with all different types of new products, malpractice reform, changes in consumer preferences, especially during the last six months of life, and finally the whole political fiscal discipline of how we're going to handle the expenditure of this money.

The Accountable Care Organization under the Medicare program is an entity that's going to really create population health management and give the providers an opportunity to take advantage of and arranging for the provision of healthcare for quality

costs, but it's only for the Medicare beneficiaries who remain in the traditional fee for service program, and then the whole issue of how they get assigned to the ACO.

There are non Medicare accountable care relationships already in place. There are private payers who have already launched relationships with providers in their community, and they sometimes do it with their commercial risk business, and sometimes they do it with their self funded business, but those are not necessarily according to the types of rules that are now in the proposed rule.

Not to make matters any more complicated, but sometimes I hear people talk about accountable care, and what they are really talking about are some of the other Medicaid payment reforms where there's bundling of payments based on episode of care, patient centered health and on the recent Federal Register notice that was issued on value based purchasing.

To be eligible, we all know it's at least physicians. The question is who other than physicians will be participants, and there is some controversy and questions about the role of hospitals and other types of institutional providers playing a significant role, and then the Secretary did extend her discretion to include

some critical access hospitals.

Savings are shared based on actual costs compared to a benchmark, and it allows the Secretary discretion. The partial captation model may end up in the center for Medicare Medicaid innovation rather than through this type of section of CMS.

I'm not going to go into all of the requirements. There is an issue about agree to participate for less than three years, what happens after the three-year period, issues about do you need a new legal entity or can it be an existing entity modified, having sufficient information to support it.

For purposes of today's discussion in the area of antitrust compliance, I think the more important issue is clinical integration, leadership management. A lot of what CMS is requiring for clinical integration is going to be really relevant to the antitrust analysis, and of course everything is supposed to be patient centered.

Finally this whole issue of how the math works. It's retroactive. They look at a certain amount to set aside, that you have to achieve savings greater than a certain percentage. There are two tracks you're allowed, one track that will give you some time before you're at risk for losses, and I do have people ask me

who do I share the savings with, and sometimes they don't realize the savings are shared with the Medicare program.

So it's the Medicare program and the ACO, and then last but not least the quality area and that the Medicare beneficiaries are still in that Medicare ala carte fee for service program. There is no lock in or any type of enrollment per se.

Last but not least, comments. There are four Federal Register issuances. Beware, they have different due dates. The CMS one and the OIG one are June 6 based on when they were published in the Federal Register, and the other two are May 31, and I am with the Federal Trade Commission and DOJ joint issuance because that's the purpose of today's presentation and discussion.

It is supposed to be about let's take a deeper dive on how to make sure that when independent, competing providers want to set one of these things up for the CMS application, that they do it in a way that's pro-competitive than rather anticompetitive.

Just one final note, this is a voluntary program. I mean, companies have to get together and decide this is what they want to do, and the more we can make the rules clear as to what is the guidance, the more likely people will know whether they want to

volunteer for the accountable care under Medicare.

Thank you.

(Applause.)

MS. DESANTI: Thank you, Lynn. I am now going to begin our discussion with each of the panelists giving us a two-minute summary of what they view as the most important issues to be discussing today.

I'm going to introduce each panelist and have them do their summary, and then move to the next, and we'll just start with Bob Galvin and move all the way around the room, and after that I will introduce the FTC and DOJ staff who are participating today.

So we will start with Bob Galvin. Dr. Galvin is chief executive officer, equity healthcare, Blackstone Group. Bob, the floor is yours.

DR. GALVIN: Thank you for that brief introduction, and thanks actually for asking me to speak today. I know everyone is going to get slightly different aspects of this, so I wanted to get a couple things on the record.

First, I do appreciate the FTC's interest in this. I think I'm going to be speaking on behalf of employers today, not only the 35 companies I represent, but my prior experience with GE and my knowledge of this part of the space.

We really agree that competitive marketplaces are important to get to the next kind of -- to really to have effective health reform, so we agree that that is the right model, and I think it's going to be challenging.

I think the whole move to a way for fee for service, which this represents, is the broader concept that we're dealing with here because I think when you try and be accountable and when you move to some sort of prepayment which I think shared savings is on the way to, you are going to have bigger organizations because they need to coordinate, and bigger organizations are going to have more power to price, and that is a big deal to the private sector.

I think it's also opportunity because I have spoken many times with the FTC about the extent to which I think our marketplaces are not optimally competitive today, before this change in payment, and we have great concerns about what's happening to our affordability.

So speaking on behalf of employers, I do want to mention that I started an organization that now has about probably 20 employers. It's called CPR. It's Catalyzed Payment Reform. We started it a couple years ago. We use the acronym CPR because we thought the payment system needed. We thought it needed

resuscitation, so we're happy to see a lot of this movement. This group is not formed to talk about ACOs as much as it is to try and give an employer private sector coordinated voice because all of the action or most of the action is happening on the Medicare side.

So speaking on behalf of the employers in general but kind of representing the CPR's thoughts, let me get into specific comments about directives. I think they're really solid work. I think they're thoughtful. I think people work very hard to try and listen to the concerns that many of us had.

I have two big issues with them, and I think it will come out in Q&A. The first is it appropriately does what it's asked, which is it talks about the model shared savings in Medicare. I think that's important. The issue it doesn't discuss, which I think is equally important, is what happens to the private sector.

So, for example, even if you have cost sharing on the upside so that there is kind of less reward and even a penalty payback in Medicare, that has nothing to do with what might happen to raising prices to private sector, so for any economist in the crowd, just so you know, I believe there is cost shifting, and I'm happy to debate it now or later with you, but on that presumption, obviously you weren't asked to do that. It

doesn't do it, but it's a key issue to us. We're seeing it in markets today.

The second issue is this talks about new entities, entities formed after March or independent organizations. You're getting exactly what you were asked to do.

I just want to get on the record that while I think that's important, I think that an equal or far greater risk is organizations that aren't independent organizations coming together, organizations that are a single entity that in many ways are kind of hospital owned, and so the ownership and the kind of active number of physicians wanting to and hospitals purchasing such practices is greater than I've seen in my 30 years in the field, and again very large organizations with the ability to have a lot of influence on pricing, so those are our issues.

A couple of suggestions that again I would like to get on the record, and hopefully they will come out in the Q&A. The first is I believe that I would ask you to rethink kind of non exclusivity as a remedy. I think non exclusivity is important. I am more interested in a buyer, not in having an ACO have to contract with different organizations as I am as a buyer with wanting to get to different parts of the ACO.

So if I want employees under me to seek cardiologists in a community that happen to be part of a big ACO, can I do that without going to the rest of the ACO? Can I contract with them individually? Are they going to be encompassed by a larger organization that is obviously going to be a different contracting situation?

The second one I mentioned already, which is I think the idea of taking this as an opportunity to look at organizations that are independent groups forming towards this but that are already entities, particularly hospital and physicians are important.

Finally I would like to strongly ask, and we would be willing to help on this, that we could establish a realtime tracker to find out what is happening to prices. I believe some costs shifting is happening. I believe pricing power exists. We have very little ability I think in the current time in the private sector to find out what's actually happening to prices.

There's some methodological issues. There are some other issues involved, but I think it's going to be very important because this is just the beginning of a whole waive of a new kind of payment.

MS. DESANTI: Thank you, Bob. Next we're going to hear from Trudi Trysla, who is associate general

counsel with Fairview Health Services.

MS. TRYSLA: Thank you, Susan, and I also want to reiterate the previous comments. Thank you for the opportunity to have this discussion. It's a valuable opportunity to talk about the potential for changing the way healthcare is delivered today.

I'm speaking from the perspective of a provider that's trying to do this work. Fairview Health Services is a healthcare system located in Minnesota. We have eight hospitals, many of them community hospitals, an academic health center and a physician practice group.

Several years ago we started on turning to change our model of care delivery. We worked with our employee providers and also with the payers in our area to change the financial model as well, so that the exchange wasn't based on the usual conversation around price, but on the actual value that's delivered to patients.

What we've seen in our early results is that it has made a difference. It's made a difference in terms of cost. It's made a difference in terms of quality. It's made a difference in terms of the care providers engaged in the work, and most importantly, it's made a difference to the patients that are being served.

From our perspective and from many across the

country who want to do this transformation, and needless to say it's a significant transformation, to try to carry this model deeper into the community across organizations that are independent but want to actually change that care model.

So we're hoping and hopeful that the final regulatory structure actually supports that and allows again that deeper ability to reach more patients in any community and make a change in the way care is delivered.

Specifically I know we're going to get into it more in the Q&A, but there are significant challenges for providers with the change, with the required review process, particularly within the timeframe that's committed here, within the very short timeframe to try to transform, to react to and observe the CMS requirements and to consider all the work that's necessary for the antitrust review.

The data limitations to doing that review are very significant, and in terms of the exclusivity piece, I think there should be -- the old model doesn't necessarily reflect the model that accountable care represents, and so the issues relative to not being exclusive that has the opportunities, particularly for specialists engaged in multiple providers, I think the

historical view should be different in looking at the view of a healthcare organization, and we welcome further discussion about that.

MS. DESANTI: Thank you very much, Trudi. Next we'll hear from Bob Leibenluft. Bob is someone who was head of our healthcare division at the FTC in the 1990s, and he is now a partner at Hogan Lovells.

MR. LEIBENLUFT: Thanks, Susan. Let me preface my remarks, I represent both providers and plans, but my remarks are totally based on my own views and do not represent necessarily any of the clients.

I want to commend the agencies for three things upfront, and then I'll do a few more things at the end and that I want to focus on some things.

In terms of things that I would like to commend the agencies are on are the following: I think the body rule of reason treatment to ACOs, which is in the Medicare Shared Savins Program is a good idea.

I appreciate the clarification that in the context of ACOs that are sufficiently integrated to participate in the Medicare Shared Savings Program, that joint negotiations with health plans are ancillary, are necessary for their operation. I think that's a useful advance.

Third I think sharing an expedited 90 day review

for those ACOs that want that greater certainty is also an excellent thing. So those are three good things.

Let me go to something that concerns me more, and that's the 90 day mandatory review, and I think it's important to separate out two issues here. One is providing certainty to ACOs that want it as to whether there will be issues with the antitrust review, and I think that can be done with the voluntary review. Those ACOs that want that can get it, and I think that's good.

What concerns me though is requiring all ACOs basically that have a certain trigger threshold, the need to have that 90 day review, and I think that that is going to be problematic for several reasons. One is setting forth any threshold like that upfront is very difficult. It's like a one size fits all kind of approach, and it's not market based. There's a proxy for market shares, but no matter how you do it it's going to be problematic, and I think it's going to probably end up getting a lot of ACOs subject to review which could be burdensome.

What concerns me even more is the commitment to come to an answer, a yes or no in 90 days, and to think about this right now, think about if you had HSR review where you said for any merger, the agencies would come

to a decision in 90 days, yes or no. That almost never happens. I mean, certainly with easy cases, fine. With the hard cases, with the HSR process, the back and forth, refiling, there's lots of negotiations.

And I think forcing people, forcing the staff to come to that decision is going to end up with either being too stringent a review because in a way I suspect it may be easy to say no, knowing that ultimately you're not going to be going to court. You're just saying no, or maybe it's going to be too lenient, and there will be ACOs that will get through, maybe getting through with the kind of regulatory consent, which become I think not the kind of business that the FTC and DOJ are used to doing.

How to fix this? One suggestion is to have a filing process. The agencies know ACOs are being formed, but they don't have to say yes or no within 90 days, particularly if the ACO doesn't want that.

Secondly, I suggest there could be a structure -- if the agencies still really want to have 90 day review, I suggest it be a very structured process, that the ACOs know within a certain period of time, 30 days, what issues are surfacing, 60 days where the recommendation is going. They have a chance to review that, talk up the chain with the decision makers.

Finally, and then I think at the end of the day, they should still have the flexibility if an ACO and the staff have concerns that there be more time to review it.

Lastly, three more things to commend the agencies on. First, I commend them for trying to tackle some really hard issues, particularly where we have ACOs that are like the proverbial unicorns and so forth.

Secondly, for working closely together with each other, and particularly with CMS, and I think in an unprecedented way, and finally for publishing proposed statement which is not always done and having a hearing on this.

MS. DESANTI: Thank you very much, Bob. Next on the panel is Christine White, who some of you know from her long experience in the private sector in healthcare, but we are now fortunate enough that she is a staff attorney in our northeast region, so she doesn't get to give a two minute summary.

The next person on the panel, Stephan Katinas, does get to get that. Stephan is vice president for provider network contracting, BlueCross/BlueShield of Massachusetts.

MR. KATINAS: Thank you as well for the opportunity to participate today. I come at this from

the provider -- from the payer perspective from the Massachusetts market. In our market, our plan has been changing the way you pay for care that the providers are following.

It is very similar in structure to ACOs. The alternative quality contract was developed in 2007 and launched in 2009. Its modeled combined financial incentives are low budget, modest inflation rates over a five year contract period, and robust performance point incentives based on a broad set of quality targets.

The model now governs payment over 40 percent of our HMO population or 500,000 markets. Our experience with this model to date is providing evidence of improvements in both healthcare quality and spending that's achievable through models that establishes provider accountability for quality and outcomes and overall resource use.

There are many factors in our market leading to provider consolidation. Some of this activity may be encouraged in part by our agency delivery model. However, in our opinion, consolidation of smaller practices with limited infrastructure has served to advance coordinated care delivery that would otherwise be left to the managed care service environment.

The absence of our delivery model we believe

would be contracting and interacting would be the essentially the same. Organized health teams, large integrated systems, smaller community hospitals and provider organizations their interactions would be governed by a managed care for service agreement.

We would like to see support for modification statements, to learn broader provider interest in ACO participation while safeguarding against guarantee inclusion and anti steering contract provisions independent of an ACO's PSA share size.

MS. DESANTI: Thank you very much. Next we have Mindy Hatton. Mindy is --

MS. HATTON: General counsel.

MS. DESANTI: -- general counsel and vice president of the American Hospital Association and we are very glad to have her with us today.

MS. HATTON: Thanks, Susan, and thank you very much for the invitation to be here today. I hope that throughout this workshop that we can keep the bigger picture in mind, and by that I mean the Medicare ACO program was designed to be the center piece of the administration's effort to change how healthcare is delivered and paid for in the U.S. I think it's a very ambitious, very worthy goal.

As Lynn mentioned at the outset, the ACO is a

voluntary program. No one has to be an ACO. The hope I think was that there would be broad and enthusiastic participation that would really chart a new direction for how healthcare is delivered in this country, and as you know, the ASH has been raising concerns about the legal and regulatory barriers for making this kind of change for many years.

As a matter of fact, by my count this is the third FTC on this issue. I think the very first workshop where we articulated our concerns about the panoply of legal and regulatory issues was one on clinical integration that you held about five years ago.

When we evaluate the FTC statement, we're evaluating against the benchmark of whether it eliminates or even has a positive impact on the barrier that we know antitrust law can be to an ACO like clinically integrated organization.

We agree with Bob Leibenluft, that there are some very positive aspects to the statement, but overall we think it fails to accomplish its objective, which is to either eliminate or significantly lower the antitrust barriers to participation in an ACO or even a clinically integrated group, rather than relax the antitrust law, which the AHA has never advocated or supported. We're really concerned that it may confound it.

In my allotted two minutes, let me just make three observations. On Friday some of you may have seen that there was a report in Congressional Quarterly that the Cleveland Clinic, Mayo Clinic, Intermountain Healthcare and Geisinger Healthcare doubt that they will participate in an ACO. These are the very institutions that were the model for ACOs, but because of the regulatory regime, it is doubtful, and it was doubtful that they will actually participate in this program.

We've also had an opportunity to do some preliminary analysis on the PSA structure, and I apologize, I'm not going to be able to stay for the second panel, although I will tune into the webcast to see how it went.

Our preliminary analysis of 162 cities where there are three or four hospitals shows that in virtually all of those cities, that either the largest hospital or a combination of hospitals will be subject to the mandatory review, and that certainly any hospital that has a center of excellence is more likely than not to be caught up in the mandatory review, and that's true whether or not the center of excellence serves Medicare patients or not.

We're also I think disappointed that the FTC didn't at least consider and give us the opportunity to

comment on using something more akin to the model that the Department of Justice uses to evaluate banking mergers when they were considering some kind of regulatory regime in connection with ACOs.

While I'm far from an expert on exactly how this works, we have been trying to educate ourselves, and again we would have liked to have had the opportunity to at least discuss a model where the agencies do the overwhelming bulk of the work, and not those who are seeking to participate in an ACO.

So again thank you for inviting me today. I really look forward to this discussion and hope that it will have a positive impact as we all strive to make ACOs the kind of center piece that we all hoped it would be.

MS. DESANTI: Thank you very much, Mindy. I want to point out that the proposed policy statement is joint with the FTC and the DOJ, so whatever kudos and criticisms we get together go to both agencies.

MS. HATTON: Fair enough. Since I was at the FTC, I was just trying to give you more credit.

MS. DESANTI: Next we're going to hear from Patricia Wagner, who is a member at Epstein Becker.

MS. WAGNER: Thank you, and thank you for the opportunity to be here today. I too work at Epstein,

Becker and Green, and we represent entities in all aspects of the healthcare, so my comments are not as representing any client. They're really my own thoughts.

I too have concerns with the constraints of the timeframe. I think everything is getting even more compressed because the CMS final regulations won't be out, estimates now are late summer, and if you do the math, the 90 days for review then kicks in pretty quickly, and as I read the proposed statement, part of what needs to go to the FTC and DOJ is the application that will be submitted to CMS.

That means that a whole lot of work has to be done in basically September, and so I think that that's important from a practical perspective, but I think it's important from a theoretical perspective too because it might be chilling some of the innovative arrangements that otherwise might be being formed and really getting the ACOs that are willing to participate to be those that are self sufficient and don't have to do any collaborations with any other organization, and maybe people are fine with that, but it does seem to question whether we're really going to get some innovative arrangements out of this program.

The other question I have actually, I went back

to the CMS regulations over the weekend, and I noticed in the CMS regulations, as I read them, non PCPs must not be required to be exclusive to be ACO, so I guess I'm looking for a little clarity on how the FTC and DOJ are distinguishing their exclusivity provisions. I guess it's a difference between a choice and a requirement and maybe seeking some clarity in that as well.

Thank you.

MS. DESANTI: Thank you very much, Patricia. Next we are going to hear from Dr. Larry Casalino. He is the Livingston Farrand Associate Professor of Public Health and Chief of the Division of Outcomes and Effectiveness Research at Weil Cornell Medical College.

DR. CASALINO: Thanks. It's a pleasure to be here.

MS. DESANTI: Let me interrupt you. I made a mistake earlier. Each of the panelists, can you please move the mike closer to you so that you can actually be heard. I'm sorry, Professor.

DR. CASALINO: Like Bob, I think the agencies overall have done a very good job dealing with some very difficult problems, and the specific compliments he gave are ones that I would agree with, and I would also add that I'm very happy to see that the CMS proposed regs

are very congruent with the way that the FTC has been looking at clinical integration. I think that's a good thing, and it wasn't inevitable.

So in just the very brief time that I have, I will focus briefly on two areas. First I want to talk a little bit about the likely effects of antitrust policy on hospital employment, physicians and hospital market power, and second, just a brief comment on clarifying the exclusivity.

I think both the -- if indeed there are ACOs that form, and I think there still a question about how many of those there are going to be, at least in the shared statements program, but both the ACO program and the antirust policy I think are likely to lead to increased hospital employment for physicians and increased market power for the hospitals that employ physicians.

I think this will be unfortunate because not only for raising prices but it will reduce patient choice, so there will be -- if large numbers of physicians move from small practices or medium sized practices to hospital employment, there will be few of those practices left, and patients will not have a chance but to pursue care in that kind of a setting.

This has been happening anyway over the last

decade with increasing speed, and now even more increasing with the talk about ACOs, but both primary care physician physicians and specialists have increasingly been employed by hospitals.

Now, hospitals that keep adding physicians, two here, four there, six here, can have a very large market share and may not really be scrutinized under the merger guidelines by the antitrust agencies, and such a hospital can have or hospital system can have quite a lot of market power both because of the large market share they can be in the physician market, but also because, although I'm talking about this as well, I think most people in the industry think that a hospital and physicians do have more market power than either one alone when they can go jointly to these payers.

I think an API, sort of a network, typically smaller and medium size practices, is really disadvantaged in that. First of all, it needs to get antitrust review, and the hospital that employs physicians that doesn't, but secondly, there are people here I'm sure that know more about this than me, but it appears to me that it may not be that hard. The hospital may be able to employ physicians and gain a market share in certain parts of the physician market that's really quite large that would never be permitted

or it would get intense scrutiny for a network because the one is evaluated under merger antitrust policy, and the other under basically the clinical integration regs we have now.

I actually don't think that the policy of the agencies about networks is wrong. I don't think it should be more lenient toward the networks. I think what's projected there is fine, but it would be useful, and I don't have -- I'm not sure how this can be done -- to find a way to limit the share of the physician market that can be possessed by an ACO that consists primarily of a hospital and its employee physicians, and I guess the most obvious way to do this would be to have stricter criteria for looking at mergers. So that's the first point I wanted to make.

The second one very, very briefly, I think there just needs to be more clarification about exclusivity. The proposed regs and guidelines say that a hospital cannot be exclusive within an ACO, and specialists can't either.

I think that if we're talking about a hospital not contracting with payers except through the ACO, I think that's pretty much a slam dunk. I think it's pretty obvious that in no way should the hospital be prohibited or a specialist be prohibited because it's in

an ACO from contracting with payers outside the ACO, so I don't have a problem with that.

There's another question that I don't think is completely clear in the guidelines, and that is does not exclusivity through a hospital mean that it's gotten -- it's kind of written into ACO bylaws that this hospital must be exclusive with this ACO, and that's I think fairly obviously going to be prohibited, but what if the hospital just doesn't want to participate in ACOs?

It's going to take a lot of effort for hospitals to participate in ACOs, and it may not want to -- legitimately it may not want to work with more than one ACO. Also, if the hospital is helping form the ACO, really why should it help its competitors and join a competing ACO? So I think that part of the exclusivity policy needs to be clarified.

I will just mention this, and I agree with Steve, and I'll say this in one sentence. I think that the finest things that ACOs are not supposed to do if they have a certain market share -- I agree, they shouldn't be able to do things like try to prohibit payers from publishing quality and cost information no matter what their market share is.

MS. DESANTI: Thank you very much. To my immediate right is Josh Soven who is chief of the

Litigation One section in the Department of Justice Antitrust Division, and therefore like me, is precluded from giving a two minute summary.

So moving on to my immediate left is Professor Tim Greaney, who is director, Center For Health Law Studies and Chester A. Myers Professor of Law at the Saint Louis University School of Law.

MR. GREANEY: Thank you much, and first, thanks to the agencies for making it financially viable for me to put out a new supplement to my case book every six months, and let me first congratulate the agencies. My Roger Ebert review here is two thumbs up. I think they've done a really good job. It's a well crafted rule. It does the difficult job of balancing administrability, and at the same time dealing with what I will speak about in a minute is really this severe problem of health reform, which is provider market power.

I think it's well crafted in the sense that it places the burden on those who should be bearing the burden, those with market dominance, and it makes them come forward, and answering a bit of what Bob Leibenluft said, I think that timetable does a good thing. It does put the burden on those with market power to come forward in a timely way with proof that there's not a

problem there.

At the same time it takes off the table issues for small ACOs, gives some comfort, and probably most importantly, it powers private attorneys to do the job they should be doing, which is counseling and telling clients what is and is not risky, and that's where all the work has to be done, by private counseling.

Let me just mention at the beginning that just the big picture here is I've been trying to convince people that the Affordable Care Act really depends on competition up and down the line, and so much of it depends on that and the risks to provider market power are really the Achilles heal of the entire reform movement.

When you think about not only what ACOs and deliver system reform is trying to do but how exchanges will work, et cetera, competition really, really is the driving force there.

Let me just mention I think there are three kinds of market power here to deal with, and they have to be dealt with separately. One is extant, existing market power that's been around forever, hospitals that got there by superior skill, industry foresight or dumb luck, and are dominant and have been there for awhile.

The second is market power created by mergers in

the run up to reform, which is 12 or 18 months, however long it's been going on, and the third is market power going to the ACO formation itself. Does it create an entity that forecloses competition in some way or another?

Each of those may be dealt with differently, and let me just mention a couple articles coming out, I hope one by me, but I'll mention one by -- those of you know who Clark Havinghurst, the godfather of antitrust in healthcare and a long time articulate advocate of competition in healthcare, has a good article coming out in the Oregon Law Review, and his concern is called the monopoly -- The Provider Monopoly Problem in Healthcare, and he advocates, as I do, many of the reforms that are in the -- many of the processes of reforms that are in these policy statements.

But there's a word of caution there, and it's a stunning word of caution, in which he said -- he concludes in the opening paragraph: "The provider market monopoly power is severe enough that we cannot exclude the more radical alternative of regulating provider prices." It's stunning coming from Clark, but that's I think where we are if we don't get market power under control.

I guess the final piece I'll mention is what is

worrisome to me is not in the FTC DOJ policy statement but what's elsewhere. I think there are real concerns about the CMS regulatory regime, whether that creates its own barriers to entry for smaller ACOs, those who may not be financially viable to go forward.

I think they're colleague at OIG, I'm not sure they gave enough help on the stark and fraud and abuse issues there, and finally I have a couple points, that I won't repeat what Larry just mentioned, but I think there are issues about hospital employment and foreclosure coming out of that.

So I think the three tiered regime that I mentioned earlier, three tiered problem has to be dealt with different problems, with approaches. As to extant market power, I think you really have to worry about coming up with effective enforcement, be it tying law or bundling law or perhaps a regulatory approach that helps with the unbundling.

I'm very heartened by the fact that the policy statements say require the participant to come forward with information about recent mergers, and I think there are some of those that can be looked at under merger law with the possibility of unwinding, especially physician acquisitions, those aren't entirely impossible to unwind, and finally dealing effectively through

effective review on the ACO entry level.

MS. DESANTI: Thank you very much. Next we're going to hear from Toby Singer who is partner with Jones Day.

MS. SINGER: Thank you, Susan, and I do want to echo the remarks of others in thanking the FTC and the DOJ for giving us an opportunity to talk about this. I know in private practice already we represent providers. We represent payers. We represent employers, and so of course these are my personal views from what I've observed in the marketplace and also based on being a former FTC enforcer myself more years ago than I would like to think.

So I will start again as many people have by saying there are a lot of good things in these proposed regs, probably the one that we received the most favorably is by the provider community is the clear establishment of entitlement to rule of recent treatment, which means that there can be a focus simply on market power, which is a very good place I think for the agencies to focus.

Nevertheless, I think there are a lot of things in the way that the mechanism has been set up that are very troublesome from both the policy standpoint and a practical standpoint. I'm very troubled, again as a

former law enforcer, by the regulatory approach that the mandatory review process takes.

It is not a law enforcement approach. It's a regulatory approach, something the antitrust agencies have steered away from in all the years of it, and to it places the burden entirely on the ACOs, the proposed ACOs without any indication whatsoever that there is a potential for unlawful conduct or even the exercise of market power.

In so doing it allows the agencies and sometimes just the agency staff to block a proposal based on, as Bob Leibenluft described a very quick review, without a comprehensive investigation and without really determining that in fact this is likely to have a negative effect on competition.

Beyond the policy problem, the process itself that was set up by these proposed regulations is overly burdensome and overly expensive, and I think that just simply calculating the PSA and measuring the shares in the primary service areas is going to be far more difficult and far more complicated than the agencies are assuming, and by agencies I include CMS in that as well.

I would like to differ with what my old friend Tim just said. The burden is not simply on those that are proposed market dominant. The burden is on every

proposed ACO to figure out what the common services are, figure out what the 75 percent PSA is for those common services and then go to CMS and attempt to obtain data that nobody has seen or used before to try to measure shares of that PSA.

That's going to be expensive, time consuming and most difficult for those ACOs that have a very comprehensive range of services because there will be more to look at and most difficult for those ACOs that are composed of multiple small practices instead of large quote, unquote, dominant systems, which may be integrated and may have the computer capabilities that the small physician offices don't have. That's even before you get to the question of whether you have market power.

Then assuming the 50 percent threshold is to one specialty, then that particular ACO must go through a very comprehensive document production and subject itself to the mandatory review with no mechanism in the guidelines or the statement as of now to do any kind of quick look, look at it quickly and say no, no, no, you don't have to worry about it. None of that is built into the process.

So I think that the regulatory burden here is far out of proportion to the potential for the exercise

of market power because there are plenty of ways to identify ACOs that might be in a position of having market power without burdening the entire universe of ACOs, although a footnote, that may be a smaller universe than anybody thinks going forward, giving the ACOs management.

Let me conclude by saying I have limited my remarks because we have a short period of time to a critique of a mandatory review. I don't disagree that the agency has the responsibility to look at the potential exercise market power, but there are many ways to accomplish that in a much more streamlined process with a voluntary process where we can have a simplification of the kinds of information that must be submitted without putting unnecessary burden on the people who are really trying to do a good thing.

Thank you.

MS. DESANTI: Thank you very much, Toby. Next we're going to hear from Dr. Lee Sacks who is executive vice president and chief medical officer -- oh, I'm sorry.

MR. MILLER: I thought Toby was obscuring me.

MS. DESANTI: Joe, we definitely want to hear from you. Joe Miller is general counsel for America's Health Insurance Plan.

MR. MILLER: Thanks. I would like to add to the chorus of complements for the agencies, but add mine also to CMS, who delegated the antitrust function to the experts instead of doing it themselves which they could have done but didn't, so that tells me that they're taking the competition value seriously, which they should.

It wasn't a given that they were going to do that. I agree with Tim that competition among providers and insurers is very important to the entire Affordable Care Act working, and so at the outset, it's good to see that they're taking it seriously.

The first comments on the guidance is where it applies and where it doesn't apply. It doesn't apply to mergers. I think it probably should apply to mergers that are subject HSR that it wouldn't get picked up in the traditional Section 7 analysis but would otherwise qualify, however they're set.

There can be individual practice mergers that can prove to be antitrust that would be under the HSR thresholds, and I think those should not be treated differently than any other ACO formation.

Entities that existed before March 23, 2010 or entities that are already single specialties I think are not covered by the guidelines. I'm not sure what the

agencies are thinking how those are going to be treated. There are existing groups with significant amount of market power. I don't know if the intent is to not apply the same level of antitrust grouping that would apply to groups that are just forming and if there's a basis for treating them differently.

As to the guidance itself, I think the agencies had three choice. One, they could have offered no guidance, and they could have told providers that they exist under the same antitrust laws as the rest of the world, who doesn't get prescreened review from the agencies every time they want to form a joint venture, so they could have treated this the same as the rest of the economy functions, and I think that would have been a defensible choice. I get there was some pressure to add some clarity, so they went down this route, but they didn't have to.

The second option is to do what they did, which is to set a screen, and the screen I think is just intended to or I think will function as identifying those ACOs that require greater scrutiny. I don't think it's intended to be an actual antitrust analysis.

The screens that they set using PSA shares looks like even half of an Elzinga and Hogarty test which is even by the FTC discredited, and it is done just for the

purpose I think of being objective and administrable, so you can go get a public data set and see whether you're under the threshold or over the threshold.

Same thing on the private market side or the service market side, you can tell whether this is intended to catch you or not. It takes away these sort of judgments and discretion that actually antitrust analysis entails and by necessity.

So actually defining markets is a difficult job. It takes also a lot of data, but also a lot of judgment, and this removes that for something objective. It sets up a proxy, so instead of setting up of a screen, they question whether the screen is set up at the right level, and I'll talk about that in a minute but I think that's what it does.

The third option was to do an actual antitrust analysis either on a hit or miss basis or for all of them, and I think that would be pretty difficult, resource intensive for the agencies, and I think difficult for providers as well for every single one of these things to get an actual antitrust review with all market definition, understanding the competitive dynamics, trying to understand actual anticompetitive effects, it would have been a more intensive undertaking than I think would be realistic given the program goals

and limitations.

So I think the agencies chose the right approach of setting a screen. Whether they set the screen at the right level, my advice, which I actually wrote down and published in a blog in health affairs for those who want to go into more depth, is to set the screen at the beginning at a relatively low level to have more review rather than less review.

I think if you look at what they're actually going to do, it's relatively light by antitrust standards, and I heard Toby complain about the burden of a 90 review, which I guess is -- right, maybe leading up to the 90 review, but compare that to what? To an actual antitrust review, a real merger analysis takes quite a bit longer than 90 days, costs quite a bit more money.

The document production, at least as I read the pool, is relatively light again by antirust standards. Antitrust work is not simple or easy. It's hard. It's difficult, and if you're going to get it right, then you have to delve into quite a lot of depth.

If you're just looking to do what I think the HSR Act does in the first initial waiting period, which is simply identify those transactions that require greater scrutiny, then I think this is likely to work.

My comment to the agencies is you should set the review such that you really at the beginning don't let through ACOs that will have market power, more market power because once you've let it through, you're kind of done. It's very hard to go back and fix that once it exists.

So what you're doing is comparing two costs of error. The cost of reviewing too many or the cost of letting through ACOs that would do damage to the market. If you set the rule relatively low, say 20 percent of a PSA screen, and you find after a year, 18 months, two years, whatever it is, that all the ACOs between the 20 and 30 percent share are competitively benign. You can move it. It's not a statute. It's guidance. It's not even a notice in common regulations. It's relatively easy to move. I think if you let through those ACOs that should have been screened out, you have a permanent problem or in effect a permanent problem.

The last comment is again picks up the thread of what's already been discussed. There's lots of innovation going on on the private side, having nothing to do with Medicare, alternative payment methods of shared savings, of partial risk, capitation. That's happening in a lot of places, in a lot of different formats. All of that should be encouraged and not

stifled by the rule.

One thing that I'm a little worried about is that the Medicare rule is not convenient to antitrust aspect, but generally will have the effect of chilling advancement in innovation, and that would be very undesirable.

MS. DESANTI: Thank you very much. Now we will hear from Dr. Lee Sacks who is the Executive Vice President and Chief Medical Officer of Advocate Physician Partners and Advocate Healthcare.

DR. SACKS: Thank you, Susan, and it's a pleasure to be invited to be here and share our perspective as our clinically integrated network operates in the marketplace, and I agree with Joe's last comment.

There's been a lot of innovation predicated on what everybody thought was going to be the opportunity in Medicare, and if that doesn't turn out to be something that delivery systems are interested in doing, it probably will stifle a lot of the innovations.

I've got five areas I want to comment on, and a number of them have been mentioned. One, the issue that the existing rules will tend to hasten the gravitation of physicians to employment in large medical groups or in integrated systems from a slightly different

perspective. The CMS rules treat physicians as tax ID numbers, and once you become an ACO, the ACO can't add a new tax ID number for the three years, which means you cannot add new physicians coming into practice, and when practices break up, and that's all too common, we get married and we get divorced, the split, who goes into a new tax ID number couldn't continue to participate in the ACO.

It gives an advantage to an entity that can employ physicians, and our organization has 2,900 independents, 900 employed. That would greatly shift that balance.

The rural exception, advocate entered central Illinois a little over a year ago. It's not exactly a rural market, but it's a two hospital market, and Mindy commented on that, and one of the things that we've come to appreciate is that the primary care physicians are aligned with one hospital or the other, and specialists work at both, and likely that market would have few ACOs.

The specialists will be in both, but it will require mandatory review because every significant specialty practice has commanding market share, and it might become a reason not to go ahead as the higher burden there.

The March 23, 2010 so called grandfathering, since we predate that, we would be very interested in some clarity in terms of what changes could take place and still allow you to not have to reapply. Could we enter a new market? Can we add physicians? Do we form a new PHO? And those are things that have all happened in our organization in the last year.

The PSA methodology, and I know we'll talk about that in-depth in the last hour, but in metro Chicago, there are over 230 Zip Codes. We have 2,900 independent physicians. I spent a few minutes with my senior vice president of planning and realized to do all the permutations and combinations is going to cost an incredible amount of money, chew up resources and will be a barrier to some.

Then lastly, in the CMS rules on the quality outcomes, there are 65 measures, and I have no issue with the measures. We're doing all of them essentially with some slightly different data definitions, but the requirement that you have to perform at a minimum threshold on all the measures to participate in shared savings is just unrealistic.

We had 116 measures in our clinical integration program in 2010, and on 7 of the measures, we didn't improve? I'm not embarrassed by that. I think if we

had improved on every single measure, some might say we're gaming it and we're setting the bar too low with that.

So if we're going to continue to see the innovations, the efficiencies, the improvements in quality that these types of changes can lead to, and we're involved in a contract with the largest payer in our market for over a billion dollars in revenue that started in January, so it's still early on, but have lots of glimpses of what those improvements are going to be. The rules can't be discouraging.

I look forward to the other comments and the Q&A.

MS. DESANTI: Thank you very much. Next we're going to hear from Henry Allen, who is antitrust counsel for the American Medical Association.

MR. ALLEN: Thank you, and the AMA thanks the agencies for their efforts here. We of course plan on submitting written comments at the close of the month, and so my comments here are preliminary, and I have two minutes, and so here we go.

First a bit of background. The AMA has urged the FTC and DOJ to clarify within the context of ACOs requirements for financial integration, sufficient to avoid the Per Se Rule against price fixing. We have

also stated that the current clinical integration standards published in the statements and FTC advisory opinions to date are overly burdensome and likely to detur the formation of ACOs.

Unfortunately, the proposed ACOs statement ignores the question of whether provider collaborations that participate in shared saving programs and posing downside risks are free of price fixing characterizations.

We think that such programs do entail sufficient financial integration, making a price fixing characteristic or characterization inappropriate, and we would like FTC DOJ to say so. This is necessary if only because the CMS has proposed clinical integration eligibility criteria that are expressly premised on its mistaken understanding that avoidance of per se price fixing liability requires ACO adoption of a leadership and management structure detailed in the FTC's MedSouth Grippa and Tri-State opinions or letters.

Surely CMS is needlessly preoccupied with following the FTC's clinical integration guidance given that a price fixing characterization is inappropriate by virtue of the ACO's financial integration. Under the shared savings program, participants must share the risk that if the ACOs does not meet its cost savings targets,

it must compensate Medicare for those losses.

It is hard to predict the possible exposure the ACO could face, but just as the savings could be large, the losses could also be large. Further, given that the ACO's participants will have to contribute substantial time and money to make the ACO viable, the added risk of loss takes on even more importance.

This is especially true of physicians, many of whom do not have a large amount of capital with which to work. Physicians should have the ability to experiment with a variety of organizational approaches aimed at reducing medical costs, and it is inappropriate to mandate prescriptions for clinical integration.

Accordingly, the FTC and DOJ should use the ACO cost savings program as an important opportunity to clarify the requirements for adequate financial integration and to declare that arrangements prompted by the need to participate successfully in a two sided shared savings program are not subject to the Per Se Rule against price fixing.

Now, moving on to the PSA, use of the PSA. We were not aware of any of supports for the claim that the PSA market share model is a reliable indicator of possible market power. A PSA model represents a stark departure from the market definition process set forth

in the case law and in the FTC and DOJ's other antitrust guidelines.

Without even research supporting the use of PSA shares of the reliable market screen, physicians should not be expected to shoulder the substantial costs of determining their PSAs. More importantly, these PSAs are likely to be small and I think Mindy eluded to the fact that they're likely to result in misleadingly high market shares for PSA participants. Physicians are risk adverse and will not want to join an ACO that has PSA shares falling outside a safety zone or that supposedly trigger an antitrust investigation.

In sum, we think the usefulness of PSA shares should be studied before they are adopted as a market power screen.

MS. DESANTI: Thank you, Henry. Next we're going to hear from Betsy Gilbertson who is chief of strategy for Unite Here Health. Betsy?

MS. GILBERTSON: Thanks again.

MS. DESANTI: Maybe you can pull it closer.

MS. GILBERTSON: Thanks again for the opportunity to be here. In this robust company, I think I may be the only representative of consumers, and although I'm here with half of that hat, we also operate our own health plan and function as purchasers as well.

So that said, in our world, provider market power is already a very significant problem. Especially in small and medium sized markets, hospitals are the most likely ACOs developers, and often they're already market dominant with the ability to command very high prices.

For example, the rates we pay at eastern market dominant hospitals are double Medicare overall and for specific services more than that, and 50 to 60 percent higher than our rates at competitive markets, at hospitals in competitive markets.

So there's a very significant price consequence to market power that we're already experiencing and, the consequences of experiencing it are that, to be perfectly blunt, our workers cannot get raises and our employers are cutting jobs.

Hospitals have to make large investments to develop ACO capabilities, and those are high risk that the cost of that investment will get shifted under commercial payers unless there's some way to prevent it.

Our reading of the proposed statement doesn't give us any confidence that there is in fact some prevention mechanism built in. The thresholds that are set forth seem to apply only to horizontal integration. They don't appear to apply to vertical integration,

which is already an issue and is likely to get worse if hospitals expand and strength their relationships with other healthcare providers, especially physicians to qualify for recognition as ACOs.

The only data for monitoring ACO behavior as I read it is coming from CMS. There's no provision for tracking the impact on commercial payers. ACOs that results in higher prices and/or diminished providing for commercial payers must be prevented, and we're going to need regulatory mechanisms to do that.

The clinical integration that's the foundation concept of ACOs is a very good thing. It's what we all wish for, but if it's achieved at the expense literally of commercial payers, the result will be ACOs that will become an important part of the problem of healthcare value instead of an important part of the solution.

MS. DESANTI: Thank you, Betsy. Next we will hear from Christi Braun who is a member of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo.

MS. BRAUN: Thank you. The song that I woke up to this morning on the radio, and I don't even remember the name of the song, but just the little snippet I caught was "be careful what you wish for, you just might get it all." That's really what we're facing here

because the clients that I represent, physicians, hospitals, healthcare systems and payers all wanted some guidance, so they are grateful that there's guidance, but yet they have all criticisms, and I would say they all have different criticisms.

So I'm going to try to bring up some of the top points, understanding that these are my interpretations of some of their criticisms. One of the big ones is: What does formed before March 23, 2010 really mean? I have some clients that put together their structure many, many years ago but haven't been actively contracting with payers. Are they formed?

I have some clients that were clinically integrated but not contracting with payers before March 23, 2010. Are they formed in the meaning of this statement? And then there are those who were actively contracting with payers and clinically integrated, and obviously they were incorporated before March 23, 2010. Were they formed as an ACO before the date of this statement takes effect?

So I think that's a big question because it appears that if you were formed before March 23, 2010, then you don't have to go through the mandatory review, and yet they still ask, So do we have to calculate our PSA shares to go into our Medicare application? And we

don't know that either, and you may not know because we haven't seen what the Medicare application is going to look like, but there are a lot of organizations out there that I think a lot of people would expect to participate, and Mindy alluded to this, there are some big ones out there that say they're not going to participate.

I have some that are not quite as well know, but still if you asked CMS, they would probably say, yes, we expect those types of organizations to participate, and right now they are pretty much feeling that they are not going to participate, so I think there are many reasons why but the formed will help in articulating that.

The second point is this mandatory review, and I know a number of my fellow panelists have brought this up so I'm not going to go into this too much, but even one common service having a 50 percent PSA share or greater than 50 percent share in one common service could put an ACO into this mandatory review, and that means they have to produce a lot of documents and a lot of information.

So some of these groups are saying, well, what if we kick out some of these people or who can we do without so that we don't go over the 50 percent share? But even that isn't necessarily an option for some of

the groups I'm working with, and they say, But this really isn't fair because if I just acquired everybody, nobody's going to say you have to do a mandatory review if you acquire more than 50 percent, so maybe I as the hospital should just acquire everybody and form an ACO and then we're not subject to this review, and I think that should be a concern at the agencies.

Then I think there's also the point that there's nothing in here that says there will be any consideration of non exclusivity, so that if in that common service they have more than a 50 percent PSA share but they're non exclusive, and as was mentioned if you're in some of these more rural areas, probably have more than one hospital or maybe have more than one hospital at which these physicians practice, those physicians aren't going to want to be exclusive.

They wouldn't agree to exclusivity even if the ACO asked them to be exclusive, so going through the mandatory review when it's unlikely you could exercise market power because these physicians aren't going to give you that ability has some significant indications.

Then the third point that clients have brought up with me is the five types of conducts that the ACOs should avoid as recommended by the FTC and DOJ have some pretty strong implications; that is, if you don't have

market power, then putting together a closed panel or asking for some steerage to your closed panel is not necessarily going to have anticompetitive effects. In fact it could have some significant pro-competitive effects.

I would make similar points for a number of the other types of conduct that the FTC and DOJ have said that those groups that are outside the safety zone but below 50 percent should avoid. I think that there needs to either be further explanation or at least the explanation that groups should analyze with their attorney whether or not some of this conduct is viable because I think it's giving the wrong impression to groups that things that they thought they could do are going to be prohibited.

MS. DESANTI: Thank you very much, Christi, and finally I will introduce Saralisa Brau, who is Deputy Assistant Director in the Healthcare Division here at the FTC, and with that we will conclude the opening remarks, and we have certainly gone over the time allotted for them, but I think that they have all been very valuable.

What I would like to do now is just run through the topic outline which I think in fact that the panelists have which I think captures many of the

comments that have been articulated here, and what I would like to do is give people who have additional things to say about particular topics the opportunity just to speak up and respond to some of the points that have been made.

And I'm going to take the moderator's prerogative, and starting with the first topic in the outline, which is: What organizations does this policy statement apply to? I just want to clarify, and I can only speak for my own thinking, but I think that from my perspective, looking at the March 23, 2010 date was a way of looking at what organizations will result from the enactment of the Affordable Care Act, but I take the points that have been made that that's not entirely clear to anybody who is reading this, and certainly, Christine, the examples you raise are good examples for us to think about.

I wanted to ask if there are other people who wanted to add to the discussion on whether the statement should include or address some situations that people have raised or should exclude some other situations, and I should always -- our tradition is if you have something you want to add, please put your table tent up on end. Bob?

MR. LEIBENLUFT: Just a quick comment. If the

intention was that if an ACO has been out there in the marketplace for a certain period of time, therefore you don't need a review, and I think that was maybe the thinking. I'm not sure I agree with that, but putting that aside, that's the intention.

It seems to me there may be a number of ACOs that will be working with commercial plans for some period of time but may not apply to the Medicare Shared Savings Plan Program until sometime after 2012, so think forward, think about 2014, having that date in there doesn't make a whole lot of sense.

You may want to say have been in existence a year and a half, two years, something like that as opposed to locking in that day, so if someone applies in 2014 and is working commercially, they get the same benefit.

MS. DESANTI: You said you weren't sure you agreed with that. Why is that? Can you bring the mike closer?

MR. LEIBENLUFT: The whole notion of the grandfathering, I'm ambivalent about it. I have to think more about it. I mean, part of the issue is the one Christi raised. It's hard to define who should be covered by that. Part of the goal goes to the whole notion of the mandatory review altogether, so it's a

larger concept about whether you want to do this, so I'm sort of putting this into your framework and just focusing on that.

MS. DESANTI: Thank you, Bob. Trudi?

MS. TRYSLA: Just one or two further comments actually. I agree with the issues around the questions on what constitutes formation. I also encourage the FTC to think about the end dates because at least the notice contemplates that it's during the agreement period, and there may be -- I think the focus should be on the organizations that meet the model of an Accountable Care Organization, and consistent with that is that it should extend to Accountable Care Organization models that may have an alternative pathway through CMS like through the innovation center.

MS. DESANTI: Okay. Yes? Larry?

DR. CASALINO: Just looking at your fourth bullet under what kind of organizations the policy statement should apply, do they have the effect of encouraging certain kinds of organizations rather than another?

I guess I will just go back to what I said earlier but I'll say it in a slightly different way. I think that as things stand now, with the way the agencies' policy has gone towards network versus towards

mergers, it's very likely that you will be in a position if in fact organizations do try to form ACOs that you will have to explain to a network why you're really looking at them really carefully when they have 40 percent market share and concerns with specialties, while the hospital system that they're trying to compete against has 48 or 52 or 60 percent market share in a lot of specialties.

I think that's a situation that could arise frequently, and it is a question when I talk to physician groups I get a lot. Actually what I really get is how can a health plan have 70 percent market share, but we're not here to discuss that, but I think to me the answer lies not in weakening the policy toward networks but strengthening the policy towards quote, unquote, mergers or acquisitions by hospitals or for that matter by large multispecialty groups of large market shares in a physician market.

MS. DESANTI: Okay. I think then we will -- thank you. Let's move on to the proposed CMS eligibility criteria which include the clinical integration criteria that the FTC and DOJ have been interested in as evidence of clinical integration. Please, I'm sure some people will send comments to CMS. Please also send them to us.

Are there more points that people want to talk about in terms of whether these are the correct criteria to show clinical integration? Are some of these criteria unrealistic from a business point of view, and if so, which ones and why?

What other problems do you see with the CMS proposed eligibility criteria that relate to clinical integration that's relevant from an antitrust point of view? Bob Leibenluft.

MR. LEIBENLUFT: Just, quickly, the leadership and governance requirements --

MS. DESANTI: Bob, can you move that mike closer because even I can't hear you?

MR. LEIBENLUFT: Is it on? I don't know if it's on. This is better. I think it's the mike, not me. The leadership and governance requirements, I really don't see the connection to CMS, and I think Medicare may have all kinds of reasons why want leadership and governance requirements as they do, and someone can debate those, but I don't see the connection.

I see a connection between having the kind of processes in place that you would have with CMS, and by the way, it's interesting, CMS doesn't actually say what's clinically integrated. They say we will determine when you apply what's clinically integrated,

so what the FTC and DOJ are essentially saying is, we will trust CMS to determine what is clinically integrated, and we'll accept that.

I think that's fine, but I think you should really be concerned about the clinical integration such, how doctors are working with each other. I don't think the leadership and governance really applies to that.

MS. DESANTI: Christi Braun?

MS. BRAUN: I would definitely agree with Bob on that point. I obviously worked with a number of groups in forming clinically integrated joint ventures, and not a single group that I have worked with has a Medicare beneficiary on their board of directors, and in fact, some of these groups are trying to figure out how the heck they're going to do that, and that actually is a big barrier to them becoming ACOs because they're going to have to modify their bylaws.

They're going to have to figure out how to identify those Medicare beneficiaries and empower a single voting member of the board of directors in a way that will make it patient centered, and frankly that isn't what has made them clinically integrated to date.

It has been the fact that they have doctors and hospital representatives working together on their board

of directors, talking about how to approach the improvement of quality, the reduction of cost, how it will benefit the community, so they definitely have those ideas in mind, and some of them do have community representatives, business members on their board of directors, and they do think that that's important, but I can't say that having community representatives on the board of directors necessarily makes them more clinically integrated either.

Some other points I might make. Every single one of them has a medical director but not a full-time medical director. In fact, some of them have a couple part-time medical directors who have their own private practices on the side, and in fact they think of having doctors who are still practicing as medical directors makes them better participants in the clinical integration program because they relate to them.

They understand what they're going through in trying to meet the clinical practice guidelines, in trying to achieve the scores of the measures, and those are really important to the doctors who are being judged, knowing that it is true peer review, that the person who is overseeing the whole clinical quality program is themselves subject to it.

I could go on through the list of things, but I

think the important point is that CMS is very prescriptive here, and what they've been prescriptive about has not necessarily been what groups who have succeeded in clinical integration have done, and I don't want people to think that you must follow CMS's guidelines to be clinically integrated.

MS. DESANTI: Thank you. Now we're going to move on --

MS. HATTON: I'm sorry, can I ask a question? Since we have representatives, this is one of the things I think that we were most pleased about because this is really a historical collaboration between agencies on this whole set of rules.

I wonder since we have someone from DOJ and a number of representatives from FTC whether or not you actually can speak to what the thinking was behind some of these requirements on clinical integration and CMS.

Particularly I agree with the leadership and governance, whether or not there's any discussion that you would be able to share with us about the thinking behind that as an indicia point in the deliberation.

MS. DESANTI: I think that on a broad scope kind of point of view, at least for me, I was thinking about having the same organization operating in the private market as was operating with CMS, so that you wouldn't

have sort of ACO "lite" in the private market as opposed to the real ACO operating with CMS.

Having said that, I certainly can't speak to CMS's thinking on all of the criteria that are in there, and I think we're all interested in learning about ways in which the criteria may be not exactly the right ones, and maybe we should be rethinking some of it, so we're inviting this discussion.

I think from a broad point of view, our look was let's make sure we have the same ACO in the private sector that we have working the CMS, and then of course focusing on the kinds of clinical integration criteria that have been discussed in the healthcare policy statements and in the FTC's staff advisory opinions.

MR. SOVEN: Yeah, I'll just add very quickly to that. I agree with everything Susan said. I think there were two broad objectives at a very high level, and obviously a lot more as you work your way down.

The first was across all of the agencies that participated in the process was, as Susan said, to have a robust sort of the set of criteria for clinical integration, clearly a substantial interest in making the program work, and the thinkings was this was the opportunity to put ideas out there that we thought had a good chance of driving the program to success in a

viable period of time.

The second was as Susan said was this we thought would promote and I think everyone thought would promote an efficiency across the board as it was not viable to essentially add two parallel hospital systems or ACOs operating, one in the Medicare program and one in the commercial market, so therein lies the tight link both between the clinical integration requirements and the linkage up with the antitrust requirements.

But as Susan said, and I stated to everyone I work with at least on the antitrust side, none of us run a hospital, and none of us run a physician network, and none of us run a large integrated providers group, so it is critical that those who actually do that on a day-to-day basis be quite precise in their comments because I'm quite certain there will be a receptive audience for modifications that make sense.

MS. DESANTI: Lee Sacks?

MR. SACKS: Along the same lines, the more I think about it, what you're really interested in is the outcomes and the results, and you don't need to be as prescriptive about structure and process and Advocate owns 12 hospitals, and we drive to get the same health outcomes at all 12 sites but we don't tell each of the hospitals how to structure and that we need a full time

director or part-time medical director.

We're large enough that we fit within all of these, but I think as you already heard, that smaller organizations aren't -- and I absolutely agree that a medical director is much more effective and are practicing in terms of their credibility.

Another one of the requirements from CMS is that 50 percent of the primary care physicians have meaningful use for electronic health records. There are so many variables to that including would a vendor meet the requirements, and I'm waiting for three vendors now who promised us for months that they will be complaint, and they aren't yet. Multiply that by networks that have independent physicians and the complexity.

And yet we've achieved the results that we have in clinical integration and outcomes and efficiency without electronic records, so I don't think that's the be all end all.

MS. DESANTI: Thank you. We'll have Larry, and then we're going to move on because we have to in the interest of time.

DR. CASALINO: I think we've moved a little bit into the critique of the CMS regs, and I'm not going to do that, but I think it does raise a question that I haven't actually heard addressed anywhere which is that

let's say that ACOs don't become very widespread in the last five years but that there are still networks that want to be clinically integrated and contract with health plans as clinically integrated networks just like ACT over the last year.

I think that those organizations are going to want to know, are the clinical integration principles they would have to meet the same as they've been all along or do the CMS ones include thing likes governance and full time medical directors so on, so forth.

I think the agencies' answer would be, no, they're not the CMS regs, but it's a little -- and groups are going to want to know that, and I can see how clinically it's a little tricky to come out there and say, yeah, the CMS regs are a little different than our clinical integration. They're maybe a little bit burdensome, but that's okay, you can certainly become clinically integrated like it has to be.

I think that's what the policy will be, correct?

MS. DESANTI: It's certainly true that what we've been saying is that the CMS eligibility criteria could be used as guidance along with the guidance that's already out there, but nobody in the private sector should assume they have to meet -- they have to touch every single point of the CMS eligibility.

MR. CASALINO: They'd be clinically integrated from your point of view?

MS. DESANTI: Josh, do you agree?

MR. SOVEN: I agree.

MS. DESANTI: Let's move on to the safety zone, and I want to point out that we're going to have a detailed discussion of the highly controversial PSAs that you've already heard about from 12:00 to 1:00 or the last hour of the program so we're not going to focus on the PSAs, but we're going to focus on other issues in the policy statement such as whether the policy statement should require that hospitals and ACOs should be nonexclusive to the ACO to fall within the safety zone?

How well does the rural exception work? We've heard a little bit about that already, and how well does the dominant provider limitation work? Are there revisions that should be considered there, and in that context, we primarily are thinking about are those exceptions overbroad or are there circumstances -- are they under inclusive? Are they circumstances that they should be capturing that they're not? Toby?

MS. SINGER: I have a comment on the exclusivity point. I think that the proposed statement could be a little bit clearer on the two types of exclusivity that

are potentially at issue here. The first is whether ACO participants are exclusive to that ACO in the sense that they will not participate in other ACOs.

The other and the more troublesome type of exclusivity is having the ACO as those participants' exclusive contract vehicle, so that any time a health plan comes along, they think the health plan would have to go through the ACO. I think that as I said the second is much more troublesome and deserves the kind of treatment that it's getting in terms of the safety zone.

But the first type of exclusivity especially when you're talking about a safety zone so by definition talking about providers that probably have a relatively low market share, simply saying we're going to dedicate our resources to one ACO but if a payer doesn't want to contract with that ACO, they're free to come us to directly, that's perfectly fine and it should be allowed for any kind of provider in the ACO.

MS. DESANTI: Anyone else on the safety zone? Patricia?

MS. WAGNER: I'm actually going to talk about exclusivity as well because I can imagine situations where let's take a three hospital town where one of the hospitals is dominant, and therefore in order to participate in the ACO can't be exclusive to the ACO,

and I guess I'm back to my original point of: What does that really mean?

Does it mean if one of the other hospitals in town forms an ACO, that they have to get the dominant hospital in or that they have to ask the dominant hospital in? I mean, I can see a lot of situations where you might not want the dominant hospital in your ACO, and in some cases you might want an ACO without a hospital or you might be able to drive utilization so that having the hospital and the ACO is really not necessary.

So I think I kind of like the language of the CMS regulation, which is it cannot be required to be exclusive because add dominant provider to that, and then you have, you can't require it, but if someone decides not to participate in other ACOs, then maybe that's okay.

MS. DESANTI: Thank you. Mindy?

MS. HATTON: Actually somebody else had theirs up before me.

Just two comments. Obviously we could talk about these all day, and we'll certainly be sending you comments on them, but you're probably aware that we suggested some guidance for the last couple of years, and in looking at whether or not 30 percent is the right

number, we actually thought that 35 percent would be the right number under -- that it should be a little higher and certainly not the 10 to 20 or 20 percent that Joe suggested so just to put that on the record.

Also I think with respect to the dominant providers, I think the agencies are going to really need to look hard at whether or not those provisions -- again if the benchmark is whether or not -- of these regulations whether or not they accomplished their, objective which is to lower or eliminate a barrier to ACO participation, whether or not the dominant providers are the ones again who are most likely to be able to meet all the panoply of requirements that there are to be in ACO and whether or not some of the limitations that you, the agencies, have included in the statements, whether or not those will discourage again the participants that are again likely to be the most ready for innovation and the most anxious to in many cases include Medicare and Medicaid participants in a clinically integrated organization that is either ongoing or that they have on board.

MS. DESANTI: Thank you. Christi?

MS. BRAUN: I'll be brief. I could go on for hours on just this point, so I will just point out two things.

The first is there seems to be a disconnect between the rural exception and the dominant provider limitation. 9 the exception says an ACO may include one physician per specialty from each rural county. Dominant provider limitation says this limitation applies to any ACO that includes a participant with a greater than 50 percent share.

So it seems like for the dominant provider, they could be a whole practice group but to fit within the rural exception, you could only have one physician, and I'll just tell you from a standpoint of how healthcare operate, they don't generally single it out one doctor from their practice group to be a part of a provider network. It doesn't really work from a call coverage standpoint, from a billing standpoint, from an operational standpoint so I would encourage the agencies to rethink that.

The other point I would make is in a lot of rural areas, they're only going to cover one county, so while it may seem somewhat generous that they include one physician for each county in which the ACO operates, it's likely that a lot of ACOs that would fit into this are only going to cover one county. So you may want to think about whether it makes sense to say one county.

The last point I want to make is about

exclusivity, a little different variant from other folks have said. To fit within the safety zone, the hospitals and the EFCs must be non exclusive regardless of PSA share, so you could have a market like a Lee Sacks market where there are a lot of hospitals, and even if one of the smaller hospital systems has less than a 30 percent market share, you're telling them that they can't be exclusive.

And I guess I kind of question whether that really makes sense because I actually think that it's going to be the more metropolitan areas where folks are actually going to qualify for the safety zone, so I would encourage the antitrust authorities to possibly rethink whether or not hospitals and ACOs must be nonexclusive to be within a safety zone.

MS. DESANTI: Thank you. Joe?

MR. MILLER: I just wanted to talk a little bit about what Mindy said in terms of lowering or limitation barrier to ACO formation. I disagree. I think the guidance does achieve that. It provides an objective benchmark to know when you're going to get a look.

I take it doesn't mean or shouldn't mean that you should get a pass on antitrust considerations that the agencies can provide it. They can't. The antitrust laws apply. The Affordable Care Act didn't provide any

sort of antitrust limitation or relief or waiver authority or anything of the sort, so it's providing guidance as to when you're likely to get something, and it does it I think on objective criteria.

We'll talk I guess in 20 minutes as to whether it's actually going to work that way, and that's a fair question, but I think it does provide the guidance that folks have been asking for.

MS. DESANTI: We'll finish with Bob and then move to the next one.

MR. LEIBENLUFT: Just a quick point --

MS. DESANTI: I'm sorry, Bob Galvin.

MR. GALVIN: Thank you. This is not -- it's a complex conversation as it ought to be because it's all about the details. I just wanted to answer the question is 30 percent the right number? While many of us on my side, Betsy, probably feeling the same way as I do kind of look at it and will say, I don't know but it's not working today.

So, in other words, however it is we came up with 30 and whatever it is that -- I think we're all trying to do the same thing by keeping competitive markets. If it's the same number we're using today applied in the same way we're using it today, then we need to rethink it.

MS. DESANTI: Okay. Henry, and then we're going to move on. We're running out of time.

MR. ALLEN: With respect to the rural problem, I agree with what's been said about one physician per speciality doesn't give you exactly the pooling of knowledge and the subspecialization of function that you would expect to get in a well operated ACO.

So the question then is: How can you measure the competitiveness of ACOs and say in areas like Grand Junction, for example, where ACOs have reputations for being very, very effective, but where market shares will, because of the accident of geography -- active market shares will be necessarily beyond the market shares that are called for in these guidelines.

So I would suggest that we consider performance metrics to be a substitute for market share streams with respect to those groups that are you could argue a natural monopoly.

MS. DESANTI: Okay. I want to spend, I'm sorry, just five minutes on the next topic of mandatory review, market power and nonexclusivity. I think we've covered a lot of those topics already, and then I want to spend the final ten minutes on the list of conduct.

So does anyone have anything they want to add to the discussion on mandatory review, market power and

nonexclusivity? Trudi?

MS. TRYSLA: I'll offer a comment similar to the previous discussion. I think the ACOs, in order to foster the providers that really want to do this, should be able to have nonexclusive particularly --

(Discussion off the record.)

MS. TRYSLA: So I think that's point number 1. It's been repeated by others.

In terms of the review process, I would -- again I stated previously it's going to be a significant challenge particularly within the timeframe provided, and I would encourage the FTC and DOJ to maybe think about if they are going to have a mandatory review, that they focus it on the groups of providers that are going to be exclusive so that cuts down on the burdensome, focusing on the primary care provider group and focuses on the traditional approach to really focus on what they actually may observe in terms of anti-competitive behavior.

I think that's something to consider, particularly in the current timeframe by which providers have to transform themselves to accommodate the structures.

MS. DESANTI: Thank you. Let's move on and discuss the list of conduct that's in the policy

statement that the agencies have suggested is conduct that if you really, really want to avoid antitrust scrutiny, you could avoid the conduct that's listed there, and I know that there are some here who want to have a discussion about particular types of conduct, and we will start with Toby Singer.

MS. SINGER: Thank you. I think that the list of conduct are very interrelated, and you can accomplish the same thing with just a slight alteration. For example, if the prohibition on anti steering language were limited to simply prohibiting providers with large market shares from preventing payers from not contracting with the ACO as opposed to prohibiting anti steering language for payers that do contract with the ACO, which I think is a specific point, I think it's related to the exclusivity point, I think that's a very important distinction.

In order to make the ACO work, in order to have the clinical measures actually work well, you need to in many cases have the providers know who they're referring to, the same set of physicians following the same set of guidelines, and if a payer chooses to steer away from the group of physicians who was chosen and agrees to follow those guidelines, that could interfere with integration.

As long as those providers are not exclusive so that a payer doesn't have to contract with the ACO, you can set up a separate contracting forum, then the requirement that the referrals stay within the ACO and that a payer not steer away from it shouldn't be a competitive effect, in fact should foster the possibility of the ACO to follow the guidelines.

MS. DESANTI: Thank you. Bob? Bob Galvin?

MR. GALVIN: Yes, thank you. I think this is a good start. I like these. I had one issue with number 4, which had to do with information to consumers or to payers, and you limit it by saying it has to be similar to what's going on in the Medicare Share Savings Program.

I think there are two issues with that. One is there is no price information there because they administratively set prices. If you're a consumer trying to make a decision, what it costs you is very important, and you wouldn't get that out of Medicare data.

Secondly to go back and review the regs, my sense is that the level of quality data that the shared savings program is going to demonstrate might be at a much higher kind of aggregate number than many of us who work on my side actually are satisfied with this big

debate, so to limit it to say if you do what Medicare does, you're okay, I think we need to work on that language a little bit.

MS. DESANTI: Henry?

MR. ALLEN: Yes, hi. So on the exclusivity, the idea that the networks cannot have exclusive arrangements with their physicians to prevent insurers from contracting with the individual doctors rather than to contract with a network and for the service of the network the ACO is providing is something that the AMA has been arguing with the enforcement with the FTC for quite awhile.

We believe that there are too many networks that are commercial failures today because they are not permitted or believe that their market shares would be troublesome to the agencies were they to exclusively contract.

So it's hard to understand why they could feel this kind of prohibition in shared arrangements from 30 to over 30 percent, over 50 percent when market power share -- market power associated with shares of two-thirds or greater, so we don't understand why the shares are being set so low with respect to exclusive dealing.

MS. DESANTI: Tim Greaney?

MR. GREANEY: So I nicknamed these the five no nos when I first read them, if anybody remembers the IP no nos, and I think clearly number 5 is probably a no brainer for most antitrust counselors, but with respect to the other four, there's an interesting issue here about just how they're going to be enforced or negotiated vis-a-vis applicants.

One approach might be to see them as a ticket of admission to get your clearance letter, and I don't think the agencies are going to do that, but I think that's a concern because there is some nuance here. Some of them could be relatively benign in certain circumstances, certainly when there's not real dominance, but I think they are all important.

I think they are indicia that there is a problem there when a dominant entity engages in these behaviors, so I am heartened that they're in there, and what I'm hoping the purpose they might serve might be again to sort of stiffen the backbone of antitrust counselors when they talk to their clients and say, This thing is really problematic, the agency thinks it is, we can't tell you for sure this conduct will get you in or out.

But they are the kind of things that I think do amount to a problem, what the nuns used to call an occasional sin in the Catholic church.

MS. DESANTI: Okay. I think we will conclude with Betsy Gilbertson, who we included with in October as well. Betsy?

MS. GILBERTSON: I'm just going to raise the issue of enforcement. This is all prospective, and the question of how enforcement will occur if any of these were to be violated seems not to be addressed, and since we already have significant challenges, it would seem -- and these were considered significant enough to specifically outline in the guidance, which seems to me valuable. Having some mechanism to enforce them seems like it would be relevant.

MS. DESANTI: Thank you. With this we will conclude panel one, unless anyone is dying to add something more on the other policy issues that are listed in the last topics, which I think we have covered in terms of the regulatory law approach and cost shifting, if there's anybody else that wants to add anything? Let's take one comment, Toby.

MS. SINGER: Yeah, I don't see why that's just a problem of ACOs. It's like a function of the healthcare marketplace whether it does or does not occur, but it's not a special problem for ACOs.

MS. DESANTI: Thank you. I want to -- Bob?

MR. GALVIN: I agree. It's just like putting

lighter fluid on a fire.

MS. DESANTI: All right. With that inflammatory comment, I want to thank all the our panelists this morning for what has been a very educational, and illuminating discussion. We're going to take a ten minute break now rather than the 15 minutes that was advertised so that we can start again at 12:05.

(A brief recess was taken.)

PANEL 2:

PARTICIPANTS AND AGENCY STAFF:

CHRISTI BRAUN, Mintz, Levin, Cohen, Ferris, Glovsky & Popeo, P.C.

THOMAS GREANEY, St. Louis University of Law

ROBERT LEIBENLUFT, Hogan Lovells

JOSEPH MILLER, America's Health Insurance Plans

DR. LEE SACKS, Advocate Physician Partners & Advocate Health Care

TRUDI TRYSLA, Fairview Health Services

PATRICIA WAGNER, Epstein Becker Green

STEVEN WOJCIK, National Business Group on Health

MODERATORS/QUESTIONERS:

CHRISTOPHER GARMON, FTC, Bureau of Economics

DANIEL GILMAN, FTC, Office of Policy Planning

JOSHUA SOVEN, U.S. Department of Justice

CRAIG PETERS, Economist, U.S. Department of Justice

MR. GARMON: Thank you. This is the second panel, a panel on shares in primary service areas. My name is Christopher Garmon. I'm an economist with the Federal Trade Commission. Many of the panelists from the first panel are on this panel as well, but we have a few new faces.

To my right, to my extreme right is Steven Wojcik who is the vice president of public policy for the National Business Group on Health; Craig Peters, an economist from the economic analysis group of the antitrust division of the Department of Justice; Dan Gilman, an attorney advisor from the FTC's Office of Policy and Planning, and we were hoping to have Professor David Dranove from Northwestern University. He was called away at the last minute for a family emergency, but he has given me some comments, which I will read.

Before we get started, I wanted to give Steve an opportunity to have some introductory comments as the initial panelists did.

MS. WOJCIK: Great. Thank you very much, I appreciate it, and I think it's a testament to the importance of the topic that most of you have stuck around for the more technical, probably more boring part of the session rather than go to lunch, so I appreciate it.

National Business Group on Health represents 330 of the nation's largest employers. Two-thirds of the Fortune 100 companies are members, but having said that, I'm speaking for myself.

As for the National Business Group on Health

that has long been supportive of and interested in and trying to foster more organized system of healthcare delivery in this country, and the ACOs have a lot of hope -- we have a lot of hope riding on the ACOs as a key way to truly reform healthcare and move toward an effective efficient healthcare delivery system that we really need in the 21st century world.

Having said that, we have some concerns that have been addressed by a number of the panelists in the first panel, but I just want to reiterate some of them and maybe add some additional information.

We very much appreciate, first of all, the Federal Trade Commission's and the Department of Justice's being proactive on the antitrust implications for ACOs. We believe that this is the right approach to try to avoid antitrust problems at the outset rather than trying to fix them after the fact when, as the panelists in the first panel some of them mentioned, it's harder to remedy antitrust enforcement of ACOs.

It's particularly important for private payers such as our members, largely self funded employer plans, commercial insurers and individual policyholders because unlike Medicare, we don't set prices through administrative rules, which gives Medicare some protection and immunity from the price setting market

power of healthcare providers where it exists.

To the extent that ACOs increase their market power and use it to increase revenues from private payers rather than controlling costs by better managing care, the nation as a whole could lose even, if an ACO saves Medicare money and satisfies the metric to qualify for the bonus, so that that's our perspective.

I just want to add that we shared a study that we had commissioned, and it's conducted by Milliman with the CMS and the White House Office of Health Reform when it was still around in which Milliman, at our request, did a study and then it was released this past March that used Medicare and commercial insurer inpatient claims data, so it's only looking at hospital inpatient data, so it's not the entire picture, but it found that while in some cities hospitals have low per capita inpatient cost for Medicare relative to the national average, low inpatient costs for private insurers and positive financial arches, there are places where hospitals provide high value for Medicare but not for private payers, and that's obviously the geographic areas where we would be particularly concerned.

Those are my opening remarks and where we're coming from on this issue, and I look forward to the details.

MR. GARMON: I also wanted to read into the record comments from Professor David Dranove who was unable to make it today. He sent us some comments about his suggestions for the PSA approach, so I'll read those in.

(Comments from Professor Dranove.)

It is not obvious how to assess ACOs that have multiple sites. I would recommend computing a separate primary service area for each site. For instance, if the doctors are in sites A and B, compute PSA A, PSA B. When computing market shares in PSA A, be sure to include the ACO's doctors from both sides, likewise for market shares of PSA B.

The second point: Things are more problematic if the ACO is a loose collection of independent doctors practicing in different sites. If they are tied to specific hospitals, you treat the hospitals as the sites and do step one.

In addition to Medicare data, the FTC should permit a use of HCUP, healthcare cost and utilization hospital data for the 30 plus HCUP states. This will allow market share calculations for obstetrics and pediatrics.

I state this in my report, but I want to emphasize it here. Market share calculations can be

automated rather easily. It would make sense therefore for a consulting firm to do all this work on the contract at the FTC. The FTC should put this out for competitive beating. I think you can get this done for no more than $20,000 per ACO proposal and perhaps for much less.

(End of comments from Professor Dranove.)

I will leave it to you decide whether ACOs or tax payers should foot the bill for this, and he's mentioning a report that he also submitted to the FTC in his public comments with some back up work on the PSAs and how they work with that.

With that, I just wanted to give a little bit of an introduction to the primary service area approach. When we were first presented with this with the Accountable Care Organizations from the health reform legislation, we were told we may get hundreds of applications for these Accountable Care Organizations.

Can you come up with some quick screen that would tell us those that are not going to be problematic, very unlikely to be problematic that wouldn't need review? One of the things I was hearing from the first panel that I want to clarify is that -- maybe this is not clear in the statement. We intended the PSA share approach to be a quick screen for those

ACOs that would not be problem, that would not have to be reviewed.

Those above the thresholds, many of them, maybe most of them, we don't know, could still be pro-competitive, but those are the ones that might need some review, and so that's why we set the thresholds and maybe the thresholds aren't correct, and that's what we would like some feedback on.

We were also told these would not be for mergers. Merger of healthcare providers and doctors are in many cases are irreversible. The guidelines will be for ACOs joint ventures between independent organizations, and again these will be for organizations only involved in the Medicare Shared Savings Program so they will be accountable, they will be monitored by CMS.

So with that we wanted to build a quick screen that is not a substitute for geographic market definition, product market definition, in a normal anti merger or non merger case, but that reflects the competitive dynamics of the market, that is straightforward calculating and interpret, and they can use that rather than the available data so it's transparent, and providers can calculate their shares.

So with that, what I wanted to put out there are three sets of questions. One, what are the advantages

and disadvantages of this approach, and for those panelists that don't like it, is there something you propose is better given those limitations we're working under?

The second set of questions specific with issues with how PSAs are calculated and the categories: Are there improvements we can make in doing that?

Then is there anything that the FTC and DOJ can provide to make this easier on providers in calculating their ACOs? We would love feedback on that as well.

So with that, let me put out the first question: What are the advantages and disadvantages of calculating shares within the primary service area, and are there any approaches that are better that the panelists would like to talk about? Bob?

MR. LEIBENLUFT: Bob. I guess given that you might have some screening device, I'm not sure I can think of necessarily a better screening device that would work for everybody off the cuff. I guess that's your challenge, but I can see how this doesn't work for a lot of situations so.

One suggestion is that -- the problem is once you trigger it, you have to provide all this information, so a lot of things begin to happen, and so one thought is that the agency should be open to an ACO

applicant coming in and saying, Look, I'm in Schenectady and it doesn't make sense to look at the PSAs, let's look at the geopolitical market, geopolitical area, or here's my situation. I only exceed the threshold in one common service by a little bit.

So there's some sort of -- a lot of flexibility built in so let's say within 10 days or 15 days, you can go back to the applicant and say, you're right, you would have been covered by this but you don't need to go through the whole analysis and provide all the documentation, you're okay.

Right now once you're in, you're in, and you're in for the whole thing, and even though you may say don't worry about it, it's just a quick threshold, and many of you won't have any problem, you do have to provide all that information, and then you may be further down the line as to how you get cleared because you are working with the ones that are close to call.

So I just think having something where someone can come in in a short period of time, and maybe that 90 day clock doesn't start until after there's some decision about whether or not you need to go through the whole thing, but something intermediate where if you otherwise would trip it, you really don't have to deal with it.

MR. GARMON: Something like an early termination.

MR. LEIBENLUFT: Yes, without having to submit the whole range of documentation that you have to submit.

MR. GARMON: Christi?

MS. BRAUN: I guess one of the biggest disadvantages of the PSA share is that it is costly to calculate. I appreciated Dr. Dranove's comment because on behalf of a client, I went to some economists first and said, give me an estimate, what would it cost, and the lowest estimate I got was $15,000, and the particular group that I was shopping around for wasn't a large IPA. It was roughly 250 providers.

So I wouldn't want to know what it would cost Dr. Sacks to do that kind of calculation. It would be nice if the government footed the bill and did the calculations, but knowing that they're not likely to do that, then there are smaller, more rural groups that say, it's going to cost me this much to do it, I have this potential amount that I can make with CMS.

At the end of the day the costs of getting into the CMS program are so high, it's probably not worth it for us to do it, and I don't think that's what CMS intended, but that is a consequence of the PSA share

market share.

UNIDENTIFIED SPEAKER: Christi, was that 50,000 or 15,000?

MS. BRAUN: 15, 15.

MR. GARMON: Thank you. Lee?

MR. SACKS: I would second that, that this just becomes one more hurdle that will keep organizations for being interested in doing it. This may be harrassee, but I'm not in the antitrust profession, but if you look at what you have to do to be successful as an ACO, you have to improve service. You have to save money and create efficiency, and you have to improve quality, and if you don't do the latter, you don't get any of the savings, why do you care if I have 20, 30, 40 or 50 percent market share because even if I have 50 percent market share and I save money for Medicare, provide better outcomes and better services and my patients have free choice on whether they want to stay and get care in our ACO or opt out and even if they're in the ACO they can go to Mayo Clinic or M.D. Anderson any time they want and they're still responsible?

We've theoretically improved the system. Then we'll know at the end of three years if I have to write a check to Medicare, we're not going to continue to participate, but for organizations that are willing to

take that risk, and I assume and certainly based on my experience in negotiating with the commercial payers, they're sophisticated enough to put in similar protections if they're going to enter into a contract with us on the commercial side that would make sure that there's protection to assure that we're performing as we intend to with that.

Could it be simpler? Could it just be number of physicians compared to number of physicians in the market? Anybody could do that calculation pretty easily. It's not perfect in terms of market share. I have real concerns that if we have to get data from our independent physicians, many of them don't have the systems in place to easily extract the data in a form that would go into the calculation that you were talking about.

We still have some physicians who don't have computerized registration and billing systems with that, so if that's a requirement, that probably means they will not be in an ACO. They won't be on the pathway to approved care.

MR. GARMON: Joe?

MR. MILLER: The $15,000 is costly compared to what? You have to ask: What is going to happen if you don't do that? Does it mean you can't calculate PSA

shares? Do you need an economist to do it? If you do is $15,000 a lot or a little to participate in the program?

Again by antitrust standards, economists generally won't pick up the phone unless you commit $15,000 or more, so it may just be simply a disconnect between what antitrust practitioners are accustomed to and what people would like to get into the program. My suspicion also, without knowing this, is that that number will come down as the consulting firms become more proficient at this.

To go back to something Dr. Sacks said, why are we doing this at all? What's the problem? If I'm good at this, I'll be doing all the things the government wants, and shouldn't that be enough? The way I heard Dr. Sacks describe this, it's kind of like an antitrust violation. We'll get up to 50 percent, who should care? People can contract around it and the Medicare program can set prices, what's the problem?

I think there is a significant problem. As far as this potential program goes, you could go the route of I don't need any guidance and I'll take the risk which is how I interpret your comments, that you can bear the antitrust risk yourself if you go into enter into those contracts and into the program, that you're

willing to defend the suit.

What I'm not sure whether you meant or not was there shouldn't be a suit. There shouldn't be a cause of action. As a legal matter, the antitrust laws still apply here so all that still should count for something, and I think the question here is whether this screening mechanism should be available to providers as they're looking at the program.

I have think it's certainly defensible to say it shouldn't be a screening mechanism. They should take or bear the full risk. Agencies should be regulatory, less involved, but if they're going to go down this path, I think setting the screening mechanism is right.

$15,000 is cheap compared to what you're going to get if you actually draw the attention of the agencies to take a hard look at one of these.

MR. GARMON: Patricia?

MS. WAGNER: I actually like the concept of having or starting maybe starting with a head count, and part of the -- I'm aware of a couple markets where the fee for service Medicare is not actually representative of the market share of the physicians in that market, and I'm not talking about OB-GYN or pediatrics. I'm talking about general internists.

It seems to me if you did an initial screen

based on head count, then there may be a second trigger, right, if you had 51 percent of all internists in the market, then maybe it would make sense to do the PSA calculation to see whether that really translates into some significant market share, and that way maybe is eases the burden and also gives them a safety net to make sure you're not letting things go through inadvertently.

MR. GARMON: Did you have anything else you wanted to say, Joe?

MR. MILLER: I left that up by accident, but yes, I'm glad you asked. There are three tests in the beginning that reflect competitive dynamics, straightforward to calculate or interpret, and readily available data.

The second two are right. The first one I think is wrong. I don't think you can ask a concentration metric to reflect the competitive dynamics of a market. Even real market shares, which these are not, don't tell you that. For instance, compare the '92 merger guidelines to the 2010 guidelines.

There's an emphasis on actual effects as opposed to market definition and shares, and I think that's for a good reason, that it reflects the learning of antitrust practitioners over a couple decades and better

at it than we used to be, and you don't need to rely on market shares to tell you what apparently 20, 30 years ago you used to do.

So I think it's really asking too much of a share statistic to tell you much of anything about competitive dynamics, so I think you've set the bar a little high for yourself there.

MR. GARMON: Tim?

MR. GREANEY: Yeah. First of all, I thought Bob had a good idea about some kind of quick look mechanism for doing the review where the party could come in and substitute for PSA some other kind of more probative data, but here's a question I had.

The PSA could be also under inclusive as well. It might not count things. The economist David Argo did a presentation a few weeks ago where he pointed out the NDCs are pretty lumpy. I mean, I think there are 87 DRGs in NDC 4 or NDC 5, and some may be doing one cluster and some doing another.

So if you're in the safety zone based on the PSA count, are you home free? In other words, on further examination, it turns out it undercuts and you're upwards of 60 percent, is that a ticket to ride or not? It wasn't clear to me how the safety zone reality operates in the regulatory review.

MR. GARMON: Bob?

MR. LEIBENLUFT: Yeah. I guess I'm not worried about too many people getting in the safety zones in these thresholds, and I think what Joe just said about PSAs don't really reflect market dynamics when we look at normal effects, that can harken back to that. We're asking for a 90 day up or down on entities that haven't formed or operated yet and for the agency to say, I'm going to challenge that, based on what?

I just think it's really -- we have to worry about getting into a very regulatory -- I know it's a little bit off the PSA definition issue, but this comes up all the time when we talk about this. What are we asking the agencies to do in 90 days?

And I think to come up with an up or down is going to force them to make a very regulatory type decision, saying no to things that they know they don't really have to challenge and because Medicaid doesn't like it, but once they say no, then here's my fear.

An ACO gets a no, and you might say it doesn't matter because what that means is they can't participate in CMS, but then the agency has gone directly and said we're going to challenge you, and so then they want to go participate in the commercial market, it's kind of like make my day.

If the agency doesn't challenge it, then it's like it has no teeth, and so I think there's a tendency here to maybe accelerate things more quickly than anyone is quite ready to go just because we want to have certainty in 90 days.

MR. GARMON: There was a proposal, instead of using the Medicare revenues or general revenues, using a number of physicians in an area. When we've tried to do that in the past, there's not a good list of physicians that will eliminate the ones that are dead and retired, semi retired.

Do the panelists know of a good list of physicians that could be used by ACO applicants or the agencies for that kind of review? Bob?

MR. LEIBENLUFT: Well, it just occurred to me, doesn't CMS have a list of who is submitting claims?

MR. GARMON: Well, that's another thing I want to mention. CMS, we're working with CMS now to produce the denominators for these shares, so those will be public, the Medicare denominators, the Medicare revenues within -- by category by Zip Code, so that will be available, and maybe this is something we need to jump ahead to.

Are there things that we can -- in the agencies we can provide to make sure you don't have to go to an

economic consulting firm and pay $15,000? Can we provide programs, Excel map roads that allow the ACOs to do it themselves? Is there anything else you we can provide to the ACOs?

DR. SACKS: It would certainly make it easier, it would be attractive. I think you're right, there isn't a simple list, and there's all kinds of unique issues in my market with five academic medical centers.

There's a thousands of physicians that .1, .2, .3 patient care. They all submit claims to CMS, but they have a lot less impact when someone's working full time with that, and then you have the administrators like me who are semi retired. It's just a high level proxy.

I didn't spend a lot of time looking at the definition of specialty for Medicare, but there's 20 or 30, but is it critical that every single one of them be below the threshold or are we going to change the marketplace if one specialty is an outlier?

Probably not, but that would lead us into further review and it's just another one of the hurdles on top of everything else that are going to keep organization from becoming an ACO.

In my market, if Bob Galvin was here, he would say that one of the provider organizations that has

market power probably draws from the whole Metro area and would be below the threshold because the number of Zip Codes in their PSAs would be large as opposed to some of the more community hospitals which draw from five or six Zip Codes.

But it's the ones who spread across the Metro area that's a must have and has a commanding presence and would certainly make Joe's members -- they're the ones who get anxious about the impact of that one versus the community hospitals that could have a higher market share in the immediate community.

Then it depends on the concentration of hospitals, and the denser of an area, there's hospitals every two miles and they have a small market share. We have a hospital in the outer ring of suburbs where there's no hospital within ten miles of them, and it's not a surprise, their market share is higher.

In our case none of our hospitals are above 30 percent with that, but I'm sure if we break it down by specialties that are relevant to Medicare, some of the physician groups will be outside of that safety zone.

MR. GARMON: Christi?

MS. BRAUN: Answering your first question about is there a good source for a head count, I would argue that CMS's list of participating physicians is probably

no more inaccurate than using the PSA shares, the money paid in claims, and in that respect if you're looking for a screen, I think it's easier to do head counts as an initial screen, and I certainly liked Trish Wagner's suggestion, let's do a head count first before you go into the costly PSA share.

To answer your second question, what could the agencies do to make the calculation easier? It would be great if you could provide us with the numerator too, but assuming that you can't provide both the numerator and the denominator, at least providing some type of Excel spreadsheet or calculation that makes it easier would certainly help.

Going back to my comment on the numerator, one of the things we struggle with as Dr. Sacks said is there are a lot of physicians who couldn't tell you what their PSA is because they don't have good electronic records on their patients, but Medicare could tell them what their PSA is because Medicare will know who those patients are, so at least if we had that information, it will make calculating the numerator easier.

MR. SOVEN: On the physician head count, idea what would you use as the denominator?

MS. BRAUN: I would have CMS provider members of providers in that area.

MR. SOVEN: Of PSA or MSA or where?

MS. BRAUN: I have a big problem with PSAs because that's not necessarily how the providers I work with define their primary service areas. It's not contiguous ZIP codes. It's often a spotty map. But I do I think metropolitan areas and rural service areas are better indicators than the PSA is.

MR. GARMON: Christi, can I ask a follow-up? What do you think it would do, plus or minus, just to address the continuity factor? How much of an issue is that?

MS. BRAUN: The contiguous Zip Codes?

MR. GARMON: What if we just dropped contiguous.

MS. BRAUN: I think it might be more accurate, and the reason is the places from which the patients come from tend to be more spotty, and particularly where you have providers who do some outreach, so even if their main office is in a local town, if they go out to some of the surrounding areas, they may actually have more of their patient population outside of the main area.

But if you go out from the center, I'm probably arguing against my clients right now, you may actually underestimate the extent of their geographic market, and so the PSA may actually be a smaller area, and in fact

then they may have a larger market share for that smaller geographic area than what they actually covered.

MR. GARMON: Bob?

MR. LEIBENLUFT: Two points. One, on the head count, I think there is an issue about geographic market. It's going to vary by specialty, and you may need to provide some guidance, maybe certain miles, and that's why I think it's flexibility. I think if someone comes in and says, This is what we should do, you could do it.

Second, in terms of data, I think it would be really efficient if DOJ and FTC detailed one economist from each agency, seriously work for six months at CMS and get the numerator data.

I think you would have -- everybody would have much more -- it would be much more reliable. The agencies would know how it works a whole lot better. It would be consistent, and I think unless the data is not physically available at CMS, if it's in there somewhere, I always underestimate how much work is involved in these things, but I think it would really make a whole lot -- it would also I think diffuse some of the concern about the burden on the PSA side.

I think it still should not be the end all and be all, but if someone could just say, here's my TIN,

give me my numerator in some sort of portal or something and you have the macros, that would sort of solve a lot of some of the noise around this, at least initially on the initial burden.

MR. GARMON: Following up on that, our assumption is that the providers would know their numerator. What types of providers is this going to be burdensome to, to get their Medicare revenues?

MS. BRAUN: Primary care providers. Your most important participant in the ACO are also your most difficult to get your data from.

MR. GARMON: Why is that?

MS. BRAUN: Because they often practice in much smaller practices. They don't invest as much in their technology because they don't have as high income, and so they try and keep their costs as low as possible.

MR. LEIBENLUFT: Chris, I think realistically let's say you have 500 doctors, and you ask them all for that data. Just think about how long it's going to take to actually get it back, to figure out whether it's reliable. I mean, it's just the level of reliability and accuracy and efficiency is so much lower I think in asking it that way than having it more centrally done even if it takes a couple of economists to do it.

I'm probably underestimating it, but I think

really it's theoretically possible, but I think if you ask particularly for any kind of large ACOs, it's going to be a whole lot of work and you're going to get a lot of stuff that people are going to have to certify to and there are going to be concerns about how good is it and so forth. I think it's going to be overly burdensome.

MR. GARMON: Yes, Lee?

DR. SACKS: Don't underestimate how hard it is to get data from physicians. I would start with how many patients have their ZIP code coded wrong into the information system with that and then even for the practices that have an electronic system, can you generate the report by payer and by Zip Code?

And I'm guessing for a lot of our physicians, the answer is no, and then go to the vendor and ask them to customize so I think the comments that getting us out of the CMS database levels the playing field, it's the same for everybody, and it would greatly ease the burden, and we probably shouldn't underestimate how hard it would be to get that out of all of them, and maybe it will take a year with the whole team, but it would probably be worth it.

MR. GARMON: Relating to the burden and the lumpiness that was mentioned before, should the PSA -- should the categories be combined from what they are

now or should they be split up that was mentioned at one of the even disease, a lot of DRGs? What do the panelists think about that? If we have more finely defined categories, we're going to get a sample size issue where there may only be one patient in that category, and you have 100 percent share automatically, even though it doesn't mean anything.

So what do the panelists think is the right trade-off there if you thought about that, or maybe you haven't thought about it? Are there problems following up with the way we've classified physician specialties in patient categories and major diagnostic categories, the outpatient categories? No views about that?

MS. BRAUN: I do have one thought.

MR. GARMON: Christi?

MS. BRAUN: In looking to get the example, looks at a couple physician practice groups, recognizes that if a practice group has more than one speciality or provides services in more than one specialty, then it essentially decides which one is the plurality of care, and that's the specialty for the practice, that makes the most sense, and my clients may hate me for saying this, but it also in some ways skews the market share then because if you have a multispecialty practice that has five cardiologists and four cardiovascular surgeons

and you decide, Oh, we're just cardiologists, that doesn't necessarily give you an accurate reflection of what their market share is.

So I think in that respect the head count is actually much more accurate because you can go in the practice groups and break it down by specialists and actually know who you have as opposed to saying, okay, this practice is going to be this speciality, and that's what we're going to attribute all revenues to.

MR. GARMON: One of the questions we put out for public comment is what to do about those areas that are not representative, for example, obstetrics and pediatrics? Do the panelists have any ideas for even if a CMS list of head count would get at that issue? Do the panelists have any idea what we might do in those situations?

Our concern of course is that ACOs will form and have market power on the commercial side, and that's one difference between the commercial side and Medicare side, those specialties? Is there any ideas about that?

MR. LEIBENLUFT: I haven't thought too much about it, but again if there's some way that centrally the agencies could do the best job that anyone could possibly do at once to figure out where OBs and GYNs are, whether that's going to licensing board or going to

the specialty societies, but it seems like to find out where they are and get the ZIP codes of their offices, it seems like doing it once makes a whole lot more sense than asking everyone to figure out how they do it in their own areas, and if there's some central ways to do that, I think that would ease the burden too.

DR. SACKS: I think for peds and OBs, I think almost all of them participate in Medicaid, just because it's the nature of their patients, so you could -- it could be 50 times to go to 50 states, but there would be the Medicaid database similar to the Medicare database.

I'm going to come back to what's kind of gnawing at me, that we're creating all these artificial silos by specialties or by DRG area, but one of the things that I've come to better appreciate as we've been on this journey of clinical integration, it takes a team to manage most chronic disease which is where the big opportunities are, the big spend, and certainly in the Medicare population, and that team crosses specialties.

We can't succeed in changing the outcomes in diabetes unless you have ophthalmologists, vascular surgeons, endocrinologists, primary care physicians, and shouldn't we be looking as the team as opposed to the individual components with that when you think about the outcomes that you want to get?

Healthcare doesn't neatly fit into the same box that retail or transportation does, and that's obviously the challenge that you have, to figure out how to give us guidance and not retard the potential for improvement.

MR. GARMON: So following up on that, should we develop a screen that's based on overall physician services instead of specific specialties? Does any other panelist have an opinion about that, for instance, PSA shares based on overall physician choices, not by physician specialties?

DR. SACKS: It would be much easier, and I think we would be more comfortable with it, with that, and at least at the first pass at the high level, I think everybody would have a good idea where we stand as networks come together with that.

Remember the conversation on the previous panel about that all of this seems to create a bias towards vertically integrated organizations versus the networks of independents, and again be careful what you ask for in terms of stifling innovation.

MR. GARMON: Steve?

MS. WOJCIK: I can recognize the dilemma that you're in. You can get some information about general physician services, but that will miss a lot of the --

if you don't look at at least some of the high cost specialities, you will be missing a lot, especially in areas where there may be one dominant specialty group in those high cost, high volume, specialties, and that what be our fear if you just looked at physician services in general and not have some kind of combination that might be the solution and just take the top -- the ones where we do need the better coordination of care where the high costs are and where there tends to be a lot of concentration and potential cost shifting.

MR. GARMON: Bob?

MR. LEIBENLUFT: Yeah, I think there maybe some combination. The concern I would have about just lumping all the physicians altogether is you could have -- particularly as a screen, you could have a network that has 70 percent of cardiologists, but they're below the threshold.

So I think -- but I'm not sure you need it for whatever number you have there. So maybe you could try to determine the main kind of physicians you're really worried about exceeding a screen so it's somewhere in between.

MR. GILMAN: Can I just ask a follow up for Dr. Sacks, and maybe this will plug into things that I've heard from Christi and Trish and Bob as well. The

Medicaid database seems to be an interesting solution, but also a problematic one, even for the specialties; that is, I haven't looked at this, but it seems to be the sort of thing that could be an exceedingly good or poor proxy as you march around our geographic areas.

And I don't know the answer to that, but I would be interested in your thoughts, and one thing that made me think about with some of the other comments is maybe we could get comments from stakeholders on this more general question where the Medicare data may be more proxy, Bob said to be more flexible but Trish and Christi have brought up this question, maybe it's not just specific areas like peds.

Maybe it's to some extent geographic areas. Maybe there's other ways to cross cut the data. To the extent that stakeholders can help us sharpen in a sense areas where this is likely to be maybe not an adequate second best measure but more problematic, that would definitely help advance the ball too, but I'll ask you first about the Medicaid. I don't know if you have any thoughts about that.

DR. SACKS: I said Medicaid just thinking that in all of our hospitals, 20 to 40 percent of the deliveries are paid by Medicaid. It's the nature of the population, and the fact that at least in our state

Medicaid has made a better job of making reimbursement attractive to obstetrics and pediatrics than in the rest of them.

There certainly are internists who will not touch any Medicaid patients and since it's such a small segment, they can get away with that, but there's 50 states and there's 50 databases and 50 different rules, and we know the problems with that.

I jotted down something when I listened to the last few comments, and it strikes me that this whole discussion is designed to address the concern about market power which is unit pricing. The real opportunity in ACO has nothing to do with unit price. It's utilization, getting rid of unnecessary care, reworked from complications, and I would estimate that that's a 20 to 30, 35 percent opportunity and will overcome any market power in unit pricing with that.

I think the people who are trying to reform the system recognize that we're not going to get out of the fee for service as the basis, but how can you align the incentives so suddenly more isn't better and everyone is focused on the value proposition with that.

So keep that in mind as you think through of the framework of the analysis.

MR. GARMON: Josh?

MR. SOVEN: Just to sort of broaden it out for a second to go back to a point Bob made on the 90 days. The agencies have been fairly critiqued at times for taking too long in the way they think about these things, and so part of what was driving the 90 days was the thinking that if you allowed the antitrust analysis to stay inchoate for months, that would deter various organizations from applying in the first place, that if they knew the prospect, substantial antitrust enforcement was 12 to 15 months out after they had invested hundreds of thousands if not millions of dollars, that that would be a problem.

So what do you think is the happy medium, if you will, or the plan B to this sort of abbreviated view, abbreviated review?

MR. LEIBENLUFT: Perhaps one happy medium is when I'm getting towards the end of my 90 days -- and this happens all the time with mergers. You say maybe we can work this out but we need more time, I think you should allow more time, and so at least if the entity wants more time, it's not like the agency says, Geez, too bad, I have to make this decision and it's going to be thumbs down, and if we had more time, maybe we could work it out. I think at the very least I think we should have that.

MR. GARMON: Patricia?

MS. WAGNER: Just so I understand though, more time would be more time to see whether you can transfer the ACO to the commercial market, right? Because nobody is going to want to put in an application if in 90 days they don't know in they can participate in Medicare.

MR. LEIBENLUFT: Well, okay. That's a good point. One thought is CMS right now is saying you have to have a letter before you can submit the application. Presumably they're not going to decide the application immediately, so there could be a little bit of a parallel where an entity that wants to submit the application goes ahead and does it.

CMS starts looking at it, and it's conditioned upon a favorable letter but which may come after 90 days. So that's one way of doing it. The other way is you prolong. Maybe you don't apply on that side, but we apply it in the next 180 days if someone will allow it. There's ways of dealing with that.

MR. GARMON: Okay. Did you have something, Trudi?

MS. TRYSLA: The comment I made in the earlier panel is one happy medium is focused on those providers that are exclusive and to not focus on those that have the ability to participate in multiple ACOs, and again I

guess I'm not clear on the connection when they have that ability of what's anti-competitive about that approach.

So that might be one thing to look at along with a different screening mechanisms. I think the data limitations are real. You can have a small network of providers, even if they do have the EHR, they have 30 different systems, and the ability to try to bring those together even with the EHR is a significant challenge, so that might be something to consider.

MR. GARMON: One thing beyond PSAs, and we talked about the Accountable Care Organizations, the objective is to make utilization more efficient, improve quality, but the worry is the cost shifting on the private side. We know that Medicare is going to be monitoring these. That's what the shared saving payments are going to be based on.

Is there anything that we can do to monitor them on the commercial side? One limitation I know we have is there are only 10 states that have comprehensive claims data available, and the other 40 don't. Is there anything that we can do to see whether ACOs actually do cut costs, improve quality or on the other hand engage in cost shifting? Do the panelists have anything? Steve?

MS. WOJCIK: I'm not a data expert, so I will leave that out, but what we would like to see is some kind of baseline metric. We know there's cost shifting now at the outset, and then make sure that the cost shifting is not increasing over that three-year period or the period for which an ACO exists.

We actually believe that only ACOs that have constant or declining ratios of private payments or Medicare payments should be eligible for bonuses. I mean, if there's evidence that the cost shift has increased, maybe I said that wrong, but I think you know what I mean -- if the cost shift has increased, we don't see that that -- somehow that has to be factored in whether a bonus is warranted or not if it's due to undue -- I mean, that's one evidence of undue market power, cost shifting increasing I would think.

MR. GARMON: Bob?

MR. LEIBENLUFT: I think you should just acknowledge you're getting into price regulation, and maybe a decision has been made whether I need that or not, but I don't think a lot of this -- this is a step towards that.

I think it's very regulatory, and why should this sector be subject to looking at how their prices are in any different way than the rest of the economy is

under traditional antitrust enforcement?

I mean, payers have concerns that they're being squeezed. They make complaints, and you will get that, so this is a big question, but I think it's a fundamental question. If you're going down that track, you're really going down a track of price regulation, and I think people should be open about that.

MR. GARMON: Joe?

MR. MILLER: I'm not sure I agree with the last comment. I think what we are talking about is whether we can observe cost shifting and whether that should have an effect on your participation in the program, so I don't think at least what the premise is if there's cost shifting, therefore you should get sued under the antitrust laws, because I agree, that would tend toward price regulation.

I think it's an indication the program is not working as it should, if you simply are reducing your spend in Medicare in some way but shifting it over to the private sector and simply making it up on the other end. You're not achieving the program goals of lowering episodes of care, lowering spent for episodes of care in general.

So I think it's an indication that the program is not -- that the shared savings program is not working

as it should. It might be an indication of market power as well, but I don't think the suggestion is that this should be monitored for its own sake for an antitrust violation and therefore should be regulated.

MR. GALVIN: Can I respond to that? Because I think this is the mechanism. The mechanism isn't CMS saying we won't approve you for the program because we're concerned about it.

The mechanism is the agencies are saying they will bring an antitrust suit, so I think you have to disconnect those two things. I think if you want to say it's a CMS decision for CMS purposes, but that doesn't basically commit the agencies to suing the entity, right now they're tied together, and I think that's problematic.

MR. MILLER: I think maybe one way to thread the needle is this would have to be done as a look back, so if you collect the data over time and see if there has been a cost shift, and then it would be CMS's decision as to whether that ACO should be able to continue to participate in the program or whether it would affect their shared savings I don't think necessarily results in an FTC or DOJ suit.

MR. GARMON: Lee?

DR. SACKS: I think you need to step back and

look at the really big picture, and certainly the conversations that I've had with the health plans in our market post March 23, 2010, they've all started to focus on what's going to happen in 2014 with these changes , and if your cost position is above X and X is a lot lower than anything we're comfortable with today, you are not going to be able to participate in the exchange, and you run the risk of losing market share.

From the health plan perspective, if they can't deliver a product that's at that price point, they're going to cede that market to the exchange, in particular the small and individual market as well as the large self insured.

So there's all these dynamics going on putting pressure on creating efficiencies with that. Up until January, we have deliberately not participated in a small network HMO product that paid 15 percent below what the large network product paid. It was one of our goals for 2011 to get back into that product because we were starting to see an erosion of market share and pulling physicians to other organizations that were in that.

So the market is starting to work. We hope that through the efficiencies that we're creating, we can overcome the gap on unit pricing, but there's all these

mini experiments going on as the market recalibrates, but the employer community is crystal clear, and I think I can speak for providers across most markets in the country.

Volumes are down this year, a combination of still the impact of the recession and changes in benefit plans related to the cost pressure, and that's something that every hospital and physician is very aware of and is going to be very sensitive to when they think about pricing going forward.

MR. GARMON: Thank you. Any other comments about PSA topic or any other topics? I would like to thank all the panel participants from both panels today. It was a very useful discussion, very informative.

Thank you very much.

(Applause.)

(Whereupon, at 1:02 p.m ., the roundtable discussion was concluded.)

CERTIFICATE OF REPORTER

MATTER NUMBER: P111205

CASE TITLE: Another Dose of Competition: Accountable Care Organizations and Antitrust

HEARING DATE: MAY 9, 2011

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the steno notes transcribed by me on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: MAY 16, 2011

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DEBRA L. MAHEUX

CERTIFICATION OF PROOFREADER

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

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ELIZABETH M. FARRELL