Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws
Transcript
October 5, 2010
9:00 a.m. EST

Dr. Don Berwick: Good morning everyone. I'm Don Berwick, the administrator of CMS, and it's my complete pleasure to welcome you all here to this very interesting day of learning and discussion and exploration together.

The interest in this meeting has been phenomenal. And I want to begin by offering my thanks to the staff who helped to organize it on very short notice, led by the wonderful Liz Richter from CMS. We had from our organization Troy Barsky and Tricia Rogers and Tom Carey and Jim Weber who pitched in and helped.

From the OIG's office Vicki Robinson and from FTC Mike Wroblewski, who actually, I think, first had the idea of having the meeting here. So thank you very much, Mike. It's really a pleasure to be with you.

I'm actually proud to host this meeting because I think we're headed in this really important territory. I want to say first that I wish we had enough space here at CMS to house everyone that was interested in the meeting, but that actually would be thousands. The interest all over the country in this topic has been phenomenal.

And we're going to keep meeting the interest every way we can as we explore with you where we're headed. We have arranged for Web streaming and archiving of the meeting so that those who are unable to be in the room can attend in a more convenient way for them.

I'm very honored to be here with my friend, Dan Levinson, the OIG, the inspector general at DHHS and with Jon Leibowitz, chairman of the Federal Trade Commission. Jon and Dan will follow me with their own remarks.

I know that they both share my commitment to what we're trying to get done today and in this process and that is to make accountable care organizations in the long run long-lasting and successful.

We are working very well together. CMS is in continual dialogue with the I.G.'s office, with the Federal Trade Commission and the Department of Justice. It's been terrific to work with these people from my point of view. And this meeting is just one part of the process of interaction and joint planning that we're doing to have all of our agencies joined together in helping to shape the ACO idea and program.

As you know, we have underlying statutory requirements. For example, CMS will have to enforce the Stark provisions, but we can interpret those statues wisely and in a manner that while still consistent with the plain language and the intent of the applicable statutes, does not unnecessarily impede the development of accountable care organizations.

And we can and we will work together towards assuring the health care community clarity and uniformity of purpose and guidance. That's our aim.

Prudence and wisdom require us to navigate our way carefully between two important objectives. First, we need to help integrated care thrive in America. We need to make it possible for entirely new levels to emerge of seamlessness, coordination, cooperation among the people and the entities that provide health care so that we can smooth the journeys of patients and families, especially those coping with chronic illness through their care over time and place.

Second, and at the same time, we need to be proper stewards of appropriate markets and corporate behaviors. We need to assure both patients and society at large that destructive, exploitative and costly forms of collusion and monopolistic behaviors do not emerge and thrive disguised as cooperation.

Frankly, what we want and I think I speak for all of us, is we want our cake and we want to eat it, too. We want cooperation without corruption. We want aggregation without hegemony, and we want synergy without collusion. We

believe that we can have all of that if we think clearly and continue to work together.

In this workshop in what precedes it and what will follow it, we're trying to solve some very important technical problems in designing the regulatory regime under which accountable care can thrive.

I think we will do best at that if we take a moment to touch base first, though, with our underlying purpose, our goals in health care, what we in CMS are now referring to as the Triple Aim. The Triple Aim refers to better care for individuals, better health for populations and lower per capita costs without any harm whatsoever to patients.

What we know from decades from research is that at the heart of the capabilities to deliver the Triple Aim, better care, better health and lower cost, is one core design concept in the delivery of care and that is the integration of care. And I want to take a little time to explain a little more what integrated care looks like.

You already know, I'm sure, probably from personal experience what disintegrated care looks like. It is disorganized care. It is care in fragments. You have to tell your name and your address and your story again over and over to everyone you meet. No one seems to talk to each other. Your record is forgotten or it's unavailable.

One doctor prescribes a medicine that conflicts with the medicine that another doctor prescribed for you. You wait endlessly on hold, and you can't get an answer to your question. It's all in fragments. And you and your loved ones end up holding the bag. Integrated care is care that offers people journeys not fragments. And that is the whole idea in my view behind the design concepts of the accountable care organization.

Suppose I got a message handed to me just now, and it had a name on it. I couldn't read the name. It's someone here. Maybe it's me. And the message says, I have bad news and I have good news. The bad news is that you have cancer. You don't know it yet, but sometime in the next day or two you're going to have pain.

And you're going to go see your doctor, and she will run some tests and then she'll tell you to sit down and she'll say it's cancer. It has spread. And I'm sorry, but don't lose hope. You've still got a 50/50 chance of being cured.

But you're going to have a rough time your doctor would say. In the next 12 months you're going to see probably 15 or 20 specialists. You'll have to go to 10 or 12 places. You'll probably have 500 blood tests in 10 different places.

You'll have surgery first. Then you'll have chemotherapy and then maybe some radiation therapy. You'll be on maintenance medication for a whole year, maybe more. You'll probably get depressed and you're going to need some counseling. So will your kids. So will your spouse.

The side effects will debilitate you, but we'll add in some physical therapy when it would be helpful. You'll need pain control and nausea control and maybe some blood transfusions. And we will get you through it. We will get you through it together because we're a team.

If you get that note, if that note's meant for you, you would be at the beginning of a long expedition through the technological storehouse, the wonders of modern health care with enormous potential to help and to heal you.

And it would have nearly equal potential to confuse, to misstep, to waste and to harm you. Spiderman says, "With great power comes great responsibility." Medicine has power. Who has the responsibility? Who's got your back?

The truth to tell, every single one of us in this room will get that note someday. It may not be cancer. It may be diabetes. It may be the threat of a stroke. It may be chronic depression. It may be an auto accident and subsequent disability. It may be your child, not you with asthma or your mother with macular degeneration.

But somewhere, sometime, more than once life will throw you a curve ball like this and you'll need integrated health care to hit it. We are now engaged, in my opinion, in a great national expedition to seek, expand and design

systems of health care that can create journeys where now we have only fragments.

We have lately come to call such systems ACOs, accountable care organizations, and with American ingenuity and with local concern we are, I think, successfully going to craft these into realities. But the term ACO, even though it has become very charismatic, is just a label for a deeper idea that we all need stewards to help us make sense of the complexity of modern medical care.

And I mean us all. It isn't just the patients and the families. It's those of us who give help to patients and families that also need those journeys. The caregivers themselves, the clinicians themselves need the integrated experience to do well.

I had the opportunity to practice pediatrics for 20 years in an organization that is remarkably close to what we probably mean by ACO today. It was the Harvard Community Health Plan. I remember one day being the officer of the day, the doctor seeing walk-in patients, and I met one little boy whose name was (Timmy).

I was practicing in an integrated system. If that system existed today, as I've said, it might be called an ACO. I practiced there with seven other pediatricians and we served an inner city population in the Boston area.

As I said, I was seeing walk-in patients and I walked in the consulting room to meet this five-year-old child. He was breathing very heavily with an acute asthma attack. He was very sick. And he was with his very young probably still teenage mother, a single parent.

This kid was sick. In normal American health care I would have had only one choice. I would have sent him straight away to the emergency department of the children's hospital where he would likely have been admitted very fast.

But that's not what this story – how this story went. Before I even had begun to speak this young mother handed me a chart of (Timmy)'s breathing tests at home, his FEV1, his forced expiratory volume in the first second, which she

had been taught to measure at home by a visiting nurse deployed by the organization, who had also given her the simple machine that she needed at home and taught her how to keep the chart.

She'd been responding at home, immediately and expertly by adjusting (Timmy)'s medications with appropriate changes. She then told me that she thought (Timmy) needed a medication she didn't happen to have at home and that we should try that one.

I was starting to respond to her when there was a knock on the door and in walked the chief of allergy whose office is one floor above mine in our multi-specialty clinic. He was carrying a vial of the medicine the mother had just mentioned to me. I was beginning to feel quite unnecessary.

He knew that (Timmy) was there and he knew that that's the medication that (Timmy) needed because the visiting nurse was also employed by our ACO and who knew (Timmy) very well, had spoken to the mother on the phone and then had called the allergist while the mother was coming into the office.

Of course, I already knew all of that because we had an electronic medical record, which was handed to me as I entered the room, (Timmy)'s room in the first place. Within 10 minutes he was getting the new medicine that his mother had recommended. And one hour later he was on his way home, much improved, with a visit from the nurse scheduled that afternoon just to be sure.

No emergency department visit, no hospital stay, no scary trip for a four-year-old, and lower cost for everyone. That is integrated care. And every single person in America can have it if we play our cards right. If we keep our wits about us we can build it.

I'm certain we can develop under this broad banner of ACO inventive forms of care, organization and delivery that help transform health care so that people can count on getting the care they need and want exactly when and how they need and want it every single time at a cost we can afford.

To achieve that, ACOs are going to need to have certain common characteristics and capabilities. I don't regard ACOs primarily as a financing

mechanism. I regard it as a care delivery organization, and we need to work together to refine what those specifications are. For starters here, speculatively, might be some of mine.

An ACO will put the patient and family at the center of all its activities. It will honor individual preferences, values, backgrounds, resources and skills. And it will thoroughly engage people in shared decision making about diagnostic and therapeutic options.

An ACO will have memory about patients over time and place. It will not have amnesia. In its care, people will find themselves not having to repeat their stories, not having to carry the burden of making sure that everyone taking care of them has the information they need. They'll feel like teamwork is in place around them.

An ACO will attend carefully to handoffs, especially as patients journey from one part of the care system to another. It won't drop the baton. It will pass the baton. An ACO will manage resources carefully and respectfully. It will make sure that waste is continually reduced and that every step in care adds value to patients.

It will be able to make investments where investments count and to move resources to where patients need those resources. Because it will be so capable at prevention and anticipation, especially for chronically ill people, it will be able continually to reduce its dependence on hospitals.

Instead its patients will be able to be home where they want to be. And when they do go to a hospital they can be assured that their discharges will go smoothly and that they will not bounce back with complications.

An ACO will be proactive. It won't wait for trouble. It will help prevent trouble. It will reach out to people with reminders and advice that can help them stay healthy. And when it's time for a checkup or a test it will make sure that people know it and can get it.

An ACO will be data rich. It will be able to measure what it achieves for patients and communities. It will be able to track outcomes over time and to

learn about how to do better and better. It will use registries mindfully. It will be transparent with its patients and its community about its successes, its failures and its progress and its cost.

An ACO will be inventive, innovative in the service of the Triple Aim, better and better patient care, better population health and lower costs without harming anyone at all. It will draw upon the best advancing models of care using modern technologies, tele-health, electronic health records and more to continually reinvent care in the modern age.

It will be curious about who performs better than it does and will have ways to find those better approaches, study them, learn from them, adapt them and adopt them. An ACO will continually invest in the development and pride of its own workforce, including affiliated clinicians. It will maintain and execute plans for helping to build skill and knowledge and teamwork and joy in work every day.

The transition from a fragmented system to an integrated person-centric delivery system, to integrated care is not going to be an easy one. The ACO I imagine is not the status quo repackaged. It is a new and better way to organize care. It will involve changes for almost every stakeholder.

Further there is no one size fits all model for an ACO. All, I believe, ought to pursue the Triple Aim in their own way. But I suspect there'll be many different breeds needed to match the enormous diversity of settings and communities and histories in this textured nation.

A rural ACO may not look much like an urban one. An ACO led by a hospital will follow a different plan of development from one launched by a group of physicians or one especially closely aligned with Federally Qualified Health Centers. We will need to assure the space and the time for these many adaptive forms of accountable care to harvest their successes.

But every single form a successful ACO will have in common, I think, is a strong and consistent commitment to cooperation among those who care for a patient on behalf of that patient. To allow that to occur we will need a

regulatory framework that nurtures cooperation even while it guards against the lingering threat of inappropriate practices.

We are here today to discuss ways to create a framework consistent with integrated care, consistent with both of those goals. Throughout the time ahead I say CMS will be a strong partner in stewardship for the success of ACOs.

We will find ways of our own to encourage cooperation and simplicity for patients who intend to be in integrated care and for their providers. We will also support learning networks to help spread new care models and lessons learned.

And one way we will be a strong partner is to work with our colleagues in government to craft a regulatory framework that provides clarity to providers and organizations around antitrust rules, enforcement of Stark, anti-kickback provisions and related concerns.

We in government will need to do this together. We know that. And it will not be acceptable if organizations hear one message from CMS and a different message from other agencies both within and outside HHS. You who wish to leap into this new era of care integration and consistency and clarity and predictability, you need clarity and predictability about the relevant regulatory regime.

You will help most today, by the way and in the future, if you don't just identify the legal issues and the barriers that you see, but you also help to outline the solutions that you would like to see emerge to overcome those barriers.

I hope you'll feel free to raise any concerns you have or interested in hearing how CMS should exercise its waiver authority under Section 3022 of the – of the Affordable Care Act. And if fraud and abuse protections are waived how we can ensure that our regulations appropriately protect patients' health and lower costs.

And as I say, this isn't going to be easy. We're all going to have to change the way we do business and there's plenty of work ahead. I see the problem solving that we're doing today, though, to be part of a much larger, I daresay, a majestic process that we have now engaged in America to help a new and better health care delivery system emerge.

Better for patients, better for helping the public, better for our economy as a whole, and not at all incidentally, better for the dedicated professionals and managers who come to work every day to try to relieve human suffering and to restore and maintain health.

One thing I know is this. We will not succeed separately. We will either build the new health care system for America together, patients, hospitals, physicians, organizations, nurses, managers, employers, communities. We'll do it together or we aren't going to build it at all.

There's one final note I'll say in closing. It's about a matter that concerns me, and I call it authenticity. Authenticity matters. Those who only wish to preserve the status quo under a new name or not are not going to be constructive contributors to the nation's future. They cannot be effective partners. We don't have time to pretend that they are, and we don't have time for games.

Those who agree that this is a historic time, perhaps the last time in my lifetime to navigate the nation to better care, better health and lower cost, to navigate us to the care we can be proud of and confident to hand to our children.

Those who welcome change and will agree to lead it will certainly find a friend in me, levers I think in the new law and gratitude in the communities they serve. So welcome to the day. Enjoy it. And may I now turn it over to my colleague Jon Leibowitz.

Jon Leibowitz: Well, let me – thank you so much, Don, for those wise and prudent opening remarks. I'd like to join Dr. Berwick and HHS Inspector General Levinson and welcome all of you to the workshop today. I also want to thank Zeke

Emanuel who has been a driving force behind the scenes for moving this process along, both thoughtfully and expeditiously.

The promise of ACOs, that creative health care practitioners can collaborate legally to deliver higher quality health care at lower cost, offers a real opportunity for health care reform. I think we all know that.

And our job or our jobs at the FTC, at CMS, at the Department of Justice and at HHS is to ensure that regulation encourages that innovation, and just as importantly, benefits health care consumers, patients like the woman that – the young single mother that Dr. Berwick referred to from Cambridge and really patients and people like all of us in the room.

And today's workshop reflects, I think, an unprecedented effort among all of our agencies to come together and coordinate our requirements for ACOs based on the Stark law, the anti-kickback laws, civil monetary penalty statutes and the antitrust laws.

From an antitrust perspective, we want to explore how to develop safe harbors so doctors, hospitals and other medical professionals know when they can collaborate and when they cannot.

And we're also considering whether we can put in place an expedited review process for those ACOs that fall outside of safe harbors as some may. And let me assure you, if we can do this we will.

Your job in the private sector or our wishes for you or our hopes is really to tell us how best to proceed. We need to learn more about your ideas for and your concerns about ACOs. We received a number of terrific written comments last week. We have been reading them carefully.

And we're also keeping the comment period open so that if today's discussion sparks additional thoughts, you can bring – and I certainly hope it will and I'm sure it will – you can bring them to our attention. We hope you can do that within the next two weeks.

We need your input because we need to get this right, and here's why. If ACOs end up stifling rather than unleashing competition, we will really have let one of the great opportunities for health care reform slip away. And none of us in the room can afford to let that happen.

But before any of us can do our jobs today and going forward, we have to let go of the stereotypes that define and sometimes divide those of us in the room. The stereotypes that suggest government agencies can't work together no matter how high the stakes, the stereotypes that led so many of our private sector audience members to wince or chuckle.

I saw a few of you do this when I began my remarks by saying in essence, "We're the government and we're here to help you." I saw three of you chuckle. I saw five of you chuckle then.

So our challenge today reminds me of a story of a doctor and a lawyer who were driving towards each other on a remote country road and collided head on. They both got out of their cars, and they stood by the side of the road to wait for the police.

The lawyer, seeing that the doctor was shaken up, offered him a drink out of his hip flask. The doctor accepted and handed the flask back to the lawyer who capped it up and put it in his pocket. "Aren't you going to have a drink yourself," the doctor asked? "Sure," replied the lawyer, "after the police leave."

OK? I know you're sort of an audience of medical professionals, insurers, but that was a joke. And Cecil, I think we can both agree that that joke worked better in Chicago than it did today in Baltimore.

But I'm here to tell you I am not that lawyer. And I'm here to tell you no one at the Federal Trade Commission or the Department of Justice for that matter is that lawyer or the HHS Inspector General. You're not that lawyer either, are you, Dan?

Unfortunately, but not surprisingly, in the past too many health care providers saw antitrust regulators as just that. We know this from comments we receive when we resolve cases involving health care providers.

For example, last year we settled a case against a group of doctors in Garfield County, Colorado. One doctor accused the FTC of causing a shortage of physicians. Another complained that our actions, and I quote "defy logic," and this was in a settled case by the way. Still another told us that our decision quote "goes beyond socialism. It is a return to serfdom." That last comment is my favorite.

The picture painted by – and at some level we can all laugh at this, but the picture painted by these comments is not pretty by a few health care providers. And I'm glad it's only a few. We are seen as sort of surreptitious socialists bent on keeping you from charging a fair price for your services, as heartless regulators, holding you to outdated rules that no other health care player has to follow, as fastidious bureaucrats rejecting any change that would allow you to care for patients more efficiently.

But if you step back from those stereotypes, you can see that the FTC is more often than not I think on your side as health care providers who care about your patients and, of course, as consumers yourselves.

When competitors get together to fix prices, create market power or prevent competition, that's illegal because it most often leads to higher costs, lower quality, less innovation and fewer choices for consumers.

The antitrust agencies enforce these antitrust laws whether against doctors, hospitals, health care insurers, pharmaceutical companies – a big area for us these days – real estate agents or high tech companies. And too often, I believe, health – the health care community sees antitrust enforcement as impeding improved care. If there's any stereotype, I'd like to disabuse you of today, this one is it.

So take the case of Grand Junction, Colorado. Back in the mid-1990s, the Federal Trade Commission found that physicians in Grand Junction were charging prices significantly higher than elsewhere in the state.

Almost all the doctors in Grand Junction had agreed that a single organization would bargain with health insurance plans on behalf of the entire group. That meant that the plans had to pay the doctors whatever fees the organization demanded because health plans had almost nowhere else to turn for physician services. And the doctor's agreements kept new innovative health plans from entering the Grand Junction area.

Now, the FTC challenged this conduct, and the case settled before it went to trial. The commission and the doctors agreed to an order that did two things. It stopped what we believed to be the anti-competitive behavior, pricing practices largely, and it allowed doctors to collaborate when doing so could lead to cost savings and better outcomes for patients.

And the doctors in Grand Junction did precisely that. They worked together not to fix prices but to share financial risk. They worked with a health plan, Rocky Mountain Health Care, to develop ways to improve collaboration among providers. For example, instituting a community-wide electronic record system that allows them to share – it allowed them to share and they do share – office notes, test results, and hospital data for patients.

Today, Grand Junction is cited as one of the places in the United States with the lowest cost and highest quality health care, a terrific result for consumers and one that the local medical community is justifiably proud of.

But we know that not all ACOs will follow the model used in Grand Junction. That is the latter model used in Grand Junction. So the question before us today is, how can we design rules for ACOs that are flexible enough to allow the health care community to collaborate to improve quality and decrease costs but obviously not to create undue market concentration and not to affectively end up fixing prices?

It is not easy to craft safe harbors that can replace an antitrust review that analyzes the specific facts of each case and market. But we're going to try to do this. And to do it effectively and properly we need your input. We need your real world experience and expertise to help us understand better what

kind of ACOs you're considering and how you see them operating in the health care marketplace.

And all of us need, and I think – I think certainly speaking for my agency, we're a part of this, all of us need to cast aside our stereotypes and approach each other not as regulators and the regulated, not as doctors and lawyers and patients, but as Americans who all want to realize the potential of true health care reform.

I think we all want to. I think we're going to make great progress through this process. And I thank you so much for listening to my remarks. And now, I have the pleasure of introducing the Inspector General of the Department of Health and Human Services Dan Levinson. Dan, why don't you come up here?

Dan Levinson: Good morning. It is a pleasure to be here today with my distinguished colleague from CMS, Administrator Berwick and the Chairman of the Federal Trade Commission, Jon Leibowitz. I also would like to express our appreciation for the involvement of our colleagues from the IRS and from the Department of Justice at this very important event.

Today's workshop is an opportunity for sharing views about what the government needs to do to ensure that bona fide ACOs striving to achieve the important goals of improving quality and achieving savings are not unduly inhibited by existing laws including the fraud and abuse laws for which our office has enforcement and regulatory authority.

Our office has been working closely and is committed to continuing to work closely with our law enforcement partners and other government agencies to address this issue. We are keenly aware of the need for innovation in business arrangements to fully implement the ACO provisions of the Affordable Care Act.

To that end, let me say this. The fraud and abuse rules enforced by our office should not stand in the way of improving quality and reducing costs through ACOs. As the Medicare and Medicaid programs incorporate and test new

payment and delivery models, there is a need for fresh thinking about program integrity and the type of risks faced by our programs and beneficiaries.

The Affordable Care Act gives the secretary authority to waive certain fraud and abuse laws as necessary to achieve the goals of the ACO programs. We and our HHS colleagues are looking closely at how the secretary might exercise this authority most effectively.

The waiver authority is a central issue for this afternoon's portion of the workshop. We feel very strongly that the goal of ACOs is consistent with the mission of OIG to ensure integrity in federal health care programs, promote economy and efficiency in program operations and promote positive beneficiary care and outcomes.

The most effective way to achieve this goal is to work collaboratively with all of our government partners. Today's workshop is a perfect example of such collaboration and coordination. Only by working together can we collectively ensure that the ACO program is implemented in a way that is meaningful and fulfills the quality and cost containment goals.

Our office has a solid history of collaboration with the industry on a variety of important health care issues. We have worked with numerous sectors of the health care industry to develop compliance program guidance for providers so that they can implement processes to avoid running afoul of the fraud and abuse laws.

The input that we receive from the industry in developing these guidance documents has been critical to ensuring that we reflect the current state of health care business practices and operations. We plan to continue our efforts to collaborate with the industry in the ACO context.

Today's workshop is an important step in the government's and the industry's joint effort to formulate new health care delivery models that will provide quality health care at lower costs.

We at OIG are confident that the vast majority of providers interested in ACOs are committed to making them work to achieve these important goals.

Experience teaches that new federal programs are often vulnerable to a small subset of bad actors intent on taking advantage of the system for their own financial gain. We want to use our enforcement and oversight authority judiciously to ensure that these few cannot thwart the goals of ACOs, compromise patient care or inappropriately increase costs to our programs.

Gregory Demske, our assistant inspector general for legal affairs, Vicki Robinson, our senior advisor for health care reform and other senior staff from our office are here today to learn and participate in this workshop.

Input from providers on the front lines of ACO innovation as well as from consumers and other interested stakeholders is essential as we continue to hone our thinking about program integrity in what is an evolving area.

We thank all of you for participating today. We'd also like to thank our partners from the department and the FTC for engaging in this effort. We look forward to future opportunities for dialogue and input on these very important issues as we move forward. Thank you very much.

Dr. Don Berwick: Thanks, Dan and Jon, for those opening remarks. I think we are going to move now to the first panel. And Mike, are you going to orchestrate that? Thank you very much.

Michael Wroblewski: Thank you.

Dr. Don Berwick: Thank you, Michael.

Michael Wroblewski: Good morning. My name is Michael Wroblewski, and I'm the deputy director of the FTC's Office of Policy Planning. And I'll be moderating this morning's first panel discussion.

I'd like to invite all the panelists up onto the stage while I'm going over a couple of the housekeeping details. These sessions are being recorded for rebroadcasting purposes so please silence your cell phones and other noisemaking devices.

To get to the rest rooms, turn right when exiting the main auditorium room doors, go down the hall a bit and they're on the left-hand side of the hall before you go back into the lobby. The cafeteria is located on the lower level, and we will have a break for lunch between 12:40 and 1:30.

All visitors must be escorted in areas other than lower and first floor levels in the central building so please do not go beyond these areas.

Co-moderating the first panel with me will be my colleague Markus Meier, assistant director in the FTC's Bureau of Competition in charge of the health care division. We will discuss two topics this morning.

During the first panel the topic will be how ACOs formed among independent physicians and hospitals can engage in joint price negotiation with private payers without running the risk of engaging in price fixing that can drive up prices and reduce innovation for private payers.

In particular, this panel will discuss how the requirements of antitrust laws could or should be addressed in the regulations that CMS is developing for the Medicare Shared Savings Program. This discussion is important because ACOs that participate in the Medicare Shared Savings Program are likely to use the same organizational and operational structure for private payers.

The second topic later this morning will be a discussion on ways to encourage formation of multiple ACOs among independent providers in any given geographic market.

Let me introduce our distinguished panelists this morning. And I'm going to start all the way down at the very far right-hand side, and they're listed alphabetically.

First we have Gloria Austin, CEO of Brown & Toland, a clinically-integrated physician network consisting of more than 800 primary care and specialty physicians caring for more than 300,000 HMO and PPO patients. Brown & Toland operates in northern California.

To her left is Terry Carroll. He is leading the transformation across Fairview Health Services, which is an integrated health delivery system in Minnesota. He is responsible for partnering with clinicians to improve health care delivery and to support Fairview's care model redesign.

Dr. Larry Casalino is the Livingston Farrand associate professor of Public Health and chief of the Division of Outcomes and Effectiveness Research in the Department of Public Health at Weill Cornell Medical College. Previously he worked for 20 for years as a full-time family physician in private practice. And he has written extensively about improving the health care delivery system.

To his left is Mary Jo Condon. She is the director of public affairs for the St. Louis Area Business Health Coalition. The Business Health Coalition seeks to help its over 40 employer members improve the health of their employees and to enhance the quality and value of their investments in health benefits.

To her left is John Friend. He is the associate general counsel at Tucson Medical Center, a community not-for-profit tertiary care hospital in Tucson, Arizona. Since 2008, he has coordinated TMC's efforts to establish a provider-based organization accountable for the quality and cost of health care in southern Arizona.

To his left is Dr. Robert Galvin. He is the CEO of Equity Health at Blackstone Group, which oversees the management of health care for firms owned by private equity companies. Before joining Blackstone, Dr. Galvin was executive director of Health Services and chief medical officer for General Electric.

To his left is Elizabeth Gilbertson. She is the chief of strategy for the Hotel Employees and Restaurant Employees International Union, a national Taft-Hartley trust fund that provides health benefits for over 246,000 lives.

To Betsy's left is Doug Hastings. He currently serves as chair of the board of directors of Epstein Becker & Green, a national law firm. He is a member of the firm's health care and life sciences practices in the Washington, D.C. office.

To his left is Harold Miller. He is the executive director of the Center for Health Care Quality and Payment Reform and the president and CEO of the Network for Regional Healthcare Improvement. Mr. Miller also serves as adjunct professor of public policy and management at Carnegie Mellon's Heinz School of Public Policy and Management. He has written extensively on initiatives to improve the quality of health care services.

Lee Sacks is executive vice president, chief medical officer of Advocate Health Care, and he is also the chief executive officer of the Advocate Physician Partners in Chicago. APP is the umbrella organization over the eight advocate PHOs and the medical groups that determine Advocate's managed care strategy, negotiates the managed care contracts and enhances medical management.

Dana Safran is senior vice president for performance measurement and improvement at Blue Cross Blue Shield Massachusetts. In this role, Dr. Safran leads the company's initiatives to measure and improve health care quality, safety, and outcomes.

Joe Turgeon is vice president of National Network Strategy and Development for CIGNA. He is responsible for setting national strategy and executing business plans that support existing market improvement, assessing competitive position and establishing contracting and health care professional service standards, policies and programs for CIGNA.

Dr. William Williams is the president and chair of Covenant Health Partners, a clinically-integrated cooperative effort between Covenant Health systems, 170 physicians from Covenant Medical Group and 140 independent physicians in Lubbock, Texas.

Dr. Cecil Wilson is president of the American Medical Association. Dr. Wilson has been in private practice of internal medicine in central Florida for more than 30 years. He is board certified in internal medicine and a Master of the American College of Physicians.

And finally, last but certainly not least, Dr. Janet Wright. Dr. Wright joined the American College of Cardiology as senior vice president for Science and Quality in May of 2008 after 23 years of practice in Chico, California. Her division encompasses developing clinical guidelines, performance measures, health policy statements and appropriate use criteria for the practice of cardiology. Welcome and thank you all for participating in this morning's discussion.

As Chairman Leibowitz mentioned in his opening remarks, the agency has received many comments on how to harmonize CMS, FTC, and OIG regulatory and enforcement requirements. Many of the comments suggested that we create an antitrust safe harbor for certain conduct that would provide physicians and hospitals certainty when they form joint ventures so that they're not engaging in price fixing.

For example, if two physician practices at a hospital wanted to collaborate, what would they have to do to coordinate the care they deliver, to change their practice patterns, to, as Dr. Berwick mentioned this morning, exhibit that consistent commitment to cooperation such that they would be a sufficiently integrated enterprise? Let me give you a little bit of a background on how this safe harbor could work.

The Affordable Care Act permits ACOs to be formed from a variety of entities, including networks of individual practices, partnerships, hospitals, employing ACOs, professionals and others. We expect that many ACOs will be newly formed joint ventures among otherwise independent entities. The act requires an ACO to be accountable for quality, cost and overall care of patients.

And to have in place clinical and administrative systems and to define processes to promote evidence-based management and patient engagement, report on quality and cost measures and to coordinate care. All of those requirements that I just mentioned, for ease of discussion, I am going to refer to those as statutory – as the statutory requirements for integration activities.

An antitrust safe harbor for integration could be established when an ACO meets these integration requirements, is approved by CMS and agrees to participate in the shared savings program.

The antitrust agencies would then refrain from an enforcement action for price fixing if the ACO uses the same organizational structure and care processes as it deals with private payers. And instead, the agencies would treat the ACO under the Rule of Reason.

A second safe harbor could be established with regard to the size and scope of an ACO, but that's the topic for the second panel this morning.

With that background, let me move into our first set of discussion questions. In terms of format, I'm going to pose questions to the panelists, and given the short amount of time that we have available, it'd be helpful if the panelists could keep their responses to two minutes or less so that others on the panel can join in.

And if a panelist would like to join in or add a comment, please just turn your name tag on its side so I'll be sure to call on you. As I mentioned, let's start with number one here, as I mentioned, the statute requires an ACO to have in place clinical and administrative systems to define processes to promote evidence-based medicine and patient engagement, to report on cost and quality measures and to coordinate care.

My question that I would like to address to the five panelists who currently work in integrated health care systems, is, based on your experiences whether and how CMS should elaborate on these requirements, such that from an antitrust viewpoint ACOs formed among independent providers that meet these requirements would have formed a legitimate joint venture. Dr. Sacks, I'll turn to you first.

Dr. Lee Sacks: OK, I guess I get the first two minutes. You know, Don Berwick, a few minutes ago, said that when you experience clinical integration you know it, and I've always been struck by something I read from Steve Shortell about 20 years ago, the analogy to the Supreme Court ruling on pornography, when you see clinical integration, you know it but you can't define it specifically.

I think the high level concepts that are in the statute and that you just mentioned provide the framework. You need governance. You need an administrative infrastructure. You need clinician and physician leadership.

But when you get much more specific, I'm guessing all five of our organizations have approached things differently. I'm struck by the fact that many of the consultants and the attorneys and the advisory opinions have focused on having an electronic medical record. Our organization does not have an electronic medical record.

We're just starting to roll it out, but we've been clinically integrated for six or seven years, have results that I would compare to anything in the country and have made a difference for the patients we serve.

There's lots of other examples of specific tactics that we approach things differently. Ultimately it's the outcome and the impact that have on your patients in the community that you serve, and you really know that in retrospect.

Michael Wroblewski: OK, thank you. Gloria or Terry, do you have any comments?

Gloria Austin: I do. Actually – thank you. This is – we're a little squeezed at this, yes – at this end. You asked whether there should be, though, additional definition of clinical integration. And as an organization who's been on a clinical integration path for close to 10 years now, I think it's critical, though, to give the industry a framework. And I think this notion of – I think that, for example, when we started we heard the same. If you're clinically integrated you will know it.

I do think there's been a lot, to Dr. Sacks' point, a lot of progress made in groups that are, what I would state, on their way and on a path toward clinical integration. But at a minimum, some of the things that I think this industry has to move toward is that we have to have electronic tools in order to be able to have tools that are interoperable and that share data among the different providers in health care.

In San Francisco, we created an interoperable medical record that now creates over 1.5 million populated results per month. What it does is not only give us – we have information obviously on disease states, but it gives us real-time at the point of service information on what's happening to that patient, whether it's in the ER, a specialist's office or a primary care office.

So I do think that we have to be on a path to electronic tools, including the electronic record. I don't think it has to be in place because of capital restraints, but I do think that organizations have to demonstrate their way.

I also think that there has to be an infrastructure to monitor what the ACO is doing. So without a quality and cost evaluation, administrative arm, I don't think an ACO really has the legs to make cost and quality improvement.

I also think that, as Dr. Berwick talked about, the three aims, I think that in order to improve cost, care and coordination that we have to have evaluation of performance against peers. Not only against each other in a practice, but against other ACOs and be open to where we're not producing the kind of results that we want.

So my answer is yes, I do think we have to have a better framework. There's innovation inside that framework, but electronic tools, I think, are very critical to moving forward.

Michael Wroblewski: OK, let me turn to Terry, would you like to add a point, and then I'll turn to John Friend as well.

Dr. Terry Carroll: Yes, I will just add a point quickly as an organization very much like Advocate, we've been over the last couple of years, trying to figure how do you create the infrastructures to be able to deal with the changing roles that are going on in the marketplace?

And I think that the whole notion of being able to generate a level of clarity relative to the regulations would be really important so that the providers in the networks that we're trying to form can actually focus in and concentrating on delivering the clinical value in which they need to do and not to be hung up.

And so they're sidetracked with all of the issues associated with whether they're meeting the intentions of the laws of the land. So I would say clarity would be the real important thing to make sure that we can.

Michael Wroblewski: And what specifics would you put to get that clarity?

Dr. Terry Carroll: You know, it's as I look at the changing roles of the whole organization and network that's needed to deliver on the promise that Dr. Berwick talked about this morning, means changing relationships between employers in the delivery system, payers in the delivery system, the ability to be able to share data effectively between those systems, being able to use the transparency that's being implied by all of the environments that are evolving today.

I know in Minnesota, as an example, we are going to have all payer databases that will allow us to understand the performance that is going on between the organizations, but to be able to figure out how we could literally move to an environment where basically the data is on the table and that the public can basically see it and use it effectively.

And I think that'll be the key for us to be able to create those relationships that would allow the actual care coordination that needs to move from the entities up to the network to be able to perform.

Michael Wroblewski: OK, thank you. John and then I'll turn to Dr. Wilson.

John Friend: Yes, I think from our perspective, that it's interesting. We're in our infancy as an integrated organization; we were in the 1990s. I think, one of the things that we have used as a guideline are some of the existing standards, some of the policy guidelines that exist. So the ability to integrate – we find there's a good deal of guidance out there today.

What I think makes a difference is probably a new – a new time we're embarking on where data is available and consumerism and transparency are the rule. So a small organization like ours, or at least small in a relative sense, we embrace competition on quality and efficiency. The data in a way helps us administer internally and prove our point, but effectively, you know, can

demonstrate to the consumers in our marketplace that we are indeed delivering a better product at lower cost.

Michael Wroblewski: OK, thank you. Dr. Wilson.

Dr. Cecil Wilson: Well, thank you, Michael, and I guess I would speak from the AMA's perspective to saying at the higher level, I guess we were a little concerned, sort of related to the question. If the question is, "Will you develop requirements for ACOs that are sufficiently granular to meet current FTC rulings," then I think we would say that's not where we want to go.

As a matter of fact, we heard from Chairman Leibowitz that he recognizes there needs to be a difference in – this is a different ballgame and there needs to be a difference in terms of the rulings about antitrust. So what we would suggest is that the requirements be set at a high level, recognizing the diversity of interests, the diversity of models that will be out there. We don't know what model is the right model. And then there will be an assumption that if ACOs meet these requirements, they do meet a new standard related to antitrust.

Michael Wroblewski: OK. How do you evidence in a safe harbor what Dr. Berwick referred to as that consistent commitment to cooperation? How do you – we've talked about data and data transparency and there are different ways to get it, but how do you get that consistent commitment to cooperation ahead of time to evidence it? I'll go to Doug, and then I'll turn to Dr. Casalino.

Doug Hastings: I mean, clearly the policy goals of the Affordable Care Act and historical agency guidance on clinical integration, to me, are aligned. And I think the term care coordination is essentially a similar concept of clinical integration.

So I think CMS can advance the ball beyond the words of the statute, understanding it has to perhaps stay at a certain high level. But all that we've learned since the 90s about clinical pathway development, measuring and reporting on quality and cost efficiency, and what patient-centered care is will give CMS the ability to flush out the statutory requirements.

And I think they need to do that to an extent that will advance the understanding of clinical integration in both public and private (pay) settings and therefore provide further guidance. And then that will continue to develop over time because, as Dr. Berwick says, the idea is the keep advancing.

Done right, the requirements for ACOs under Section 3022 or other provisions of the Affordable Care Act will both help assure that true clinical integration and care coordination is taking place and thus move providers out of any sort of per se treatment.

And at the same time, it can help assure that there's enhanced competition taking place in many markets by encouraging and promoting the development of organizations that can indeed coordinate care.

Michael Wroblewski: OK, thank you. Dr. Casalino.

Dr. Larry Casalino: I think, Michael, that there's really three main tensions involved in trying how to regulate ACOs, and I'll just mention two of them now and maybe we can talk about a third one later. The two are, you know, how high to set the bar for who gets to be an ACO and who gets to pass antitrust muster. And a related tension then is how specifically to define the bar, I think.

You know, I think in terms of where to set it, the tension is on the one hand, I don't think we want a lot of, really, either sham organizations or well-meaning but incompetent organizations, who are only certain to fail. We don't want 80 percent of ACOs failing. On the other hand, I don't think we want 100 percent of ACOs succeeding. Then we're setting the bar too high.

So I think the bar, in my own opinion, the bar should be set in a place where people who sincerely want to do this are encouraged to try and that – but that the rate of success will be reasonably high.

In terms how specifically to define the bar, – there's a lot of ways to get this wrong, I think. Obviously, it would be a mistake if CMS guidelines for who gets to qualify as an ACO are much weaker than FTC clinical integration guidelines. That could cause some real problems.

But I'm not sure that they need to be a whole lot stronger or more prescriptive either. I think that the FTC has been criticized a lot for not prescribing more specific guidelines for antitrust safe harbors for clinical integration especially. And I think actually that if more specific guidelines were prescribed, the FTC would be accused, justifiably, of trying to make a cookbook, stifling innovation and so on and so forth.

I agree with Dr. Wilson, that we don't know what models are going to work here, and every year the ideas of how to improve quality or reaching Triple Aim are changing. I think that there is actually a lot of guidance out there on clinical integration.

My own opinion is that that guidance would also be very good guidance for what it means to be an ACO. I think there are issues related to the FTC guidelines especially related to ancillarity and exclusivity and market share that we can talk about later.

But generally speaking, I think they actually provide a lot of guidance for what kind of organization could plausibly claim to be an ACO. And I'll just – I'm talking too long but I'll throw out one more thing and be quiet, but the kind of kicker in all of this is what NCQA does and how CMS treats what NCQA does. So NCQA will certainly want to be in the business of certifying ACOs.

The question is how prescriptive they'll want to be, and whether CMS – what, if anything CMS has to do with NCQA certification of ACOs in terms of who CMS will consider an ACO.

Michael Wroblewski: OK, thank you. Dr. Safran.

Dr. Dana Safran: Thank you. So I would agree with the gist of what you, I think, have been hearing from this panel and that is that we needn't be overly prescriptive or specific in how we set the bar. The comments that I make come out of the experience that my company's had, Blue Cross Blue Shield of Massachusetts, in putting live on the ground in our network what is considered an ACO model. We call it the Alternative Quality Contract.

It's a model that was developed in 2007 and launched in 2009, really to accomplish the twin goals of improving quality and outcomes while slowing the rate of growth in cost in the context of the state that was undergoing health care reform, had gotten universal coverage. And now was staggering under how are we going to afford this with triple digit or double digit, sorry, to triple rates of increase triple that of general inflation or double digit rates of increase year-over-year.

And so, the way – I would say that the way that we have now put this out into the market, and it encompasses 25 percent of our network at the time, is to allow enormous diversity in how these organizations have taken shape.

So in fact, only one of the organizations that's in this Alternative Quality Contract looks anything like the Harvard Community Health Plan structure that Dr. Berwick described or the Kaiser-type model that we all might be thinking about. More than half of the organizations that are succeeding under the AQC and that are this model, are comprised of small, one to five-person physician practices grouped together for purposes of being successful in managing to a budget and managing a population to improve quality and outcomes.

And what we see is that the entire spectrum that we have in this model so far from the multi-specialty physician group, the physician-hospital organizations and the much-looser network models are, all of them, succeeding enormously, both in the managing their budget successfully and in quite dramatic improvements in quality and outcomes.

Michael Wroblewski: OK, thank you. Harold.

Harold Miller: I would distinguish strongly between the notion of guidance and requirements, because I think that having some guidance as to what could work would be helpful, but to – because for providers to know what they need to do to be in a safe harbor would be helpful to have some structure to that. But I think to be forcing people to follow a limited set of models would be problematic.

You just heard today the difference between those who think EHRs are essential and those who think EHRs are not essential, and I think that any time you get a group of people in the room they will all have their own favorite thing that is necessary.

And the truth is that there is almost no research demonstrating that any of those things are necessary – desirable in many cases, but not necessary. So I don't think that we want to preclude innovation by having the requirements be too restrictive.

I also think that it's important to distinguish between requirements about structure versus process versus outcomes, and I think that requirements about structures should be avoided at all cost. I think that CMS could really demonstrate some leadership by focusing much more on the outcome side and asking providers to be able to demonstrate outcomes.

The other thing I would say is that the way you phrased the question was about additional requirements or defining the existing requirements. I think the other thing that is missing in the law explicitly and that CMS could help on is being able to provide some greater flexibility and resources to providers to be able to actually implement more coordinated systems of care because the current payment system, for example, is very restrictive in that regard.

And to try to have providers being able to coordinate with each other or work when the payment system is working against them or when other regulations are working against them is problematic. So I would just keep in mind that it may be necessary in order to promote some other models to also provide some flexibility about other requirements as well as what additional requirements to add.

Michael Wroblewski: OK, thank you. Dr. Wright.

Dr. Janet Wright: Yes, Michael, as you know, not being an attorney …

Michael Wroblewski : You don't have to turn around and look at me. You can look at the audience.

Dr. Janet Wright: … I don't know that I can advise on the waivers and safe harbors, but I spent a lot of time both in my own practice and now in a different role thinking about the components of a system of care. And that's what I think we're all deeply invested in is a new system of care.

So if those of you who can think through the legal intricacies could develop a system that allows us to have a community of providers, a legitimate community of providers, because that's where the exchange of learning happens, and enabled by HIT now, we can exchange that much faster.

Another central component to community would be the ability to collect data. We've all agreed that that's necessary whether it's through an electronic basis or not and then to reflect on that data to improve performance. So a community of folks invested in the idea of collecting and then improving their performance.

And then the education, which I think enfolds that idea of guidance, so that you're constantly guiding and educating folks involved in this new system of care, in putting in place the proper incentives whether those are recognition or some sort of reimbursement formula that makes it worthwhile, that activates people to participate.

And then finally the research component so once again we learn what works, what doesn't, and can disseminate that through the community.

Michael Wroblewski: Thank you. You actually lead to a nice segue to the next point in terms of setting up incentives. And one of the ways that the antitrust agencies have set up those incentives in terms of forming a legitimate joint venture has been to require what we call financial integration, where the members of the provider organization share substantial risk both on the up side and on the downside.

And the thinking behind it is that it incentivizes providers to change practice patterns so that they work together and exhibit that commitment to sustained collaboration. My question then is whether the Shared Savings Program authorized by the Affordable Care Act for Medicare is sufficient sharing of financial risk to incentivize this change in practice patterns?

I'm going to ask Dr. Casalino to first, just define what shared savings are so we all have a working definition, and then I'll open it up to the panel.

Dr. Larry Casalino: Well, there's probably a lot of people here who know a lot more about this than I do, but a shared savings concept is really based on the Physician Group Practice Demonstration which was a limited number of groups of 200 plus physicians that were in a demonstration project with Medicare recently.

Basically the idea was costs were projected. That's cost to Medicare for the population of patients that Medicare attributed to each of these organizations. And if there were savings, Medicare kept the first two percent. If there were savings in excess of two percent, then these were shared between the provider group and CMS, assuming that certain quality thresholds were met.

But of course the two parameters are what percent do you start sharing savings at? Should it be two percent, four percent, one percent, whatever? And then what should be the split? Should it be 50/50, 80/20 or whatever?

And I'll – in 30 seconds I'll say although that I think this is a nice start and it's what's in legislation, this should not be, in my opinion, the ultimate model. And I hope that CMS will provide other models that will give more weight to quality and patient experience and will treat income for those – a possibility of generating additional income from those, and also to moving away from the fee-for-service form of payment.

Michael Wroblewski: OK. Gloria.

Gloria Austin: Yes, actually – again, I'm sorry. Hopefully everyone can hear me. I would agree that the incentives are a good, a very good start. And I would not anticipate that this would be the final model at all.

I do feel that it's very critical, though, especially from an FTC standpoint and as we look at groups who are wanting to become ACOs that financial integration is not sufficient in and of itself. Let me try to give some historical perspective.

Those of you who were around when I was around in the 80s and early 90s know that financial integration and managed care actually prompted the formation of many physicians into loosely bound groups.

Financial integration created the conversation. There was a start in terms of what should we do in terms of saving cost. That impetus did not, though, say, did not address to the – to the degree it should have quality and consumer types of issues. That's why we saw a lot of the HMO backlash.

So I would strongly suggest that clinical integration is the first hurdle that's important in terms of playing in an ACO model. And then frankly, the financial integration should get larger and the risk that is borne by any entity should be whatever that group is capable of assuming.

And I'm a proponent of risk and a proponent of global risk but only when it's well-coordinated and when it is also the quality measures and data are actually behind it to ensure that it's actually working.

Michael Wroblewski: OK, thank you. I'm going to turn to Harold Miller and then I'm going to ask the purchasers and the payers to jump in.

Harold Miller: I tend not to agree that shared savings is even a good start, because I think that the way it is defined actually can lead to some very anti-competitive consolidations. And the reason is because that it actually fragments risk depending on how it's defined.

But if shared savings is something that is associated with physicians, which is the way it is done in the Physician Group Practice Demonstration, it means that shared savings are not associated with hospitals.

And if you look to say where are the savings actually going to come from? They are going to come primarily from hospitals. So if you're a hospital, if you're a pure hospital and you look at that you say wow, the physicians – if they can figure out how to reduce hospitalizations, I'm going to lose all the revenue from those hospitalizations and all the sharing of that savings is going to go to the physicians.

So what's the natural reaction of the hospitals? They say I better go buy up those physician practices because it's the only way that I'm going to be able to get a piece of the shared savings or to prevent the savings from occurring in the first place.

And I think that's a very undesirable first step to take in terms of health reform, is to create a system that does that. And it's because there really isn't any opportunity for the physicians and the hospitals to actually negotiate a new deal between themselves under shared savings because the existing payment stays exactly the same and because it associates it solely with what the physicians are doing.

So I think that that needs to be looked at seriously in terms of the potential impact it may have on market structures. And I think you're seeing a lot of that happening around the country right now in anticipation of a payment model like that.

Michael Wroblewski: Thank you. While you were speaking practically everyone raised their hand, so I'm going to turn to the purchasers first. So I'll ask Dr. Galvin and Mary Jo and Betsy and Joe to jump in.

Dr. Robert Galvin: Thank you. And I agree with Harold. I'm very concerned about shared savings as a model and I'm actually very glad that we're having this session today.

And I do like Don's opening comments and your reach out to private sector employers, because obviously this is a CMS kind of regulation, set of regulations, but we know that the delivery system is combined – or is a combined public/private model. And so what happens in terms of safe harbor is what happens for Medicare also impacts, obviously, the private sector.

Two comments, the first is I'm a little bit worried about the entire concept of trying to fit protections into a safe harbor because it's an either/or model. It's if you find – if you meet the right requirements to get a safe harbor, then everything's OK. You can contract as an entity.

The problems we're having as employers where we're seeing most of our price increases actually coming from organizations of either hospitals that have merged or doctors and hospitals, is that a lot of them are doing great things.

A lot of them are – it's an and. They're doing some very good clinical integration things. I mean they're showing some very good improvements in quality and they're asking for and getting price increases of 15 to 18 percent.

So I'm a little worried about the concept that if you can show that there's clinical integration, that that doesn't mean that size and the market structure is going to lead to price increases on the private side that are going to – it's going to make health care unaffordable.

So because I am afraid of size, because I think size is very powerful in pricing in the private sector, it worries me as it does with Harold for much the same reason. That unless there's an upside risk or an upside control it could be, essentially, a lottery.

Why not come together if all there is is good things? If all there is is savings if you do well, but nothing on the negative if you don't and you can always get a 15 percent price increase. I'm worried about that message.

So I think the financial risk is as important on the up side as it is on the downside. I don't see shared savings doing that.

Michael Wroblewski: OK, thank you. Let me turn to Mary Jo and then to Joe.

Mary Jo Condon: Yes, our employers have really similar concerns too, what Dr. Galvin just spoke of. You know, when they then turn to partnerships and other aspects of their business, there's not just up side risk.

There's downside risk. And they don't just have shared savings, they also have sometimes have shared loss. And I think that (inaudible) pay for premium services. Providers (inaudible). And purchasing (inaudible) is only (inaudible) money.

So I think what we need to kind of map out, you know, what is this relationship going to look like both if it succeeds and if it fails?

Michael Wroblewski: OK, thank you. Joe.

Joe Turgeon: Thanks. I actually would agree with several of the comments that were made here, but I think there's a couple of things that we have to keep in mind. Again, if we go back in history and look at managed care needs when there was a lot of sharing of upside and downside risk, there was a lot of failure, more failure than any of us would want to really see in the system.

I think it's really important that if we're going to consider the appropriate financial incentive alignment, that we look at – that we're measuring the right things. One of the big things that we're looking at as we pilot some of these is really looking at the total cost management and trying to work around that.

And you can still do a sharing model around that that isn't necessarily going to put an organization in financial risk. And I think it's important that we don't look to try to get an organization to take on risk that it can't accommodate, so we have to allow groups to grow into that risk, to grow into the ability to handle that risk.

So being able to put some structure around there to address particular concerns about unit cost increase would be a total cost – a total cost type of goal in terms of drastically improving quality and total cost as partners.

Michael Wroblewski: OK, thank you. Dr. Williams, did you have something you wanted to add as well?

Dr. William Williams: I, you know, on the concept of shared savings, our largest contract in our organization is with our hospital. We call it our hospital efficiency contract. And in 2008, 2009 we saved the hospital over $12 million, and 25 percent of that went back to our group. And there's no downside risk, you know, if we don't perform. We just don't get anything.

So this really maintained our group and has actually fired up our group to begin with and actually gave us the physician buy-in that we needed with that

first contract. And we just – we negotiated that contract with (issuers) with similar results, so in stepping back one step, you know, you truly understand clinical integration when you see it.

I've been a patient in our organization for the past year with a hematological malignancy, and I'm very proud of the efficiency and quality of our organization.

Michael Wroblewski: Terry, did you have something? And then I'll turn to Betsy in just a moment.

Dr. Terry Carroll: Yes, I just would like everyone to consider the fact that the market forces are really changing today. You know we do shared savings relationships today in the commercial market. In fact as of 1/1/11, 50 percent of our total revenues will be in some form of shared savings within the commercial market for the system that we have.

And I think the days of getting, you know, 12 and 18 percent rate increases, you know, in some of the relationships we're talking about now over three-year periods, they're actually going from like – starting at three going down to one or so. And that the issues are going more towards can you really deliver on the promise of reducing the total cost of care and driving quality? And I think that, you know, things are changing.

And the second thing that I would say from a market force perspective, these are not things that are going on in isolation at the provider's side or at the payer's side or even at an engagement of the employers. We're now having three-way conversations relative to how that should play out and not just sort of, you know, one-on-one or two-sided environments.

So I think the notion of looking at how the environment and market is really changing and the forces associated with that and the issues of transparency about what performance really is, is really going to drive things in a totally different way than the way you would traditionally look at a shared savings model occurring from the models that we're looking to from today.

Michael Wroblewski: OK, thank you. Betsy and then we're going to go to Dr. Wilson, and then I'm going to change topics slightly.

Elizabeth Gilbertson: Coming back to Dr. Galvin's points about market power, I think we have to be particularly attentive to the circumstances of markets in which there are dominant hospitals, which are likely to be the primary sources of aggregation into ACO kinds of structures. The goal of ACOs are absolutely laudable and to be endorsed.

But the potential to have the market forces create a kind of centrifugal force around hospitals that already have dominant market positions, where the impact of further aggregation and the aggregation of physicians and other kinds of entities, into a single entity around those hospitals.

I think that as the structures that are being contemplated for safe harbors are being evaluated and as the methodologies for evaluating them are being developed, that has to be given very serious consideration, because in the commercial market, that is a terrible threat.

Michael Wroblewski: OK, thank you. Dr. Wilson.

Dr. Cecil Wilson: Thank you, Michael, and I'm going to segue but to get to the answer which is no, but I think I would be …

Michael Wroblewski: I'm not sure which question the answer is answering.

Dr. Cecil Wilson: I would be derelict I think if I did not express my feelings of appreciation for this workshop, and I suspect that others – that everyone else as well for the work you have done, the incredibly supportive comments by Dr. Berwick and Chairman Leibowitz and Inspector General Levinson. I think it's set an excellent tone.

One of the – I think in regard to the – are shared savings worth financial integration? If you're already financially integrated I suspect they are. But the reality is that we're talking about 79 percent of this country are groups – physicians in private practice are in groups of nine or less. The majority of those are in groups solo up to four. I was in solo practice for the last 35 years

and so what we are talking about is are there new models that are not already established?

If the established models were easy, intuitive, they would be covering – they would be blanketing this country. They're not. They're not easy. The people who are where they are in those models worked at it for decades.

So what we're talking about is how can you encourage physicians in small groups to come together who didn't want to be financially integrated to begin with, to do that? And so I would think that that is not a model that – and we'll get to clinical integration shortly.

Just a final observation that, you know, we know cigarette taxes reduce smoking. Well, in the end that's going to – if we are remarkably successful and continue to be successful, that tax will go away.

And I think the concern about shared savings, at some point one would hope one would get at a efficient model the savings would go away. And you would – so that as a long-term goal and as a goal for those who have not already provided this integration of these organizations, I think that would be a challenge.

Michael Wroblewski: OK, thank you. Many of you have mentioned that there should be transparent performance metrics. And so the question that I have is if we can just get maybe some facts out on the table in terms of how either providers measure their own performance or how payers and purchasers, what they look for in terms of what's an appropriate measure for payment?

Dr. Wright I can start with you, if you want to just give a little bit in terms of the effort that you've gone through in terms of defining a high performing cardiology practice.

Dr. Janet Wright: Thank you, Michael. He's asked me to tell you this because we met on a panel, an NCQA panel five or six years ago and at the break we were sharing our elevator speeches about his work at Consumer Union and mine with the American College of Cardiology. I was a member only at that time, not on

the staff. And we literally had just undertaken a new project to define a high quality cardiovascular practice.

It was in response to the health plan arrangements that were measuring doctors on a number of stars and were not revealing their methodology to us. And we just said we can do a better job of this. We do the job. That was five years ago, and our program is just about to be launched. But I entered into that effort with a great deal of naiveté on the simplicity of measuring performance of a physician.

We have made progress. I think the principles and the lessons we've learned is that it needs to be in a number of domains, not overly simplified, continually raising the bar but starting with a bar that is achievable by a number of participants in order to engage them in the process.

And clearly it has to be a transparent process. It has to use measures that are valid and reliable, feasible to collect. And ideally the biggest part of the cylinder of the lock that has allowed us to move forward is the access to electronic medical records and the ability to measure performance in the flow of care in the busy office. So as I said, our program is just launching. I would – I'd love to be able to report good results in another year.

Michael Wroblewski: OK, thank you. Dr. Sacks.

Dr. Lee Sacks: We've been very focused on measurement and transparency in Advocate Physician Partners going back to the early days of our clinical integration program. We issue an annual value report. We post it on the Web site. We share with our payers and with our employers.

But some of the things that we've learned along the way it's very critical that we have one set of measures for all of our contracts so that our physicians aren't schizophrenic and so that you can get a meaningful insight.

Even in our market, where we have a dominant payer with 70 percent of the commercial marketplace, for many specialties they don't have enough data on an individual physician or a practice to draw any conclusions. So we have the same measures across 10 commercial contracts and we look forward to having

that with Medicare and an ACO, which will make it more robust. It's measurement for improvement, as was just said.

We set the bar to stretch all of our clinicians and to move forward, and we continue to raise it every year. It's not for punishment or for differentiating and over time we've seen a consolidation and the underperformers have greatly improved.

And we benchmark and share and try to identify what the secret ingredients are for the top performers and move things along. We've seen it both in small independent practices and in our large employee groups. The key is the collaboration in providing the right infrastructure support.

Michael Wroblewski: Are there consequences if performance measures aren't met?

Dr. Lee Sacks: In our case it's tied to pay for performance, so you leave money on the table. In the early days I said that the pay for performance was the catalyst for clinical integration. It got the reaction started. At this point I think it's self-sustaining. There's a culture of improvement.

We tell the joke or the story that two years ago one of our PHO presidents decided to post exemplary physicians with a picture in the doctor's lounge, and we had a big argument about was it 100 percent of the potential score? What about guys who were 95 because they wanted to be recognized as well?

Over time, though, we've created a minimum threshold. If you score below X, not only do you get zero dollars, you're on probation. And if you don't raise your score the next year you're out of the organization. This year five physicians left the organization because in two years they just didn't get it together.

Michael Wroblewski: And I know I'm backtracking, but what Dr. Sacks just mentioned was in terms of consequences. Should something like that be a part of kind of a clinical integration safe harbor, backtracking to our earlier conversation about how do you get that commitment, that culture of excellence? Dr. Casalino.

Dr. Larry Casalino: Well, yes, I mean I think it is part of what the FTC looks at, and I think in my experience the FTC looks very carefully to see if an organization that claims to be clinically integrated has a graded plan of dealing with physicians who aren't performing well. So if you're not, you get – you get to talk to somebody about it. And if you're still not, there's a little more severe talk and eventually it's expulsion from the organization. So I think it's there now.

I do want to say very briefly about performance measurement because I don't think this is said enough. To me one of the most attractive things about the ACO concept is that ACO should be large enough so that you can actually have some robust performance measures. But let's face it, the performance measures we have now they're better than nothing, but they're pretty dinky, and they can have a lot of unintended consequences.

I tried – I had a piece in "The New England Journal" a few years ago from my own personal experience. In practice, you know, you can be sitting there going mammogram, check, ordered hemoglobin A1c, check – this check, that check and admit the fact that the patient has just in a very vague way told you that they probably have severe coronary artery disease that hasn't been diagnosed.

So I think we want to get to more robust measures and ACOs should allow us to do that. Look at things like – not at unit cost, but at total cost of care for the population of patients. Look at admissions, look at re-admissions, and I'm sure other people can think of other things, so that to me is where the – where payers and the enforcement agencies should be looking.

And I hope that we won't have ACOs and still continue with our performance metrics being did you order a hemoglobin A1c or not?

Michael Wroblewski: OK, thank you. Dr. Safran and then I'll go to Doug.

Dr. Dana Safran: On the matter of whether there may be the floor below it, you know, you – questions get asked or you're at a (BACO). I would favor an approach where the performance measures really are the basis for financial benefits in the model, and that's the model that we have with the AQC.

That is to say, the negotiated rates have increased for the organization from year-to-year are very slim and so the way to make money and do well financially in this model is to address both the quality incentives that are on the top and the incentives around managing the budget that are baked into the global budget model.

So I'd say there's really, you know, in general there is national consensus that there's three broad areas of performance measures we should be paying attention to. The clinical process include – or clinical measures, including process and outcome measures, patient experience measures and cost and efficiency measures. I think we need a balance of all of those.

I think to the extent that we have measures that emphasize primary care and ambulatory care, we guard against some of the concerns for hospitals becoming kind of the home of the ACO. When in fact some of the benefit that we have realized in our AQC model, and I think is what the ACO developers had in mind, is kind of right-sizing the pyramid so that primary care really is the hub and the whole basis for the model.

And hospitals and specialist in a sense become, I hate to say it, but vendors of their services and have to prove their worth both in terms of the quality they can provide at the cost for which they can provide it to the primary care clinicians, who are becoming the careful stewards of resources and accountable for the quality and outcomes of their patient population.

Michael Wroblewski: OK, thank you. Doug.

Doug Hastings: You know, I was just going to say that I do think consequences are going to be – need to be part of the equation, both for individuals in accountable care organizations and over time for accountable care organizations.

I think that CMS, as the program evolves, will be able to provide some helpful guidance in this regard in working with the agencies. Can look to not only where organizations should start, whether it's a safe harbor or a presumption, but where they should be moving over time.

And I would just say that given that, which is what I think we ought to be able to do and should be done, again, I think probably there'd widespread agreement that you don't want to end with shared savings, that other forms of payment reform are the longer range goal.

But I wouldn't be as dismissive as some about the ability to start there, have some teeth in the program, get more organizations in play moving down the road with progressive requirements over time as a worthwhile goal.

Michael Wroblewski: OK, thank you. Let me turn to John – actually Dr. Galvin, John and Mary Jo. We'll go in that order, and then I'm going to change topics.

Dr. Robert Galvin: Yes. I would – look, I think that kind of enforcements and these kinds of consequences are important, but we have to be realistic. If we have a payment model where organizations are largely dependent on margins from a few kinds of specialists, it is a couple of organizations that are I think mature enough, kind of, to take that on.

But I think we ought not to be naive that what looks on a piece of paper like, kind of, consequences is really de facto consequences because I think no one is going to commit economic suicide and no matter, kind of, how much they want to.

And I also – it makes me go back earlier to say, you know, the model again was that it's kind of – it's really – it's bad apples that kind of lead to some of, kind of, the price increases. And I don't think it's bad apples. I think it's completely logical economic behavior, and that's why they co-exist.

People are doing very good things clinically, who for whatever reasons inside the organization or public payment levels or whatever is happening essentially say no margin, no mission and do what they do. So I just think we ought to, kind of, not be naive about what is really going to be driving behaviors in, kind of, the current payment system.

Last thing and then I will give it up and Doug and I have disagreed, agreeably about this over and over. I don't think that a broad public policy that says

everybody should be in an ACO and let's find ways to lower the bar enough is supported by the evidence.

I think enthusiasm is so outstripping evidence in that I think you can have small practices, you can have medical homes, there are many experiments going on. And so I'm concerned about national policy that encourages the development of these kind of structures when we haven't figured out kind of the unintended but predictable consequences of size.

Michael Wroblewski: OK, thank you. John?

John Friend: Yes, as a hospital representative, I thought it was important to chime in on this. And I think that there is a good deal of concern over the role of the hospital and we've probably taken a unique position that's based upon two, three year's worth of validation and really doing both critical and prospective analysis.

But we've come to a position of comfort in our business planning where we think shared savings as a transformational tool makes good sense. And we're not on a physician acquisition mode. We're in fact looking at the ACO as a possible counter to that in our marketplace.

So we seek independence for those physicians who seek to maintain independence. The hospital appreciates its position as a significant cost center and believes if it doesn't compete effectively even within the ACO then it won't succeed. It'll be chosen against.

I think it's important though that we not – and I know there's a good deal of attention being paid to this on a national or a large system point of view. But there are smaller, and we're relatively large in our market, which is a highly competitive market, but we're not a large enterprise.

Within our market a shared savings ACO model adopted by really forward-thinking providers, both physicians and hospitals I think can and does – we intend to prove that it does make sense. I would echo, too, that when I used the word guidance earlier, we really mean that.

I think we find a good deal of evidence in FTC's, you know, history that leads us to the right place. There are certain things I would ask for, certain gets to, you know, provide further clarification. But by and large we don't feel as though we're in the wilderness trying to find the rules at the side of the road.

So I, too, would caution anything that's highly prescriptive, anything that attempts to classify appropriately. But speaking for at least one hospital out there, we think we found an appropriate place within an ACO. And from that we're seeing a lot of really positive conduct and intention.

Michael Wroblewski: OK. Mary Jo?

Mary Jo Condon: I just want to go back to the point about transparency for a minute. I think that we need to not have a safe harbor that kind of checks the transparency box by asking hospitals and physicians to report on a few select measures and therefore they are transparent.

I think we need more of the kinds of all payer databases that Minnesota has. Our organization also facilitates a multi-stakeholder claims database, Regional Quality Improvement initiative. And I think that really by bringing everyone in the community together looking at the same information, developing an understanding of where we need to go as a community, that's when we'll start to have the dialogue that's necessary to really improve care long term.

Michael Wroblewski: If we were to move to an approach in which we looked at these performance metrics in the domains that Dr. Wright and Dr. Safran laid out, and in the course of you know how many years should we be looking at before we should expect to see I think what Dr. Casalino referred to as they're kind of skimpy right now before they are more robust.

So that if in the interim there are actual price increases for individual services what should we do in the interim? OK, it's always scary when the people put the cards down, but I'll turn to – I'll turn to Harold Miller.

Harold Miller: Well, I think there are some opportunities, major opportunities in health care right now where both quality and cost intersect and where significant savings can be achieved in the short run.

I think hospital readmissions and the broader category of preventable hospital admissions, ambulatory care sensitive admissions is a key area where if we can keep patients, help them manage their chronic disease well enough that they do not get admitted to the hospital. And Don Berwick's story of the asthmatic child was a perfect example of that.

Nobody was denying the child care. They were giving better care that it ended up reducing cost. And with appropriate systems in place and support, that can achieve savings very quickly, particularly when we're talking about things like 30-day readmissions, which are for the Medicare population 20 to 25 percent.

And many programs, I've helped implement one in Pittsburgh working with physicians and hospitals that can achieve 40 percent reductions in hospital readmissions. A tremendous savings and it's good for the patient.

So and I think part of the problem is that we have had a lot of focus on quality measures that have been at the other end of the spectrum. Not that they're undesirable. They're focused on prevention but the impacts of those are very long term. I think they're going to be very important as we try to move towards more global payment structures.

But I think that trying to focus in the shorter run on the things that can save money now and be good for patients would be a very desirable area of focus.

Michael Wroblewski: OK, Betsy, did you have your card up?

Elizabeth Gilbertson: Yes. I think it's really imperative for the success of the common enterprise that we're trying to discuss here to achieve public transparency with respect to both total cost, total quality and patient experience.

I think we've struggled – there's quite – there's substantial, what I think of as fairly glib reference to measurement in all of these conversations as if we had the measures that we need and the processes that we need to move the measurement needle are moving along at the fastest pace they possibly can.

Well, I don't think that's true. I think that measurement could accelerate. And that requires – I hope that the ACO direction that the legislation promotes will have the effect of also accelerating the progress on giving us the kind of measures we really need, because if we're trying to figure out how to create incentives across all levels of organizations, we have to have to have measures that can measure across all levels of organizations.

So that we don't end up with one set of providers or, you know, one entity disadvantaged relative to others. They need to be equally incentivized to pull together. And so I hope that the folks who are trying to work on the – in the measurement arena will take this to heart.

And I think that no matter what kind of measures we have on clinical quality and patient experience, if we don't have equally rigorous and publicly available measures with respect to cost, I think we're all going to be in terrible trouble.

Michael Wroblewski: OK, thanks. I'm going to start with Dr. Safran and then I'm just going to come down this row and then I'm going to have some concluding questions.

Dr. Dana Safran: The three points that I'd make. One is that I think …

Michael Wroblewski: Can you grab the microphone?

Dr. Dana Safran: … oh, sorry. So three points that I would make, the first is that the types of cost measures that Harold was talking about are critical to the system. But what I don't want to have lost on us is that if we do move, as I think this panel has broadly been recommending, to something that goes beyond just shared savings to something is off of fee-for-service onto something around global budgets, then cost and efficiency measures take a different place in the system.

They're absolutely essential but they're not something that's being used to reward because the global budget in itself is the incentive to create those efficiencies. And so that information about 30-day readmissions and non-urgent use of the E.D. and total medical expense are critical to helping the

organization manage to that incentive around the global budget but they are not something used for the reward.

The second point is that in the context of those, as I think Betsy was pointing out and I was trying to emphasize earlier, you must have the balance of also including the patient experience in clinical quality and outcome measures.

Because without that while it's an admittedly an important goal to reduce 30-day readmissions, there are ways to do that that could be harmful to patients. And we need to guard against that with the right balance of outcome and patient experience measures.

And the third piece to your question about you know how do we get from here to there in what today what might be considered a fairly skimpy set of measures, I think one of the largest gaps that we have in measures broadly speaking is measures for accountability in specialty care particularly around outcomes.

And I know of no quicker way to stimulate the development and validation of that area of measurement then to have accountability for a performance on measures really be the basis for judgment and for revenue in the system.

So if the way that you're going to get business is – and the way that you're going to increase your margin is by demonstrating higher quality and better outcomes for your patients, what we've seen is specialists in our market starting to say how do we get some of that measurement for us that primary care seems to have in such abundance for it?

Michael Wroblewski: OK, thank you. Joe?

Joe Turgeon: Yes I think a couple points …

Michael Wroblewski: Will you pull the microphone a little closer?

Joe Turgeon: I do think it's absolutely critical that we start looking at ways to aggregate data. I think, again, there was some reference to that fact that we need, you know, whether it's multi-payer or aggregated data across an organization to

look at total performance. I think that's going to be something that we have to invest in and get to.

I think the other part is that when we look at ACOs, we do need to understand there is going to be a timeline. You had asked the question what is the timeline? I don't know that there's a particular timeline but I will tell you it's not generally in year one.

In the experiments that we've done and the things that we've seen so far, it usually takes several years to really achieve the benefits of integration, especially for a group that's newly integrated, obviously when it's been existing for a while not so much an issue.

And I think it's important that we – that in that period where you're learning how to integrate that there is some general containment on the unit cost increase side of things probably by looking at a total cost measure on an ongoing basis.

Michael Wroblewski: OK, thank you. Dr. Williams.

Dr. William Williams: Yes. Going back to the issue of metrics and I mean, you know, what an organization needs to do to go from year one and going forward. In our organization we started out with around 80 metrics. We're currently running over 100 metrics right now, not all physicians are required for all of those, but they're by specialties for the most part. Some of the metrics, roughly 15 of those are for the entire organization, but the rest are by specialty.

And we found that moving forward that by having committees of individual physicians by specialty reviewing the metrics that we're following every year and making recommendations to the board and the metrics committee on what metrics to follow forward, that by the physicians picking out their own metrics, which are usually part of a nationally recognized bundle of metrics, that they tend to follow those better because they know the metrics that are necessary for their own specialty.

And that's what we found out in the past year when we've only been organized since roughly 2006. So it's taken us four years now to finally recognize what hopefully we need to be going forward.

Michael Wroblewski: OK, thank you. Dr. Wilson?

Dr. Cecil Wilson: I think to the question of what is the time that the legislation does provide help there and, and it's three years. I think the question then is whether you look at it in three years and I think the answer to when all do we start seeing changes, we don't know.

And so I think that would mean that one should not set – start setting targets for that three-year look because we don't know what – how fast we'll get there. Or in fact we don't know what the targets will be. And as a matter of fact it's probably going to have to be a rolling kind of a target since different ACOs will be formed at different times and coming aboard at different times.

So it may not be the start of the program. It may be the start of the ACO. The other thing I did want to pile on, if you will, related to performance measures and the evidence. The reality is that – the reason for a lot of the variation in care around this country is that even evidence-based medicine is still fairly rudimentary.

If you look at the level of scientific evidence around the things we do as physicians, those that get an A rate are sort of a minority and there's a B and a C. And so there's still a lot of art to the art in practice of medicine. And so some of that variation is going – a lot of that variation is going to improve when we have the science to back that up.

To that end for the last 10 years the AMA has been convening the Physician Consortium for Performance Improvement, which now includes some 140 organizations, almost all of the special societies and have been developing performance measures, now approaching 300 performance measures in some 40-plus clinical processes.

And starting last year started focusing those measures around potentially overused kinds of procedures to reflect the concern revolving around cost.

And at the same time is developing those measures or modifying those measures in order that they can be in the electronic health record so that as we move down that path then the physician at the point of contact, at the time of seeing the patient has the evidence.

And I can tell you physicians get up in the morning, want to go out and do good. I mean that's what physicians do. And I can tell you also that if physicians are provided information which they believe – that they believe is scientifically appropriate they will do that. And I think that's where we have to be for all this to work.

Michael Wroblewski: OK, thank you. Dr. Wright?

Dr. Janet Wright: I also wanted to just speak a moment about performance measures, but probably from an anecdote standpoint because I think what we are trying to design here, again, a system of care that really is patient-centered.

And in some of the work we've done with many other organizations around Door-to-Balloon time trying to tighten up that time between the onset of a heart attack and treatment. We actually got one really profound story where a team at a hospital learning those six strategies that have been proven to work were implementing those strategies.

And they decided that the best way to track the time from the onset of the patient's chest pain or really the arrival of the patient at the door to the cath lab was to take a big stopwatch and put it on a rope around the patient's neck.

And this thing was ticking during the emergency room visit and whisking down the hall to the cath lab and on to the cath lab table and everybody was watching the clock, not watching really the patient's face but watching – and I'm not slamming them, they were trying to do the right – people with good intentions trying to do the right thing. But at some point someone realized the patient was asking a question and what he said is, "What happens when this goes off?"

So I don't want us to lose that patients should help inform our performance measures and then that learning idea of sharing that story with you all, and

again with us. The other thing I would say is that where we're learning a lot is around the idea of appropriate use of technology and interventions.

And this idea for me to progress from a guideline of a wonderful doorstop if you will to something that combines the quality of care and the evidence and the science with the cost implications, so appropriate use is about when is it appropriate or inappropriate to use a certain technology. And when do we have a gap or we have uncertainty about that?

So that helps focus our research agenda on the uncertain areas, stay away from the inappropriate and do the appropriate. We don't have those criteria for all kinds of cardiovascular stuff, but I think that's a place where just like the readmission issue we can start to focus in both of those elements.

Michael Wroblewski: Thank you. This discussion, we're going to have to cut it off in just a – I'm going to ask one last question and then we'll take maybe a seven-minute break. We've been talking about quality. And the question that I have for the purchasers and the payers, we've been talking about measuring quality for Medicare.

And my question is whether that transfers into the commercial side so that if measures or performance is at a certain level for Medicare enrollees and that entity, that ACO is using – is it reasonable to say that that would be the same level of performance on the commercial side if it's using the same ACO, same processes, organizational structure?

Let me turn to the payers first, so I'm going to turn to Mary Jo, and I'll come down. I'll do Mary Jo, Dr. Galvin, Dr. Safran and then Joe Turgeon.

Mary Jo Condon: You know, I think it would be great if it could be that easy, but unfortunately or fortunately there's a lot of care that patients in the commercial population receive that patients in the Medicare population never receive. Pregnancy is just one example. Pediatrics is another example.

There's also differences in the amount of care for certain conditions that folks in Medicare receive versus patients in the commercial population. Our organization has used Medicare data for years and years to try to get some

sense of cost and quality. And over time, particularly recently it's become more sophisticated obviously. But there are still so many things that are of great interest to our employers that we can't tell them anything about.

Michael Wroblewski: OK, thank you. Dr. Galvin? Yes. Yes.

Dr. Robert Galvin: Yes, I – look I think we all want to move to uniform quality measures and I would actually say the same thing but have a different tone to it. It's kind of other than, you know, kind of babies and kids, sure clinical measures are pretty similar across the two.

I mean obviously pregnancies and pediatrics aren't. There are differences in families, et cetera. But I think that actually you know go back to what Larry said, at the level our measures exist today, to me the least of our problems is that they're not the same between Medicare and a commercial population other than those two exceptions. It's that they're not robust for either population from an outcomes point of view.

Michael Wroblewski: OK, thank you. Dr. Safran?

Dr. Dana Safran: So agree completely with Dr. Galvin that where we're moving is uniform measures, you know, and to the extent that we can do that it will benefit clinical care, those providing it. It'll benefit patients, those receiving it. It'll benefit the payers, both public and private.

To your question of whether we could expect the same level of performance on those measures for Medicare versus commercial, I would say that it depends on the kind of measure, that particularly as we move to outcome measures it will be more difficult to have the same level of performance. With clinical process measures, the kinds of checking a box that folks have talked about, you can probably expect relatively similar performance.

But as we move to outcome measures all kinds of issues around differences in the complexity of the patients being taken care of as well as difficulties in getting those patients to manage what they need to manage outside of the clinical practice to achieve those outcomes, I think, will have us for quite

some time having different levels of performance achieved on those measures for different populations.

But the thing that I think is very important to underscore is that the same systems, the same clinical systems and workflows and creative process to outreach to patients and engage them are needed and will benefit all of those populations.

So having alignment on the measures will lead to the alignment in the systems and have the practice sort of all rolling in the same direction for all their patients, not necessarily getting to the same endpoint for all their patients.

Michael Wroblewski: OK, thank you. This concludes the first panel. We're going to take a break until 11:15 and then we'll start up again. Thank you.

Susan DeSanti: OK. I'd like to invite our panelists to please come up and start assembling now so that we can start again.

Susan DeSanti: We almost (have a quorum) so we're going to start. My name is Susan DeSanti. I'm director of Policy Planning at the Federal Trade Commission, and I'm going to be moderating this panel along with my colleague, who unfortunately has no chair, but Joe Farrell, who is the director of the Bureau of Economics at the FTC.

Joe Farrell: They say sitting is bad for you anyway.

Susan DeSanti: To begin, I'd like to introduce Trudy Trysla who has joined us down at the end of the panel, who is taking the place of Terry Carroll as a representative of Fairview Health Services. Trudy is a peer-recognized health care expert with over 18 years of experience in providing legal counsel and policy advice to hospitals, physicians, management and policy committees.

Prior to joining Fairview in 2008, she served as legal counsel for the Mayo Foundation where she served on numerous hospital and other institutional committees. So we're going to begin this panel, which is about exploring ways to encourage the formation of multiple ACOs that can compete with each other in particular geographic areas.

Now, we recognize competing ACOs may not be possible in all areas, but to the extent that they are, from an antitrust perspective we'd like to encourage their formation. And I want to be clear as with the prior panel, we're not just talking about the CMS market, but we're also talking about how is this going to work in the private market because we have certainly heard many times that most ACOs will plan to operate in both.

Now, this topic connects with possible safe harbors for market share that the antitrust agencies are considering, and I emphasize considering. No decisions have been made. We're having these panels today in part to get inputs to see how we might be able to do this.

Now, as you all know, there already are some safe harbors in the current FTC DOJ health care statements and we're interested in your thoughts on how – whether the agencies should establish some market share safe harbors that would be particular for ACOs and if so what they might be? And how should we go about assessing market power in the markets in which ACOs compete?

So I want to start off this panel by asking a basic question, which some of you have touched on in your response to this already in the first panel today. And that question is how large does an ACO need to be to deliver care effectively? I think what I heard from some was that there are small groups of even one to five providers who are already operating as ACOs. And I'm interested in exploring the notion farther.

So I'd like to start with Dr. Williams. I'd like to start with you. Now, your integrated health delivery system serves about 20,000 patients and does have electronic health records. How do you find that size? Is that successful for you, and what would you think about the possibility of operating a smaller size?

Dr. William Williams: I think that the size of the organization that we have now with our patient population is roughly approaching probably 2-1/2 million in population, is a size that's being currently divided up between our essentially ACO, since we are a clinically integrated program, and across the street the county hospital is also trying to form their own ACO.

And you know certain physicians from our ACO are going to be on their panel and physicians from their hospital organization are going to be on our panel. So, you know, the competition is already going to be there, but I don't see it as a negative impact.

I see it as more of a positive impact. I think competition is actually good, you know. But as far as the size of these organizations I think with our current 300 physicians we're handling that population fairly well in our organization.

Susan DeSanti: OK, thank you. Dr. Safran?

Dr. Dana Safran: Thanks, Susan. I think one important thing to clarify if it was my comments that you were referencing about the one to five, practices of one to five is I didn't mean to imply that they are functioning just themselves as an ACO or in our AQC contract.

What I was describing was that many of the organizations that are in the AQC and that are being highly successful in the AQC are doing so with a model that has brought together many, many practices that are small so hundreds of physicians, who in a bricks and mortar sense practice in a solo or very small practice. But through the infrastructure that's been created are succeeding and with that leadership and so forth are succeeding.

So our view has been more around patient size that's needed for adequate measurement, both in terms of budgeting in a way that we can count on as a good number that isn't just a noisy number form one year to the next. And also the performance measurement around which we have substantial dollars attached.

So we look at sort of how small is too small on the basis of the population being cared for, but the issue of aggregating up small practices is one that I think is very important and relevant because I think none of us imagined a health care delivery system that, you know, some years from now just has all multi-specialty groups.

And as Dr. Wilson pointed out, you know, 75 to 80 percent of physicians in the country are practicing in a bricks and mortar sense in a solo or small practice setting. So how do we get –how do we use that infrastructure to get accountable care? And I think the answer is we can – we can do that.

Susan DeSanti: OK. Dr. Sacks?

Dr. Lee Sacks: Yes, I don't think that there's a hard and fast rule, but one, we feel very strongly that scale creates value in terms of leveraging infrastructure, intellectual property, governance sufficiency and management expertise. And you know, in my organization with 3,500 physicians, 2,600 are in small practices of, you know, one to five. There are 900 separate offices.

We surround them with infrastructure, and if you go backwards $25 million administrative budget, 25 FTEs just focused on clinical integration. You can't put a quarter of an FTE in a practice and expect to get the kind of results or make the investment in the information technology that we're committed to do now. So while, you know, different size markets are going to have different cut points in our large metro market, we feel there's real value with that type of scale.

The other thing that we bring is we have every specialty that serves our patients' needs within the network. And it truly takes a team to be able to successfully manage chronic disease and the conditions that are really driving the health care trends. And having everybody on the same team makes it much more likely that you can be successful.

Susan DeSanti: Mr. Miller?

Harold Miller: You know, I think the real answer is we don't know and it depends. And we don't know because we have not really been fostering the whole variety of models that could potentially exist to be able to see what works. And it depends a lot on the patient population. So when we say 5,000 patients what kind of patients are we talking about?

If they are young, healthy patients it is very difficult to get any kind of reasonable measurement on them because a single event can really throw off –

or a single patient can really throw off the numbers dramatically. If you're talking about a highly complex patient, it's a very different thing. So Medicare population is different than the commercial population.

But I think the other thing is sort of why – there's only two real reasons why the number counts. One is, as Dana said, measurement because we need to have reliable measures. The other is an adequate level of infrastructure, which is what Lee raised.

And there are certain economies of scale that are achieved. You can't – you could hire a nurse care manager to help you manage your chronic disease patients, but a single physician may not have enough of those patients to be able to do it.

Now, I think what we have probably been seeing around the country is larger than necessary because we have made it very difficult for people to coordinate. We have fragmented payment systems, payers, different kinds of quality initiatives and incredible degrees of administrative overhead that people have to put in place to be able to do this.

So you need more physicians and more patients to be able to recoup a lot of those costs than you might be under a more aligned payment system and a more efficient payment structure that gives more flexibility for the providers.

So I think the issue is that we should be looking to see what is the absolute minimum in terms of measurement for the particular patient population in place? Leave it up to the providers to think about what kind of minimum level they need to be able to put the minimum infrastructure in place.

And then we should also be balancing that number against what it means in terms of market concentration in the community. And so all the discussions about the number of patients have been completely one-sided so there's a natural tendency, well, more would be better because yes, if we get more we'll have even more accurate measurement and we'll have a better ability to get lower cost infrastructure.

But we need to balance that against, well, and exactly what is 5,000 or 20,000 or 50,000 patients doing in terms of saying you're the only provider in that community because you can only have one entity because that's all the patients there are.

So I think we should be thinking about this as a two dimensional problem. How many patients do we need on the quality and cost side and how many do we need on the market concentration side to figure out what's the right balance between those two?

Susan DeSanti: Thank you. I'm going to go back to Dr. Sacks because I thought I understood you earlier to talk about a time when you did not have electronic health records. And one of the key questions here of course is, what's the level of investment that's going to be required to become an ACO that meets the eligibility criteria?

And electronic health records involve a significant investment. So I was wondering if you could just let us know how that worked and what your path was to bringing in electronic health records?

Dr. Lee Sacks: OK. Well, we made a conscious decision, you know, 2002, 2003 that we weren't ready for an electronic record both in terms of the ability to invest and implement and that the products couldn't meet our needs. We focused on disease registries to manage the population and even that was an evolution.

We started with pen and paper. We moved to homemade Excel spreadsheets and now we have a commercial-based Web product. In 2004 was a watershed year that we made a membership requirement that all of our physicians needed to have high speed Internet access in their office. This is metropolitan Chicago and it wasn't, what, seven years ago, 25 percent of our physicians met the requirement on day one.

By the end of the year 150 physicians left the organization because they chose not to have high speed Internet access, all kinds of excuses. I use my kid's computer at home. I go to the library. I do it in the hospital. You need it at the point of care. And since then we've built on top of that with our disease

registry, our database. We have all of our physician's claims. We have our PBM data into the registry.

We moved to e-prescribing for an electronic medical record. That was kind of a test for our independent physicians and the challenges of managing the changing workflow and preparing them.

And then with the federal stimulus bill we saw that as an opportunity, and along with $15,000 per physician incentive from our organization and the potential from the stimulus package we put together a program that will allow all of our physicians to be on electronic record that'll be paid for the first five years.

So they'll go through the pain and suffering and have a chance to see the value before they have to write a check. So we're early in that implementation. It's a real challenge and, you know, we've added 25 FTEs on top of our vendor just to make sure that our small physician practices can come up successfully.

Susan DeSanti: Thank you very much. Dr. Williams?

Dr. William Williams: And we're having a similar experience to Dr. Sacks' in our organization. We found out when we first started with was roughly 25 percent of the physicians actually met the qualifications to come up to high speed Internet access, but luckily we had a better response. We only lost two physicians in the first year with the rest of them came around.

We're currently – all of our employee positions, which is roughly half of our organization currently have electronic medical records and we're using our hospital efficiency contract, which I'd mentioned earlier, to use that monies to expand electronic medical records into the independent physician's office that don't currently have electronic medical records.

And we figure by the end of 2011, hopefully 100 percent of our physicians will have electronic medical records by then.

Susan DeSanti: OK. Dr. Wilson?

Dr. Cecil Wilson: Thank you. I wanted to just on the issue of the size, you know, the law says 5,000 patients, and we will see whether that works when we get there. But I just wanted to raise the issue of geography.

I mean, in large areas you may have a luxury of saying what's the ideal size? And you could actually have several of them, ACOs, and in rural areas you may find it difficult to get one within a several county radius. So I think that's one of the challenges.

The AMA does believe that good medical practice is going to benefit from the electronic health records aside from ACOs. And we're supportive of physicians doing that. We've developed a Web site that – a portal that provides physicians those options.

But the challenge is the cost. The fact that only 15 percent of the cost that a physician has to upfront for that record or that system comes back to the physician. The 85 percent benefits other parties, the payers, the insurers. Now, the Recovery Act will help with that, but it's really just a start.

The other challenge has to do with workflow. Now, when I tell you that when my hospital went to electronic health record it took – it took me twice as long, literally, to make rounds as it did before. You'll look at my hair and say, well, you know, there are others who could probably do it faster. But there will be that transition.

And when you look at a physician putting it in his or her office and the workflow reduction, income reduction, at a time when annually, Medicare is threatening to cut payments. This January 1, 30 percent of Congress does not do anything.

It does make a challenge of getting to where we want to be, where we think we ought to be, where we think will be good for medicine. It makes us a challenge that we're going to have to work through.

Susan DeSanti: OK, I'm going to go to this end of the table and start with Gloria and then Dr. Casalino. And then I'm going to change the topic.

Gloria Austin: OK, so we're obviously still on size, I think the most – as most individuals have indicated these are two critical aspects and that's having size enough for infrastructure and also for measurement.

But none of us have said much about the patient-centered medical home as it applies to size. And let me talk a little bit about that because most of us know that to care appropriately for a Medicare population, a physician might have a panel of 500 depending upon severity that might change.

In a commercial population, it may be 2,000 to 3,500 depending. But in terms of at patient-centered medical home what we want to look at and I think what we all should be looking at is what's the size of those particular entities because they ought to roll up to the ACO?

What is team-based care? What does it look like? What should the population in that type of a care setting look like? What's efficient? And in work I've done in staff model medical centers years and years ago generally, that number was 10,000, around 10,000. That doesn't mean that that should be the minimum in this setting. But generally, that was about 10,000.

I think one other thing that I would say that we haven't commented on here is that this should be primary care-driven. ACOs should be primary care driven. We're an overspecialized country, and we've got to – we've got to face up to that point and so, it's just something I want to interject while we're speaking.

Susan DeSanti: Thank you, Dr. Casalino.

Dr. Larry Casalino: Yes, I think in terms of size, I think that really there's three issues, two have been mentioned. One is how big do you have to be to get the kind of performance measurement you want?

So you can't measure readmissions reliably for a five-physician practice, right. And you can't measure them reliably for 5,000 commercial patients. I don't know if you can do it reliably for 5,000 Medicare patients, probably not, right? So one is how big do you have to be to get performance measures?

And the other is – that's been mentioned is infrastructure. So it's one thing to have every physician have an EHR and that will happen in not that many years, I'm pretty sure. But the question is what do you do with those EHRs?

You need an organization that's big enough that it can hire people whose full-time job is to think how do we improve? How do we achieve the Triple Aim? You know, how do we improve care for our population to patients? And you need some scale to do that. A two-physician practice can't hire a nurse care manager. You just don't have enough scale.

The third issue which hasn't been mentioned is risk. So this isn't so much of an issue with shared savings but if you want to move to a more – move into more of a global payment kind of thing, then I think you certainly need more patients. And I'm not sure that anybody knows how much a patients that is. I've seen wildly varying numbers.

Now, just to finish I will say, now, so I was in a small practice for 20 years. We were two to nine physicians in that time, and I'm very aware of the advantages of it and the disadvantages of it.

And I really value that setting. I think a lot of physicians and patients do but really I think one of the critical questions going forward will be can the kind of networks, that Dana mentioned, IPA, PHO kind of networks, can they really transform care with these lots and lots of small practices in a way that can really match what a large, multi-specialty group will do or even a bunch of hospital employed positions?

I think that's an empirical question going forward. And one thing for policymakers whether it be CMS or I know just FTC just wants to enforce the law and not make policy but there's lots of gray areas, and FTC decisions do have policy effects. So I think going forward I would encourage with each decision something – will it – will bias the direction of the system one way or another?

So for example, if it's really, really hard from an antitrust point of view, for example, or from a CMS point of view to form a network of practices, then I can pretty much guarantee you that in 10 years we'll have a system that's

primarily hospital employed physicians. And then, you know, some large, multi-specialty groups that are able to make it and be independent of hospitals.

Susan DeSanti: Well, this is one of the reasons we're having this panel to raise precisely those kinds of issues, the trade off. And what I'd like to move on to now is a combination of to what extent are payers and purchasers finding current problems with market power that you feel is being exercised?

And also what are your hopes and concerns about how markets will develop that have ACOs in them. And I think Dr. Casalino has already raised one of the concerns. But there may be others and so I'd like to start with you, Bob Galvin, from a payer perspective.

Dr. Robert Galvin: Yes, and thank you. I think that you wouldn't talk to an employer or most health insurers that wouldn't tell you that they're not having, kind of, issues in markets with provider dominance and pricing.

I would hasten to add that markets are very, very different. I actually completely believe there are markets where there's one or two percent increases as was mentioned earlier, that they're very different geographically. They're very different whether they're metro or rural, et cetera.

And the other thing I want to add is they can be very different in different parts of the town. So you can have the north side, the west side and the south side, all kind of carved up. And you would think, you know, as a whole, it looks like there's lots of competitors in the market but that's not how people migrate for their care.

So I think we have an issue with – we perceive anyway, or our, kind of, our pricing information shows there's just different kinds of issues. One are hospitals where hospital pricing is dominating price increases over the past several years. So that's 70 percent. It takes about a 70 percent share of the actual increase is hospital pricing.

And I mentioned earlier, those are in many, many cases the same hospitals. They're simultaneously integrating and actually doing some very good things on the quality side. But they have a pricing issue.

It can be a dominant specialty group. So you can have on the north shore of a town or the west side of a town kind of a very dominant cardiology group where I think when the law has been applied or attempted to have been applied, it actually looked like patients were willing to go far – more distance than they actually do in terms of defining the market.

And we actually have one, believe it or not, that is completed dominated by a primary care practice on the southeastern coast. That's a new one. But we actually don't have anyone else to contract with.

So I think I always – I discuss this so often with providers and I think, you know, it's the different part of the (Alavent) story. They see dominant health plans and that they organized to kind of deal with that. And I think we kind of payers see dominant providers, and we're both right of course.

But right now I think what we see and I referenced it to someone earlier who mentioned that their system was doing well and they had gotten an upside, I think it was a $12 million savings, you know, from the hospital. They shared it with the doctors, which I thought was great. And then basically it was, you know, and then if we don't do well, well we don't make any extra money, right?

What happens is prices get increased. They don't get increased to Medicare. They get increased through insurers to employers. And so we would say that things are getting worse. We have data at my prior employer which is just one employer but very, very large, billions of dollars of spending.

Where we found really across the country we were having problems with prices far in excess of anything else in their supply chain, not to mention the growth of the country. These were double digit increases. So it is kind of an issue. It isn't as simple as just hospitals. It is kind of textured in the ways that I mentioned.

Susan DeSanti: Thank you. Ms. Condon.

Mary Jo Condon: Yes, so kind of tying this back to the issue of minimum size, you know, I think it's important to note that having a lot of players is not always equivalent to having adequate competition.

And that in fact sometimes when we have a few really strong players they can compete more effectively with each other than if we have one really dominant force or maybe even two, and then a lot of weak players around them that are kind of you know dividing up the scraps, so just kind of something else to think about as we think about the right policy here.

Susan DeSanti: Thank you. Dr. Safran.

Dr. Dana Safran: So now what we're talking about are the market risks of the ACO. It's what I'd like to speak to a little bit is some of the market benefits that we've experienced by having introduced this ACO model that I've been talking about.

So keeping in mind that that's a model that uses a global budget, that has a five-year deal where the rates of increase are pre-negotiated and basically working their way down to CPI over that five-year period, and that there's accountability for a broad set of quality and outcome measures.

Here are the – I'd say five things that we've seen that are – I would say are important market benefits. One is we have had enormous momentum away from fee-per-service into this global budget model.

I mentioned before 25 percent of our network is in this model after, you know, having just launched it January 1st of 2009. That's more than twice what we expected and I think by the end of the year we'll be much higher than even that 25 percent.

So really it has accelerated our ability to move away from a model that incentivizes just producing more services as complex as possible to the model that we're trying to talk about today. We've got providers engaged in a very meaningful way and being careful stewards of resources.

And, you know, just one illustration of that for example is that one of our AQC organizations, which has had a 25-year relationship with the market dominant hospital and physician systems in the state has moved their relationship to a different teaching hospital in Boston in a pretty profound move because demonstrated quality measures were just as good and that cost was considerably less.

So some profound change is happening because of provider engagement in the importance of stewarding resources carefully. A third market benefit we see is that some of those solo and small practices that we'd been talking about that really can't effectively work on performance and deliver quality on their own are now actually organizing to be in some kind of group that can help facilitate performance improvement and oversight of quality and outcomes.

The fourth benefit that we see is the right sizing of the pyramids so primary care really is at the heart of these models and is calling the shots in the models and is really having the – calling the hospitals and specialists to task for providing what they need under the contract model. Very different from what we've seen prior to introducing an ACO into our market.

And finally, the issue of trend, and that is, you know, we now have because of this model a predictable trend in that segment of our network that is working its way down to CPI, as opposed to the, you know, double digit rates of increases that we were paying year-over-year to providers and our more traditional contract negotiations.

Susan DeSanti: OK, thank you. Ms. Gilbertson.

Elizabeth Gilbertson: I would just like to underscore the remarks made by previous speakers about the problem of dominant providers in particular markets. The scale of the dominance is something that we can see largely in the scale of the rates and prices that we have to pay. That's a pretty good measure of it.

And we have experience in markets where we pay for, and it happens to be hospital services but it certainly could be other kinds of providers, where we pay double and triple what we would otherwise consider to be reasonable.

And if the dominant provider in that area, whatever it happens to be, is a provider that has offered services that you can't not have, there is a really big problem. And to the extent that ACOs are going to create a major tailwind for aggregation around those providers who are already large and important in their markets, that is a really, really big problem.

In depressed areas this results in people getting laid off, losing their benefits, losing their jobs. And so I hope that as the policymakers who are in this room and listening to this panel take in what we say here, that the scale of the consequences and their very tangible results for people can be felt.

Whenever I hear Don Berwick describe the kind of care that ACOs are trying to achieve I think that's what I want for myself. That's what I want for our participants. That's what I want for my family. And so it's right. And that's not the problem.

The problem is that we have a pretty checkered landscape, and we have to figure out how to deliver that result in a rate-controlled environment in a way that doesn't accelerate the rate of loss of health benefits for in the commercial market.

Susan DeSanti: Mr. Turgeon.

Joe Turgeon: Yes, I think – I think one of the main issues …

Susan DeSanti: Could you speak a little more into the mike, please?

Joe Turgeon: I'm sorry. I think one of the main issues around scale, scale in and of itself it certainly can be a real problem in particular markets. We've seen it. We see it all the time in terms of dominance. I think the key issue in terms of bringing it together with accountable care organizations is that key term accountability.

I mean there's got to be a certain amount – there's got to be a designed accountability around delivering on the performance metrics that we talked about earlier for that to make that a viable alternative, because otherwise

dominance in the current payment model structure is going to create exactly the kind of pricing increases we were talking about before.

Susan DeSanti: Dr. Sacks.

Dr. Lee Sacks: I feel the need to at least provide some rebuttal from the delivery systems side representing physicians and hospitals, and one, we'd be grateful to take the contract that Dr. Safran described in Massachusetts. Our payers won't be so generous. We'd love to have an alignment as well as to have upside related to quality and outcomes.

But I think the elephant in the room is that the current system is pay-for-volume and that's what's driving all of these dysfunctions and lack of integration because of, as somebody said in the first session, the economics ultimately drive the behavior. You know, I'm in a fragmented market -- excuse me -- with the largest system having 15 percent market share.

But we have five academic medical centers where more is better. And it's not a surprise that we have the darkest color in the Dartmouth Atlas. And the solution is to create alignment of incentives that support integration because most of the things that we've talked about earlier today related to true integrated care don't have CPT codes attached with them and so they don't generate reimbursement. So it's not a surprise that physicians aren't doing them.

In our capitated HMO business we've had two out of the last three years where trends on ancillary services, imaging, physical therapy, et cetera, has been zero. In the PPO, which is the dominant product in our marketplace, trend is in the high teens.

And it's not because of unit price. It's because of demand, self-referrals and then the incentive that more is better. Medicare certainly has experienced that from day one. Every time fees get ratcheted down volumes go up and the total spend actually expands.

Susan DeSanti: Thank you. I'd like to – I think I should probably stipulate for the record that the FTC is well aware that there are competitive health care markets, and as

Bob Galvin noted, this is not the case everywhere in the country by any means.

I'd like to add in another factor. One of the comments we received said that -- without the citation -- that "mergers and joint ventures are now increasing since the legislation has been passed that allows ACOs." And I'm wondering, A, is that what you are seeing in the marketplace, and B, if so is that tied to the ACO legislation? And if so what's promoting that? Yes, Ms. Austin?

Gloria Austin: The reasons probably by market differ widely, but I think that that consolidation is happening rapidly. In our own market, for example, we've been approached by two to three larger – or excuse me, smaller network models who want to achieve clinical integration. And we have the infrastructure and the tools and it makes sense.

Actually – and I think it was Mary Jo who mentioned that it's not necessarily just a number of competitors in the market. It's how accountable and how, you know, if you had a few really good players you probably – you are going to drive cost down.

So I think that the issue is what's the –what's the motivation? If it's a number of specialists trying to consolidate in order to gain market power, one of the concerns I have is that and was asked by the FTC is how I would feel about certain specialties actually becoming an ACO and managing populations?

And, frankly, I don't think that any small group of specialists can effectively manage a population because I think that you can unfortunately cost shift and we all know some of the games that can be played.

So I think consolidation actually in and of itself is not a bad thing, especially when it's around accountable care and clinical integration. I think it's a bad thing when people are trying to look at how do you maximize your ability to gain margin at the point of care? That I think is a problem.

Susan DeSanti: Ms. Trysla.

Trudy Trysla: So I agree with those comments. In our marketplace, Fairview has got a wide continuum of services. We've got eight hospitals. We cover a metropolitan area, academic medical center and rural areas. We're not seeing consolidation.

What we're seeing is there's just not the framework or the financial base to go out and acquire. And that's not the desire that we're seeing in our marketplace. What we're seeing is the effort and the attempt to create relationships around value, around concepts of clinical integration, around providing better care.

And going back to the issue of the market dominance issue, I'm not saying it's not a – it's not a factor, it's not an issue. But one thing I'd like to comment on in terms of the benefits of the ACO that we're seeing is that – is the spillover effect.

The conversations with payers, with the macro buyers, the employers that are approaching us, are not based on let's struggle over what our increase in margin is going to be this year? But it's about how can we demonstrate value? How can we actually achieve those Triple Aims? Show us how we can improve care, how we can reduce costs.

And for us, within our organization, we're both intent on (forming) an ACO, as was mentioned earlier, 70 percent by the first of the year of our commercial market is going to be in shared savings, but we're also out trying to – we're also going to be the receptor of those sorts of requests and interacting with groups that may have high market share.

But again, all those conversations are around what is the value that you bring and not the traditional conversation about what is the increase in price we're going to try to garner out of the relationship? So I think, looking into the future, the traditional analysis around market share and market dominance are different.

Susan DeSanti: OK. We have Dr. Casalino and then Bob Galvin, and then we're going to change the topic.

Dr. Larry Casalino: I just want to mention that I think that the whole ACO phenomenon is occurring in the context of two historical trends that have gotten – demographic trends in physician practice that have been going on for 10 years and accelerating, but in which very little has been published. There's very little talk of them.

One is that, you know, with the decline of "managed care" quote/unquote and HMOs and risk contracting, the idea that risk contracting, which is going to become prevalent in the late 90s, formation of large multi-specialty groups, large primary care multi-specialty groups stopped. Very, very few have been formed in the last 10 years. What accelerated was formation of medium-sized single specialty groups.

So you can be a 15 or 20-physician cardiology group. It's not that hard to form one. You can have tremendous market power, and until recently, you could make a lot of money from imaging as well. So we've had increased single specialty group formation, decreased multi-specialty group formation. Actually, if ACOs move forward this could reverse that trend.

The other historical trend – which I actually think would be a good thing. The other historical trend is that Dr. Wilson's correct in saying that most physicians in the United States historically have practiced in small private practices.

But over the last decade, there's just been a flight from physicians into larger organizations, and we can, you know, I won't get into the reasons for that, but it's very, very fast. It's not only primary care physicians, but it's specialists. It's not only physicians at the beginning or end of their – or end of their careers but at all stages of their careers.

Many of them would probably like to be employed or be partners in a large multi-specialty group, but in most areas of the country, there is no large multi-specialty group, or if there is one, they don't need you. And so by – so a lot of physicians are becoming employed by hospitals.

It's happening very, very quickly and there's no question that the ACO phenomenon will accelerate that and, you know, depending on your point of view, that might be a good or a bad thing.

Hospitals have capital. They have leadership. In an ideal scenario, they could do some of the things that could make care better for everybody, as multi-specialty groups could. But there's also – I won't take the time to elaborate, but there's a lot of reasons to be concerned about a system that would be basically dominated by hospitals with their physicians employed.

Susan DeSanti: Bob Galvin.

Dr. Robert Galvin: Yes, just very quickly, it really buttresses what Larry said …

Susan DeSanti: Could you speak into the microphone?

Dr. Robert Galvin: Yes, sorry. It's the kind of the move towards, kind of, the consolidation among providers really predated the ACO bill by a long shot. But I think it was from the same influences that gave rise to the ACO bill.

It's been clear for a while that once managed care failed and whatever it was that came after it didn't work either, that from the IOM studies from all of the, kind of I think, messages that Medicare was giving about wanting to look at more global payment and looking at coordination, just like Dr. Berwick talked about this morning, much like DRGs. You know, there were messages before they occurred in the RVU system. I think it's been out there.

CMS payment policy has made some difference with some specialties, but there's been a flight to security. I think it's just an uncertain world for physicians and hospitals, and so the ACO legislation, you know, was part of it.

We're concerned, on the payer side that it could – if we don't deal with the unintended consequences, you know, it will accelerate it and make things unintendedly worse on a pricing side, but I wouldn't lay it on the ACO legislation that that's why this is all going on.

Susan DeSanti: Yes, Dr Wilson.

Dr. Cecil Wilson: I just wanted to emphasize the point that Dr. Casalino had made and that is that hospitals employing physicians certainly predated health system reform legislation. In my community in central Florida in Orlando, you know, the house with the mouse, we already have consolidation.

We have two mega systems. Each of those hospital systems has eight or nine campuses throughout central Florida, so the consolidation is already there. But what is also happening is physicians come to town and they are employed by hospitals, and we're seeing that from the AMA perspective across the country.

And our concern is the same that has been raised and that is a concern that if we end up with rules related to ACOs, that only big groups like big hospitals can meet, then this consolidation will go only that way.

And we don't think that's a bad way, if physicians want to do that and hospitals, but we don't think it should – we do not think it would be good for the country if that's the only way. So it emphasizes the importance of recognizing we need different models for different parts of the country.

Susan DeSanti: OK. I'm going to go back and emphasize the two-minute rule, and you didn't violate it, Dr Wilson, but, we're going to have to pick up the pace or we'll never be able to complete this. Next, I'd like to go to if we had a safe harbor, how we should be looking at the geographic area in which providers compete. And let me throw out a few questions on the table.

Does that geographic area differ depending on what type of provider you're talking about? People may be traveling farther for specialists than they would for a primary care physician who they expect to see more frequently.

Do you have, asking the purchasers and payers, do you have rough rules of thumb that you think about when you assess your negotiation potential for these types of services? And how do you assess this issue in terms of determining whether particular practices or certain providers or what has been called must-haves in this conversation? Mr. Turgeon.

Joe Turgeon: I think – let me get closer to the mike here. Again, when we look at how our networks are constructed and the way in which we would go out and actually contract with physicians or hospitals, we have to respect the actual pattern of care in that marketplace.

Essentially, the people have already dictated essentially what they're going to do around accessing physicians. They, you know, if it's an urban area, there's already been patterns set up about which hospital certain areas of that city go to and so on and so forth.

Obviously, if there's more competition I think it provides for more opportunity for negotiation, and that's one of things that we'll certainly look at. But I think in general it's very hard for us to change the way that pattern is structured in a given location whether it's rural or urban.

Susan DeSanti: OK. Mr. Miller?

Harold Miller: I think that, obviously, the size issue and the structure of the market depends on both the demand and the supply side and one's size on the supply side and one's negotiating power depends on the size on the other side.

But I think we've been in this unfortunate situation in the country on the private sector side where everybody tried to get bigger to try to beat out the other side. And, in the end, frankly, it's the providers that always win because no matter how big the health plan is you end up with a situation where the large provider has the ability to dictate prices and control.

I think that we need to be thinking about how to move in the other direction, which is to actually have the patient have some greater ability to switch. And if you look at most markets today, there are not benefit structures that actually give the patient any incentive to go to a lower cost equivalent or higher quality provider.

In many regions, there are hospitals and physicians that are delivering the same quality care at much lower cost, but there is no incentive for the patient. One of the reasons why some of those incentives don't exist is because some

of the big, dominant players refuse to contract at all if there is a tiered-network product or there are patient incentives to be able to do that.

So that is a particularly insidious kind of monopoly power, I think, that needs to be controlled because, if the individual patient can walk, that's a very different thing than a whole payer saying we're going to move – put you in or out of our network.

Because the patients will not be happy having a large provider in or out of their network, but individual patients may be able to make the choice. And in the places where there have been systems like that, a significant number of patients switch and it actually does cause the large provider to change, and that's my two minutes.

Susan DeSanti: Well, I'd like to follow up on that point. It was towards the end in the outline, but perhaps Mary Jo and Bob, you could speak to this issue?

Mary Jo Condon: Sure. You know, there are providers across our country that, not only will not contract if there is tiering, but won't contract if there's transparency of information on cost and quality. And that takes that even a step further.

So not only can purchasers not incent patients to choose the highest value provider, they can't even tell them who it is. So it's a huge problem and I think it's something that potentially a safe harbor could address, but that's, you know, just one idea.

Dr. Robert Galvin: Yes, I would say that is one way that ACOs could be pro-competitive, which I hadn't said so far today, and I see Doug nodding, which is part of the rules to become one were this transparency at a level that consumers care about, which would have to be discussed, then it could be pro-competitive.

So I know you asked the question, how far would someone go or what's the correct market size? I just really want to kind of frame what the two speakers before me said, which is that's defined by patterns already that you can tell from – that any payer can tell. People will go where they will go. It's really what happens inside where they're willing to go that makes a bigger difference, whether that's 12 miles, 20 miles, et cetera.

And that's where I think issues like transparency and the willingness to contract with someone that tiers based on value, quality and cost, really becomes the competitive issue, not 20 miles versus 50 miles.

Susan DeSanti: Doug Hastings?

Doug Hastings: Yes, just very quick, several people have said aggregation doesn't equal accountability. And so we're starting to hear some ideas of how to bring accountability to the table and trigger improvement so that if we already have situations where market concentration is a problem, we don't just move forward here out of fear of making it worse, which is part of what to be concerned with, but looking for ways to make it better.

And again, I think there are a lot of ideas in accountability that can affect that. You asked about geography. The other issue is, you know, we've been talking as if all ACOs will contract for the full load of care for everybody, and that's what this is about. We had a good comment about medical homes.

I mean there's a range of specific diseases that accountable care organizations can do a contract for, or bundling a particular kind of care, and so to me the notion of accountable care opens up a possibility of a wide range of new contractual arrangements that would potentially, you know, move us away from where we are currently to create an environment in which it isn't as much about mergers and acquisitions, enforcement can still continue there. But you have this range of contractual possibilities that create enhanced competition.

Susan DeSanti: Dr. Sacks.

Dr. Lee Sacks: You know, health care is complicated, and when I put on my clinical hat, some of these discussions have unintended consequences. When networks change and patients get forced to switch primary care physicians or the delivery system where they get their care, there's usually increased costs in the first year because lots of things get repeated because of the lack of continuity.

In our market, we have a lot of what we call splitter physicians. At our strongest hospital we only draw about 60 percent of the business from the physicians, which means they're doing 40 percent of their business down the street.

In terms of safety and outcomes, I want physicians that are 100 percent loyal. It really takes a team, and you can't measure the physicians separately from the hospital. The biggest dangers and the biggest expense are in the walls of the hospital. For those of you who flew here like me, air travel is very safe.

If you have a commercial pilot's license and you can fly a 737, you can only fly it on the airline you work for because they have different processes and procedures and technology. We're not there in health care, but I think if we're going to truly reform the system and provide more value, we're going to have to be there with loyal delivery systems that don't change based on a contract every year.

Susan DeSanti: That's the perfect segue into our next topic, which is, to what degree can exclusivity increase and non-exclusivity reduce market power, but there is always a tradeoff as you have – as you have made explicit, Dr. Sacks.

And certainly in antitrust law in general there's a recognition that exclusivity, and what I mean by that, I need to define this. If an ACO is exclusive, then its members would negotiate only through the ACO. They can't – they couldn't negotiate individually with a purchaser or a payer, and they couldn't join any other ACO.

So in theory, and antitrust law recognizes this, that kind of loyalty that Dr. Sacks was talking about and also the integration of knowing all the procedures and processes that your organization uses, can enhance competition or sharpen competition. Now, if non-exclusivity – if an ACO is non-exclusive then a member can negotiate individually with a purchaser or payer and also could be a member of more than one ACO.

Now, antitrust law, in addition to recognizing that exclusivity can enhance competition, antitrust law also recognizes that non-exclusivity can help with market power problems. For example, if the members of an ACO with market

power can join other ACOs then there are physicians available to help build competing ACOs. And also if purchasers and payers weren't happy with the rates offered by a particular ACO, then they could go to the – to the providers individually to negotiate rates.

Now, those are the themes that are recognized in antitrust law, and I'm wondering how these issues play out in your markets? And what you see really happening and what do you think the upside and downside would be for exclusivity or non-exclusivity? Ms Austin.

Gloria Austin: Yes, you know, you've raised a number of very complex issues around exclusivity, but a couple of – I think a couple of points. I think that, first of all, it's going to be really more important than ever to use the Rule of Reason as the bellwether, if you will, if you go looking at market-to-market.

The other thing is you indicated a member. Let's make sure that we're defining the member as the physician. We define members as patients as well, so you're talking about the physician. I think that not all payers have to go through one ACO and shouldn't have to.

To the extent, though, that a physician is exclusive to that ACO, it's beneficial in terms of infrastructure, in terms of capital to benefit that physician and also to have an organization that has methodologies and keep – and, just like us, creates a virtual group.

If there are a lot of fragmented physicians, and they are involved in several ACOs we haven't done much other than replicate the old network kind of competition issues. So I think the ACO with a capital A, Accountable is what we're talking about. And I don't think – I think exclusivity can be a very good thing, but it has to be made up of the right elements, and it has to be transparent.

If you offer physicians an opportunity to participate in multiple at some point when there's member assignment because of risk and capitation contracts, you will confuse the member, as well as the doctor. So I do think that that exclusivity, especially at the primary care level, can be very important for the ACO but not for all products. Just for whatever runs through the ACO.

Susan DeSanti: OK, I am going to just go down the row here. Dr. Casalino.

Dr. Larry Casalino: This really is a tough issue, and I know the FTC has struggled with it. And my opinion has – if you look at the advisory letters, for example, that have come out, has maybe put maybe a little too high value on non-exclusivity and trying to avoid market power, compared to the value of exclusivity.

I agree with Lee and Gloria that exclusivity has a real value. I mean, our medical group, our little medical group was part of four IPAs. We're part of Gloria's. I don't think Gloria was there yet. We were part of one 350-physician IPA that I helped run and two others.

Well, believe me, none of those IPAs had our – had our loyalty. I wasn't even particularly loyal to the one that I was helping to run, you know. So for all kinds – although they did have nice dinners for us, you know, when we had our little meeting. So I think that – I don't think it's going to be possible to have a high functioning ACO with physicians whose loyalties are split among multiple organizations.

Susan DeSanti: OK. Ms. Gilbertson.

Elizabeth Gilbertson: One of the biggest challenges in contracting with large provider systems is the current practice of their requirement that if you want a piece of me you have to contract with all of me. And I think that that and the ACO environment has – there's a lesson in that. I appreciate the remarks that have been made about the virtues of loyalty and trying to have aligned incentives all working in the same direction in the same organization.

On the other hand, this if you don't contract with – in order to get access to any of my services, you have to contract with all of them has been a real enemy of meaningful quality and patient experience compassion as a driver of where we try to drive our patients. Because you – there's often considerable variation among kinds of services in a large entity, some of which perform much better than others.

And in the best of all possible worlds, as a purchaser, you would love to be able to incentivize your participants to use those who perform well and not be stuck with the pieces of the system that don't perform well. So I think there's a balance in consideration on the other side.

Susan DeSanti: I would like to follow up with you and ask a couple more questions, just to clarify your remark. You talk about different services, and I'm going to pick on hospitals, but I don't mean to pick on hospitals. I'm sure it applies to other kinds of providers as well. It's just the easiest example.

Does this mean, for example, that with a hospital whose neonatal unit wasn't as good as the one at another hospital, you would prefer to be able to say, "Yes, we're going to include everything in your hospital in this contract, but not that neonatal unit. We're going to use so and so for that." Is that the kind of thing you're talking about?

Elizabeth Gilbertson: Yes.

Susan DeSanti: OK, and are you also talking about networks of organizations or were you just talking about services within one organization?

Elisabeth Gilbertson: I was talking about services within one, although I'm sure you could make the same argument with respect to networks.

Susan DeSanti: OK. Thanks. Mr. Miller?

Harold Miller: I think the way you have framed this issue here is completely biased towards the consolidated merged organizations because if the hospital goes out and hires up all the physicians in town they are exclusive. They have no ability to go and contract separately with anybody. But we don't declare that to be illegal.

But if a group of small physician practices comes together in an IPA, to be able to do the same thing, maybe better than the hospital hiring all the physicians do, we declare that to be a problem. We declare them to be acting in the anti-competitive way. If they create an exclusivity agreement to try to achieve some of the kinds of benefits that we talked about earlier, we say

that's a dangerous anti-competitive activity. And so what I think we have created in the country is huge barriers for people to create the joint ventures and great incentives to go into merged structures.

Now, if you were to – back to your earlier question what would I like to see in a market? I would like to see structures where when the providers came together, that if it didn't work, and if they weren't delivering value, that they could go and reorganize themselves.

So if you have an IPA where all of the physicians are jointly practicing together in some fashion, even under an exclusivity arrangement, and that IPA ends up not being able to deliver good value, I'd like to see some of the primary care physicians and some of the specialists say you know what? We can go and we can create a better ACO ourselves and be able to go and do that.

Now, under an IPA structure they're much better able to do that. Why? Because they're all maintaining their own individual practices. They don't have to go and try to recreate that infrastructure. It exists.

But if they go work for the hospital and they say you know what? This hospital system is not delivering good value. I'm going to go and create my own ACO – big hurdle because they don't even have their own individual practice anymore.

So I think that comparing when you talk about two different sized entities, an entity that has the ability to reform itself into other entities should be something that the FTC should be trying to support rather than creating greater burdens on those kinds of structures and in favor of the emergent entities.

Susan DeSanti: I take your point. And just to explain, not to defend, but just to explain we do have rules of law that require us to look at whether an entity is a single entity or several independent entities. And the laws are just different. But I agree that …

Harold Miller: So change the laws.

Susan DeSanti: Yes. OK. I'll talk with – I'll talk with you about your lobbying strategy for Congress after this event. Dr. Sacks.

Dr. Lee Sacks: Let me share some of my experience and you might be able to see why my thinking has changed. Advocate Physician Partner up until now has been non-exclusive. We've told our management team and our board that we need to earn the trust and confidence of the physicians every day with our performance. And for most of them they've been comfortable not having to be in other organizations, but there's variation.

A number of years ago we were out of contract with a major national payer for four years and many of our physicians chose to continue to contract through other organizations. And ultimately that payer decided to come back because they felt there was value with what we did.

Going back 15 years, the payers who offered us capitated contracts required physicians to declare which organization were you going to take that captitated contract through because they recognized if you weren't exclusive it was an administrative nightmare.

As Gloria said it confuses physicians. It confuses patients and it sure messes up the finances. And you spend all kinds of time arguing over which organizations should be charged for that expense.

We're going to announce tomorrow that we're going to be in a shared savings model with a commercial payer that's 70 percent of the market. So we've done a lot of thinking this summer about exclusivity. And since we're going to be accountable for the cost of care for the attributable patients, we're coming to the conclusion that we have to have exclusivity for our primary care physicians with that.

And we think that with data and transparency the primary care physicians will figure out who the best specialists in the network are and ultimately that will drive performance and behavior. But in our market many of those specialists are in large, single specialty groups.

And the groups are across multiple systems. Pods at our hospital and our PHO and pods elsewhere and they cross cover weekends, whatever. With that it would be incredibly disruptive to say that they had to be exclusive today, and it doesn't make a lot of sense.

Susan DeSanti: Dr. Safran.

Dr. Dana Safran: So just building on what Dr. Sacks said and agreeing entirely, you know, what I think – to me this question depends on how we're going to define the ACO and who's in it. But I think what you're hearing pretty clearly from this panel is that you've got to have PCPs in it and that for the PCPs to have it not be exclusive would undo many of the benefits that we've all been talking about all morning of having the ACO in the first place.

The benefits of, you know, sufficient samples and have measurements, the benefits of clinical integration and managing that and leadership and so forth. And so I think for the – for the core of the ACO, which I see as, you know, the PCPs, there has to be exclusivity. Then the question is how much beyond a PCP core does an organization have to be in order to be an ACO?

And, you know, you heard me say at the beginning of the morning that we started out by believing that our AQC contract was going to be a physician organization and a hospital together in one contract.

And that we've sort of evolved that over time and that, in fact, now the majority of the groups that are interested in coming into this, while they're taking accountability for that full continuum of care, everything that happens to the patient from birth through death and everything in between, there is more infrequently now a hospital that's signed as party to the deal.

And part of that is because the – it makes kind of less sense for the hospitals to be exclusive to a physician group. They're likely to be needed by other physician groups and so forth. So I – and where specialists fall, I think, is somewhere in between.

And so in most cases what we see is our ACOs, these AQC groups are having absolutely a core of PCPs, some specialists, but recognizing that they are going to have to also refer out to additional specialists.

And they may or may not have a hospital that's party to their deal. But regardless of whether they do they're undoubtedly going to be using hospitals outside of their system. They're still accountable for the quality at the hospitals that they choose to use, and they're still accountable for the cost of care that happens when the patient's in that hospital.

Susan DeSanti: Mr. Turgeon.

Joe Turgeon: Yes. I think I really want to echo a lot of what we just heard. I think a lot of the success of an ACO ultimately in my mind is going to be tied to the primary care physicians that are tied to that ACO.

And I think, again, I would say in the experiments that we've done so far in the marketplace, we've actually done some stuff with primary care groups only, with some multi-specialty groups and then with some hospital specialty groups, and I think that the challenge as you go up that chain is that that ability to be able to find the freedom for the physician to make decisions about referral patterns.

And with a primary care group, them being exclusive, I think it makes sense for all the reasons that were said here. But I think they have to be free to be able to make referral decisions outside of their – to get to the efficiency that you're looking for in the system.

So I think that that part is – it's a little scary when you start talking about an ACO organization that's hospital-driven because all of a sudden now you're really limiting a lot of choice in terms of where the physicians can take their patients.

Susan DeSanti: Dr. Wilson.

Dr. Cecil Wilson: Yes, thank you, and actually some comments in support of exclusivity, but just to make the point following on about whether we need legislation or not.

I think maybe what we're saying at one level is that to make ACOs work, this new model work around the country we may have to look at market power and market dominance in different ways.

And the per se rule, the 20 percent or whatever it is may have to be moved to basically looking at each case in a way based on the merits of it. And part of that is a realization that in very small communities in this country if you just have two primary care physicians who are partners, I mean, they have total market dominance. Of course, if they leave there's no care at all.

And even in moderate size communities, you may have an orthopedic group of nine members who have way more than 20 percent and they have much more than that so that we are looking at a different part of the economy.

And we're also looking at something we think is going to be good for patients in this country in the long run and so we would look for sort of reinterpretations of what antitrust might look like getting away from the per se rule.

Susan DeSanti: OK. Dr. Wright and then Ms. Trysla.

Dr. Janet Wright: Yes. My comments are just really in reference to the conversation we've had about specialty and primary care. And I guess from an organization standpoint I need to say something that's probably not necessary to say, but the full support of healthy primary care population and medical home. I actually come from a primary care doctor and his nurse.

But I actually – and I didn't go into it because it looked too hard so but I do want to remind us or remind myself that if an ACO works the way we all envision, it is truly patient-centered. And so looking at that I love that idea of respecting the pattern of care, but really when you get down to performance measurement it's if we continue to refine the science or performance measurement we get better and better at that.

And we're using both our administrative data and our clinical databases to help inform those performance measures and close the gaps. Then the measure – who's meeting that measure is actually agnostic. It's not so much

about which doctor. I am a doctor so I'm pretty doctor focused, but it's a little bit less about what type of doctor and a whole lot about what the measurement and what the performance is.

And so in our brief experience with an ambulatory registry we almost have a million records, we use (the) NQF-endorsed measures for coronary disease, heart failure, afib and hypertension. But when we look at the performance reports we have no idea who filled out the form or who's meeting that measure. It's for a patient who has heart disease or is at risk for heart disease. It's not about the actual practitioner. So I'd like to keep in mind that we want to keep the patient in the middle.

Susan DeSanti: Ms. Trysla and then I will ask a follow-up.

Trudy Trysla: Sure, a couple quick points. I think in terms of the exclusivity question or not …

Susan DeSanti: Could you speak a little more in the …

Trudy Trysla: In terms of the exclusivity question I think what everybody on the panel is saying is that there shouldn't be prescribed rules around what is required or not required. An ACO needs to respond to the patients that it's serving, to the populations that it's serving. It may itself decide that exclusivity is helpful around primary care physicians. They don't want to deal with the administrative issues that were described.

It's certainly in our marketplace exclusivity around specialty care is just not something that the marketplace will support. So I would just encourage the FTC to allow the flexibility for ACOs to respond to their local communities and the people and populations that they serve.

The second point I wanted to make is that the implications of exclusivity and non-exclusivity, I want to go back to the point I made and that Dr. Wilson made is that I think – I would encourage the FTC to look at that issue differently.

I mean if you look at it from the standpoint of whether it's exclusive or non-exclusive that the goals of an ACO structure are to improve care so that all relationships are triggered on quality, to reduce costs so that all incentives are aligned to actually achieve that improved quality and that better care. And that patient experience is better.

And so there shouldn't be the after effect of – I mean that is fundamentally pro-competitive. It's helpful to individuals and so I just encourage the FTC to think about the non-exclusivity and exclusivity question in that sort of framework and view it a little bit differently. Because, again, I think the times are a changing and that this historical view may not reflect the aims that the statute is intending to get.

Susan DeSanti: OK. What I'm hearing from this panel is the same kind of tradeoffs and tensions between things that are showing up in the meetings that we're having to discuss this possibility of a safe harbor. Many of you have expressed the desire that the FTC take into account the particular individual circumstances of an ACO operating in a particular market. And in fact, that's the usual way that the FTC does things.

On the other hand, we're hearing a lot about a need for certainty and certain safe harbors to allow ACOs to go forward. And so we have a question before us which says should we have a safe harbor for an ACO? Should it be similar to that is in the DOJ FTC statements now for physician joint ventures, for example, which is you're in a safe harbor if you have 20 percent of the market, if you're exclusive.

You're in a safe harbor if you have 30 percent of the market and you're non-exclusive. I think I'm hearing something about that. But how would you go about making that tradeoff? You know, A, do you think these safe harbors are necessary and if so what kinds of safe harbors would you suggest be on the table under consideration? As Michael said, it's always scary when all the tags are down. Yes, Mr. Miller?

Doug Hastings: I'll just go real quick …

Susan DeSanti: OK, Mr. Hastings.

Doug Hastings: We talked this morning about a safe harbor or a sort of deeming for organizations for clinical integration purposes. You're asking a different question here this afternoon, I think, because I would support that.

This afternoon I think, I mean, the statements have served well for a good number of years and the policies are aligned with ACOs. But I think there's so much more we can know about what we're looking for in accountable care that rather than perhaps trying to refashion a safe harbor with those kind of percentages, which kind of go to Harold's point about there's already plenty of organizations with greater market share than that now, but look instead to guidance around behaviors and accountability that we would judge organizations under the Rule of Reason.

Susan DeSanti: Mr. Miller.

Harold Miller: My radical – my radical idea is that the FTC should have a swat team and the …

Susan DeSanti: Sign me up.

Harold Miller: … and rather – and a swat team designed to go out and actually help providers that are trying to do well be able to do it in a way that doesn't cause them to incur huge, sorry Doug, legal bills and years of effort to be able to do that.

Because I think that having safe harbors as guidance is good, but on the other hand if you've got a better approach that doesn't fit into the safe harbors do you look at it and say, "Huh, you know, I've got three years of effort and a million dollars of legal bills ahead of me so therefore I can't do the really good idea."

Or could the FTC say you know what? If you've got a good idea we'll figure out how to help you and be able to get into that structure quickly and to be able to give you guidance quickly that says there's a brand new safe harbor for you.

And so I think that there could be a balance between having some safe harbors for things that seem to be OK, that many people can go into, but to have any opportunity for people who have more creative approaches to get – to get rapid help and approval.

Susan DeSanti: Dr. Sacks.

Dr. Lee Sacks: Yes. You know, when I look at things based on our experience our organization thinks we really understand what's the safe harbor for clinical integration, but when I talk to colleagues across the country there's a lot of angst. And just as Harold said, nobody wants to go through the time and the potential expense to find out are they there, especially smaller organizations without the resources.

If ACOs are going to be successful they're going to also have to be in the commercial marketplace. You know, we talked earlier about alignment. It's one of the reasons capitation failed in most markets. It wasn't a significant portion of practices or delivery systems so you didn't change the way you did things. It's one of the reasons our organization is, you know, jumping off the cliff and moving ahead in the commercial markets so we'll be ready for Medicare ACO.

But we think we need to have more than half of our business in that type of payment model if we're going to truly redesign care and be successful and get out of the more is better mindset. So there's – so my plea is that there be something pretty clear that at least in the short term allows the marketplace to respond and feel comfortable that they can do the same in the commercial side as they might do with the Medicare ACO.

Susan DeSanti: Dr. Casalino, Ms. Trysla and then Dr. Wright.

Dr. Larry Casalino: Yes. A few things about what the FTC could do in my opinion. First of all, I think that the guidelines …

Susan DeSanti: Can you speak more into the mike? I'm sorry.

Dr. Larry Casalino: Yes, I'm sorry. First of all, I think the guidelines combined with these – all the other things that are out there right now, the advisory opinions, to me they're plenty clear and to me they say if you're in a provider organization and you are actually doing things.

You're investing money. You're investing people's time in trying to achieve the Triple Aim, let's say, and trying to improve care for your population of patients and you're really doing that, you know, you're probably going to be OK. You know, leaving out market share kind of considerations for the moment.

I think the guidelines in my opinion say that now but I don't think that that's the way provider groups feel. And that's one reason that they're asking for more explicit guidance even though if you gave it it would be a mistake in my opinion.

So I think where – well, it would be a mistake because things change too fast. You'd freeze things and you'd be criticized even more for, you know, prescribing. But I think that we're more so – but I think that the concept that if, you know, you figure out and this is what the FTC has said, basically. You figure out the best way to do it. And if you're really doing it you're probably going to be OK.

But the question is then how to get providers to understand that and to feel that way, and I think there are some things the FTC could do about that. First of all, I think there's a question of what's the – what's the – what happens if an organization is doing a lot and clearly has potential but maybe doesn't quite hit a certain mark?

So Advocate, for instance, a few years ago when the FTC took a look at them, didn't have electronic health records, right? If the FTC had been rigid it could have said you don't have clinical IT forget it, you know? But I think the FTC recognized that there was an organization with potential. Let them go. And it's been a major success story.

So I think more clarity that if you're really in good faith and you're not just promising to do things but you're doing some and we think you're going to be doing a lot more in a year or two, you might get a pass.

I think the other – the other key thing, I think, is the (ancillarity) issue. And I think that every organization feels that, you know, we're going to be investigated and they're going to ask you is there a nurse care management program? Do we really – is that – or do we really have to have joint negotiations to have that? In every case we have to prove, the organization has to prove that it does.

You know, and, you know, in my opinion there is (ancillarity) there. It's there every time. You're not going to have a nurse care management program or these other kinds of things that we could be talking about without joint negotiations. And if there would just be some clarity about that from the FTC.

I know there are people in the FTC who don't want to do this. (Ancillarity)'s in the law and so on and so forth, but I think you shouldn't have to invent the wheel every time. It should be clear that if you're doing these things it would be likely to be deemed ancillary if you're really doing the things.

And then that would lead into my last point which is that a lot of organizations that we keep hearing today are deterred by the cost and time and expense of getting an advisory opinion. And I think if there was some more clarity about the kind of things I just mentioned then I think that attorneys could advise their clients as some already are doing. You really don't need to get an advisory opinion. You know, just go ahead and if you're doing the right thing and your market share is not a problem you're going to be OK.

Susan DeSanti: Thank you. Ms. Trysla.

Trudy Trysla: Just quickly, I mean, you know, I agree with all of those comments. I think, as I was saying earlier, that the previous enforcement statements and advisory opinions are helpful, but I think in this day and age that clarity in order to move with speed and the urgency that I think was expressed by Dr. Berwick and everyone else here is necessary to have that.

And I would, again, argue for a safe harbor that starts out with the concept that if the ACO is demonstrating its outcome measures and however those are configured, that ultimately, again, those factors are pro-competitive.

And the issues, the traditional approach to 20 percent or 30 percent in examining what's specialists and what's exclusivity and what non-exclusive providers are in your network is going to slow down that speed and urgency.

So if there could be either safe harbor or guidance around what are – how would the Rule of Reason be applied? What are the anti-competitive effects that would indicate that you do need to go through an advisory opinion process, certainly an expedited process is certainly helpful.

I think that's what I would urge to look at things a little bit more differently and in that framework that the fundamental concept of the legislation is pro-competitive, and if you're choosing – and if you're achieving that that should be the perspective of the regulators in that context.

Susan DeSanti: Dr. Wright?

Dr. Janet Wright: Just quickly, I would agree with Larry, which is not a surprise. I have agreed with Larry for a number of years.

Susan DeSanti: I think you're not being picked up.

Dr. Janet Wright: Oh. Can you hear me now? So I agree with Larry that the amount of guidance and the framework that you all have said is very helpful. And that's coming from someone who didn't actually know about this framework until about two weeks ago. So that's wonderful.

But what I would – the one thing that I would emphasize is – to communicate, is the permission to experiment because I think that's how we're going to find those good things that actually do work and learn more about this concept of implementation science and looking for the positive deviance out there.

Susan DeSanti: OK. Dr. Williams and then we're going to end with Ms. Gilbertson.

Dr. William Williams: Yes. I would agree with Dr. Casalino, too. The main reason I think we had trouble forming our organization, number one, was getting physician buy-in. And the reason for that, number one, was the fear of an FTC investigation number one. They said, "They're going to investigate us and we'll have to spend millions of dollars and they'll run us into bankruptcy."

That turned out not to be the case; we were investigated by the DOJ. And we spent several million dollars and they said we're OK. So we're proud to be the first organization in the United States to go through a DOJ investigation and pass muster, by the way, but the cost of forming an organization is tremendous right now.

And it's because of the legal fees and getting our – like, we spent $2 million in forming our organization in the first year. Most of that was getting the bylaws, the infrastructure, you know, our network participation agreements and all that and getting ready to present this to the FTC.

And we ended up having a very cordial interview with the FTC, by the way, so but our organization spent a lot of money, and it all goes back to the size of the organization again. Smaller organizations are just not going to have the money to form this or develop the infrastructure.

And that's why we're trying to help smaller physicians in our network, especially rural physicians, come into our fold because of the cost. The simply can't afford it. So and the recommendation of the FTC was, actually, I think their current guidelines are, as mentioned, well, I mean I think when you had (multiple) following the guidelines going back to the 1996 joint statement between the DOJ and the FTC and the advisory opinions and the consent decrees that have come down since then.

We didn't have any trouble recognizing what was right and what was wrong, except for market share. And it comes down to market share is then, well, what market are you in? Like in Lubbock, Texas we have seven out of eight pulmonologists in our group and there's only eight in the region. So, you know, we have much more than 20 percent in that one specialty. We have 50

percent of the (gastroenterologists) and currently about 30 percent of the cardiologists.

So, you know, the other hospital has similar higher percentages in other specialties, especially general surgery for a matter of fact. So, you know, the concept that market share or market power is going to have to be interpreted in each market I think. So but how do you clarify that in a safe harbor? That's going to be a tough question.

Susan DeSanti: Thank you very much. Ms. Gilbertson?

Elizabeth Gilbertson: I think if we're going to have safe harbors and we will …

Susan DeSanti: Could you speak into the mike?

Elizabeth Gilbertson: Sorry. I think we're going to have safe harbors there should be an absolute qualification for entry which is a commitment to public reporting of quality, patient experience and cost. And I think you shouldn't be able to keep the safe harbor unless those are getting better because that's the goal of the legislation.

Susan DeSanti: Thank you very much. Well, we're going to wrap up now so that you all can go to lunch. There's a cafeteria here. Thank you all very much for your valuable contributions. Please join me in thanking the panel.

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