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FALK AUDITORIUM

REFORMING STARK/ANTI-KICKBACK POLICIES

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P R O C E E D I N G S

MR. GINSBURG: Good morning, I'm Paul Ginsburg and on behalf of the USC Brookings Schaeffer Initiative for Health Policy, I want to welcome you to Brookings. Today's conference is on possible reforms to laws and regulations preventing physicians and other providers from referring patients to entities that they have a financial interest in. Often referred to as Stark from the author of the legislation and laws and regulations that prevent providers from offering or receiving a kickback for care decisions that they make.

These policies developed during an era of almost universal fee-for-service payment and the restrictions appear to interfere in important ways with alternative payment approaches and waivers are often granted. But we have a problematic situation when one approach to self-referral and kickbacks (inaudible), the health care service, health care system and another part works for the other part of the system.

In 2018, the Administration sought stakeholder feedback on how the regulations implementing these laws might be modified to promote value-based, coordinate and integrated care while still protecting taxpayers and beneficiaries from fraud. HHS Deputy Secretary Eric Hargan has worked with these issues and thought about them for many years. He will open the event with his keynote presentation. After the deputy secretary speaks, he will take questions from the audience. Note that the questions should be limited to the Stark and anti-kickback issues that this event is about. After that, my colleague, Brookings Fellow, Christen Linke Young, will moderate a panel discussion on these issues with experts in health care payments and delivery system reform.

I'm please to introduce to you and welcome to Brookings, Eric D. Hargan, Deputy Secretary, U.S. Department of Health and Human Services. As deputy secretary, he is the chief operating officer and is responsible for day-to-day operations and management of the department, in addition to leading policy and strategy development. He's served in a number of senior positions at HHS during the George W. Bush Administration. Mr. Secretary -- (Applause).

MR. HARGAN: Thank you for that introduction Paul and thank you to Brookings for welcoming me here today. Thank you to everyone who's joined us here for this important event from both inside and outside of government. I know there's nothing that sets hearts a flutter in this town, quite like a think tank event with a long speech and a panel on rewriting obscure regulations. So, welcome. But quite seriously, today's event and topic is tremendously important and I'm glad to have Brookings recognize that by holding this discussion.

Back in October, Secretary Azar was also here with Paul and the USC Brookings Schaeffer Initiative to deliver a speech on the model HHS put forth last fall regarding prices in Medicare Part B. He noted that reform to how Part B pays for drugs has been a very long time coming. A place for a long time, everyone across the policy spectrum has agreed that we need changes. The pharmaceutical market place had changed to where more and expensive and complex drugs are playing a bigger and bigger role in our health care system and yet, our payment systems aren't setup to drive competition or negotiation in these new corners of the prescription drug marketplace.

Now, we recognize that something similar has happened with the market for health care services. But here, the policies we cite at HHS are even more important. Outdated policies from HHS mean not only less than desirable results for taxpayers and for beneficiaries of our programs, but often for patients and payers in the private market as well. The role played in pain-for-services by our own policies at HHS is dominant, which means that where aren't innovating, we hold things back. Just about all health care experts agree on where we want to go. We need to be moving our payment system from volume to value. I imagine that the health policy scholars at Brookings aren't even allowed to sit down at the lunch table unless they've already thought about volume to value that day. I'm sure Paul enforces that, but it's important to recognize what this all means. Those of you up on the issues, especially, the lawyers know we're not going to move from volume of referrals to value of referrals. What we're considering is something that is much different from that.

Really, under one way or another, this is the third Administration to work towards the goal of value-based care under which I have a rubric they placed it under.

What, after all was Part D that I worked on under the Bush Administration or the revamped Medicare Advantage besides ways to drive value through competition and incentives. I worked on the medical severity, DRG Reform back then as well. That again, was something that is value-based effort in some way, even if it wasn't placed under that particular banner when we were there in the Bush Administration. And at the same time, moving in that direction toward value hasn't been all that rapid. Private actors have been innovating, HHS has as well, for example, from 2017 to 2018, the share of Medicare Beneficiaries in alternative payment models went from 13 percent to 17 percent. That is progress in which we acknowledge, but it's still under one in five Medicare beneficiaries in those models.

Now, part of the reason moving to value has been slow is because it requires a radical reorienting of how American health care is paid for and how it's regulated. That means that we have to take a holistic view of all of our policies and programs in order to push the transformation along and that's what we have done at HHS. In particular, the topic we're here to discuss today, regulation, is vital. It's one of the several significant ways I've been working on the move from volume to value at HHS alongside health IT, payment innovation and others.

Now, I will confess, I'm glad to be here at a think tank event like this because it's a little easier to get the crowd excited about a discussion on regulations. At my previous tour of duty at HHS, I served as the agency's deputy general counsel for regulation as the regulatory policy officer and institute regulatory officer of the department. Now, on my return to the department, I get to be the chief regulatory officer again. I'm also taught administrative law and health care regulations as law professor actually at Loyola Law School in Chicago alongside my fellow professor, Kim Brandt, who's here today and worked as a regulatory lawyer at my former law firm so, regulatory reform, I think it's fair to say, I

think you'd all agree, is a personal passion of mine. At least, that's how I've shown it. One thing I'm proud to note is that over half of the regulatory savings for the entire Administration in 2018 were achieved at HHS alone. We were number one among all agencies in both the number of the regulatory actions and in regulatory savings in 2018. So, this is personal to me and I can get frustrated sometimes that regulatory reform is too often viewed as a as a giveaway to industry, which is not what it is at all.

Done right, regulatory reform like this is an opportunity to examine the barriers that regulations create between market actors and determine how we can reshape those barriers or reduce them so that new arrangements, relationships and solutions can emerge. All while maintaining safeguards for innovation, competition, patient access and the sound use of taxpayer dollars. All of which are focuses of ours as we move forward on this reform. We have to keep in mind all those things that act as kind of the guard rails on the reform as we move it forward.

In health care, this is all about giving patients, providers and payers' new freedom and the right incentive structure to afford solutions to the challenges that we all face. The rising cost of health care, first and foremost, but also questions of access to care. The burden of chronic disease, the neglect of mental health care and so much more. All of which are implicated by the current structure that we have in place right now. Many of these things are restricted by the system that we have in place right now. The use of alternatives, the burden of chronic disease, which can't be addressed in many ways because of the system we have in now.

The fact that we don't have mental and behavioral health care systems in place many ways are implicated by the regulatory system that we have in place right now that I and the panel will be discussing today. In recognition of how important regulatory reform is to health care, I launched a project we've done the regulatory sprint to coordinated care. And that brings me to the topic of today's event. In particular, efforts around the Stark Law and the Anti-Kickback Statute because those are two of the four areas we've initially

chosen for the regulatory spread, alongside HIPAA and another privacy law called 42 CFR Part 2, which is a Privacy Law that's around substance use disorder primarily. So, two of the laws that were working on for the regulatory sprint, our deal with affiliations and structures and two, deal with information sharing.

So, we've got -- so the two we're going to talk about most today Stark and Anti-kickback statute, both of those are dealing with different organizations in the health care space affiliate and deal with each other. Each of the words in this initiative are deliberately chosen. It's a sprint. Sprint from the governmental point of view, okay, so let's not get overly excited here. We intent on gathering the information we need and moving to rulemaking as soon as possible. And I think we have been, from a governmental point of view, I think we've moved very rapidly and -- because the Americans' need for health care reform really cannot wait. So, sprint. So, chosen. It' about coordination above all.

This is not an ordinary regulatory burden exercise but is squarely aimed at understanding a particular problem. How regulations are impeding coordination among providers that can provide better, lower-cost patient care and reforming the regulations consistent with the laws that are on the books and their intents.

Finally, it's about care, regulating health care means regulating some of the most intimate decisions and relationships in our lives. Deciding where and when to see care; how to make decisions with our doctors and family members and more. And we believe that this effort can meaningful improve the quality of care received by American patients. And I'll add regulatory, the regulatory sprint -- regulatory is also important here. This is not a legislative effort. The laws remain in place as is. This is a regulatory effort undertaken within the Administration. So, this is an interpretation of laws, but it is not an effort to change those laws. Those are undertaken by Congress. I don't lobby, prohibited from lobby, Article II, Executive Branch, not going to get into that issue at all.

Now, I should note the examination of these laws, Stark Law and the Anti-kickback Statute really began before the regulatory spring itself. The President has made

regulatory reform one of his key drives and the aggressive attitude of his Administration toward regulatory reform predates when I became acting Secretary of HHS in October 2017. Earlier in 2017, through its annual payment rule, CMS asked for comments on improvements that could be made to the health care delivery system to reduce unnecessary burdens for clinicians, other providers, patients and their families. Including ways that those burdens might be impeding care coordination. Now, in response, we got a great deal of input to the barriers to participation in care delivery and in payment reforms, both public and private, as well as the burdens of compliance with the Stark Law another regulations as they exist today.

So, kudos to Secretary Price for enabling that, but, of course, it did not stop there. The drive towards coordinated care gathered new steam Under Secretary Azar because the importance he is placed on driving towards a value-based system, which is one of the four priorities that he has as Secretary. Underneath value-based care are several legs. One of those is coordinated care and the drive to coordinated care provokes some obvious questions that point towards the need for broad-based regulatory reform in this area. Some of the questions and challenges that we got along the way where things like: how can we expect physicians to act as navigators of the health system while also holding them accountable if their decision-making is hamstrung by outdated regulations; or how can we expect providers to get on board with payments based on outcomes if we're not willing to give them the freedom to experiment and coordinate with one another, why would they want to take on risks if they feel they have the tools they need to improve outcomes; how can we really make major steps in preventing and curing disease without also rethinking how regulations like these could impede patients and providers working together in creative arrangements where everyone is incentivized to keep people healthy and out of the highest cost settings?

So, the regulatory sprint is really the heart are value-based efforts. In fact, in the very first speeches, Secretary Azar gave last year about how he views value-based

care. Just under a year ago, he identified barriers to coordinated care as one of his top priorities. Now, another way you can tell we're serious about the regulatory sprint is, of course, we have a Twitter hashtag. That's RS2CC. It's simple, it's brief, just like we'd like to make our regulations to the point.

So, now, I want to discuss exactly why we think there's a need to consider the Stark Law and the Anti-kickback Statute. Now, I say this as attorney where these laws were probably my most significant area of specialization. I am sympathetic to what the laws stand for, as we all should be. Rightly reformed, the exceptions and safe harbors within them can be reoriented, I believe, to help us transition to a new paradigm of value-based care. So, what would this look like for each law in particular?

Take the Stark Law, when enacted in 1989, again, 30 years ago, the Stark Law rightfully addressed the concern that inappropriate motives could distort decision-making in health care. It recognized worry that some physicians might order services based on their financial interest in service providers, rather than the good of the patient. In a largely fee-for-service context, you can see why that would make sense. It's relatively easy for a doctor with financial interest in another provider to say, get their -- drive their patient towards those places to add on extra money in a fee-for-service context where you're paying service-by-service, this law was intended to operate as a break on that tendency.

And the law clearly was passed with good intentions. And it was and is responsive to the structure of fee-for-service care and the incentives that involves. The heart of it is ensuring that a patient has options for quality care without regard for whether a physician has a financial interest in that care. We don't people referred to services they don't need or steered to less convenient, lower quality or more expensive health care providers because of their doctors' financial interests.

Now, of course, it's worth bearing in mind the larger context. Fee-for-service, the inpatient prospective payment system was and is a reformed that responded to poor incentives in the previous system, which reimbursed based on reasonable costs. So,

we keep sort of going through iterations of this at each time attempting to kind of have an overall improvement, but in some ways we've seen sort of the light towards the new system that we have and we have to lay down the tracks towards that system.

The Stark Law dealt with the incentives of fee-for-service in two specific ways. As I'm sure many of you know, first, it banned doctors from referring patients for certain designated health services payable by Medicare to an entity in which the physician or any immediate family member holds a financial relationship (inaudible). Second, it prohibited the entity from filing claims with Medicare or billing another individual entity, or third-party payer for those referred services. The restrictions are absolute, just with certain enumerated exceptions, but the law grants HHS importantly, the authority to carve out exceptions for financial relationships that do not pose a risk of program or patient abuse.

Now, we believe that the exceptions that may make sense today, 30 years later, probably look a lot different than the ones when the law was passed. Certainly, our health care system looks a lot different than it did in 1989 when Stark came into being when you had a purely fee-for-service system, you think really hard about who is deciding who is getting paid those fees for those services. In a system where we're paying for value, where the provider ideally is taking on some risk for outcomes and cost overruns, we don't have any nearly as much need to interfere with who's getting paid for which service. The government and the patient are paying for outcomes, not for individual services one-by-one. Of course, in considering changes to the Stark Law, we actually have to remain acutely aware of the need for competition in the healthcare marketplace. And in an ideal world, we can do both at the same time.

We can promote coordination and competition. They don't need to be at odds, but we have to carefully balance those and our thinking on the issue. Now, in some ways, as I well know, existing laws incentivized coordination through mergers and acquisitions. For example, if a hospital can only incentivize a physician, if he's employed by the hospital, then the rational response may be for hospitals to buy up physician practices.

And we want our -- and that's just one example of how the playing field is really set by these laws. They incentivize certain ownership structures and willy-nilly. It's under the idea of preventing abuse, but it really does end up reshaping the landscape of American healthcare. And who owns what and who has incentives to own what.

We want our regulations to be agnostic about ownership as possible. So, last year we conducted a major request for information on the Stark Law which closed in August. We received approximately 3,500 pages comments. Now, this wasn't one of those RFIs where we get 100,000 form submissions, not that there's anything wrong with those. But these were by and large very thoughtful and very interesting comments. I've been reading some of them myself. We have Kim Brandt here from CMS, who's been leading the charge on this and who will on the panel later. At 3,500 pages, I assume she's read every single one of them, right Kim?

MS. BRANDT: Not (crosstalk).

MR. HARGAN: She's glazed over. Like, so 3,500 pages later and again, these aren't -- these were not that, as I say, form comments. By and large, these were very thoughtful, intelligent comments that we got. So, this is a very complicated process to be honest, both and we'll get to -- don't worry, Vicky, we'll get to Inspector General's role in this. I'm starting with Stark Law. But we got a lot of very thoughtful comments in this process, which was gratifying for having launched the RFIs was to get the level of comments and the seriousness with which for the kind of community took this process, which was great. It was a meaningful set of inputs. It reflects a longstanding desire to examine these laws and the stakes surrounding any changes we make.

We receive comments from a wide range of stakeholders including individuals, rural interests, integrated systems and industry associations. It's clear how much appreciation there was for the opportunities to submit feedback on these rules. There's a shared recognition that something has to be done about them as we move our health care system from volume to value. Most commentators believe that regulatory

changes are needed to support the move to where we want to be on a value-based payment, but there was also the recognition. A recognition that we share that there's a potential for program integrity vulnerability or other abuses. That is a significant threat that cannot be ignored. Again, we're looking ahead. We're trying to lay down the tracks to a value-based system, but we cannot ignore the current fee-for-service system and the reality is that it will be around in some form or fashion for the foreseeable future. It is the majority this system right now, but it is -- it has a smaller percentage yearly of the overall market and we need to lay down the tracks for a regulatory point of view that gets us where we don't inhibit that transition, willy-nilly by leaving in place regulatory system that does not help or facilitate that coming into being.

So, we look forward to moving ahead with rulemaking on the Stark law soon and the same goes for the Anti-kickback Statute, which I'll discuss briefly. (Inaudible) Inspector General issued an RFI on the Anti-kickback Statute last summer as well. The comment period for which closed in October. Now, hereto, we're going to be very attentive to the need for program integrity. But in a system where we want to pay for value in part by giving providers more freedom to innovate, we have to look at current interpretations of the Anti-kickback Statute.

Now, some of the questions and reflections I told you about, sort of what we had heard somewhat on Stark Law, some we have heard include, how can we expect a provider to improve outcomes for say, a patient who has a poor track record of not showing up for their appointments? If we're not willing to look how a patient can get assistance in transporting them to those appointments. How can we encourage patients to take more ownership of their own health care without thinking about providing them, maybe free of charge with patient empowering technologies, heart monitor, tablet, something else altogether and here, I'm not really talking about the government per se, but about even private actors in this space and about their ability to provide these things.

Again, I'm not prejudging these things, these are just questions that have

raised. They're open issues about what we're going to do or allowed to be done in this space that both gets to the heart of the law that has to be enforced and also allows the new system to come into place. Now, in both the Stark and Anti-kickback RFIs, we received a lot of ideas, some good. Some possibly a little too radical to pursue without having more meat in developing areas, like defining a value-based arrangement or new program integrity measures. So, we're going to have to have more definition around this space, but we got a lot of great ideas. As I mentioned, this is a sprint, so we have a lot of ideas, many of which I'm hoping if we have time, that we will be able to have a round two possibly, if we can achieve that. We look forward to hearing comments and thoughts from stakeholders in the NPRN process, so once this is done, we'll have a rule that's going to be announced in this area. Notice to proposed rulemaking that will go into OMB. That's when you all will see it -- that's when it will pop up on the ROKIS (inaudible) system and you all know that it's out there right now. We're currently in kind of the very, very sort of fermenting stage of development of the rule, but we're very far along, I would say. But -- we are taking the questions and challenges that I was just talking about very seriously.

The final area I want to touch on is that, that pertains to coordinated care, also dealing with payments within CMS' Center for Medicare and Medicaid innovation or CMMI. As you know, Adam Boller who's the head of CMMI, is also the Secretary's advisor on value-based care. So, he's kind of wears two hats, so you know that CMMI is going to have a big role in our drive towards value. Now, in creating CMMI, Congress saw the need to give the Secretary authority to waive the Stark and Anti-kickback rules. Waivers have already been put in place for using the Medicare shared savings model as well as in CMMI models, Medicare Shared Savings Program as well CMMI models. Now, these coordinated care models are already proving successful in reducing costs, improving delivery of care and we believe with the right kind of bold experimentation, we can start seeing even bigger savings and improvements. Now, we had a huge number of providers who have applied to participate in these programs and a lot of success. There's enthusiasm out there for real

innovation in health care delivery systems and so I want to add on a note of optimism, looking at reforming particular regulations can sometimes feel like you're thinking pretty small. It's complex, it's off an unsung and unglamorous work, but consider some of the roles that say incremental plays in any system.

The internal combustion engine time changed in many fundamental ways, but over time, changes add up. I personally don't want an engine in my car from 1985 much less 1925. That system is pretty much the same fundamentally, as it was 30, 40, 50, 80 years ago, but certainly, they're not the same under the hood as they were before. We sometimes we have to think in these ways. We have to think about these -- all of the areas that were looking at. From the outside, it seems small, but when we think -- when we get through this work, we know we will have had reform. We no longer hold back innovation in our health care system and then, we can dream big. We all dream of a world where American healthcare is incredibly high-quality, but competitive, affordable, accessible and patient-friendly. And we can all agree, I think, that we don't live in that world today. To get there, we have to do everything we can so that healthcare can function with same levels of competition transparency and choice as any other market.

Thinking about the topics we're discussing today will be a vital piece of getting there. So, I encourage you all, bring your ideas to us. There is no idea that is too big or too small for this. We have some big ideas that were proposed, some of which I anticipate will end up in our reforms and there are an awful lot of small ideas that we got which are very worthy and which, as I say, in the accumulation of them are going to result in big reforms and big changes. So, we're looking at both these things not just trumpets blaring, here's the large reform, which we may well have, but also there's a variety of other small things I just want to level set for what this is exactly in the endeavor we're undertaking here. It is a sprint, that is, something that is going to focus on what we think are real, achievable goals that we can get the place really this year and the earlier the better in this year given the we have to coordinate across departments and across the entire

Administration on this once we get the rule done and out. And, of course, there will be another shot at commenting on the proposals when we eventually do put them forth and so, please weigh in on them as well. We want to hear what we're doing right as well as what we're doing wrong in this endeavor.

So, I think we can take a significant stride bringing our HHS programs and rules into the 21st century and deliver Americans the kind of affordable high-quality 21st care they deserve too. So, thank you very much for having me here today. And now I have a few -- time for a few questions on the regulatory sprint if you have any.

MS. BADE: Hi, my name is Rachael. I'm a healthcare in Politico and I was curious in doing the Stark Law and the Anti-kickback reforms if you guys are planning to address social determinants of health? That's something I was hearing from providers and being interested in like giving gift cards to help people pay for food or helping pay for internet connectivity for people who could benefit from Telehealth.

MR. HARGAN: Sure, so with regard to any specific issues, like any particular issues like gift cards or those, can't kind of talk about those. We're in policy formulation, like right now and rule formulation right now. With the question social determinants of health is a much broader issue. It is a very wide net, so there's many different ways you can look at it. The phrase doing anything from healthy communities and social structures, to the cordon, that sort of no wrong door approach that you often see that's characterized, this sort of integration of health care with social services, which Secretary Azar has talked about as well and it can focus on sort of the sprint itself and how we enable private sector in many ways to sort of help provide services, whether it's gift card or whatever is come up with out of there. So, again, I'm not prejudging what the team's come up with in here. There are -- that's obviously an issue that people have spoken about in this space. I have been talking about for quite some time, but we -- I think going to -- we got a lot of proposals in. They're in the pretty final stages within the department, I think, and agencies of getting a rule together that's going to address both of these things. A lot -- a

complication of which is the fact that we're endeavoring to make sure that the Inspector General's office in CMS are coordinated on the drive for coordinated care, which takes its own level of meta coordination between the agencies before, so that they get their -- they aim at the same targets in the space so with response to any particular areas where there's gift card, transportation, nutrition -- there's a lot of things that have been proposed in this area under the rubric of social determinants of health, but I think we are undertaking a lot of efforts to kind of understand that area and have meetings on the social determinants, but it can be a pretty broad area depending on who you talk to in that field. It's everything from community structures and family structures to, as you're pointing out, things like the integration of social services to particular issues, like gift cards, which are -- you know, then there's the sprint and then there's gift card. So, there's a lot of things packed into that and so, we're not going prejudge anything that the team's come up on a particular case like that. Yep.

MR. RICH: Hi, Jacob Rich, The Reason Foundation. So, HR6 had language that suggested substance use disorder diagnoses would be voluntarily shared with patient consent, so how will your regulatory reform affect that?

MR. HARGAN: Well, the Stark and Anti-kickback is going to be separate from what we do on 42 CFR Part 2. So, that's -- what I think you're point to there is the privacy issues dealing with substance use disorder and kind of how that is. That's obviously an open issue, that's why that's part of the sprint because we've had an awful lot of -- we've been hearing off a lot of problems from people in this space about balancing privacy concerns and also care in that area where we have a lot of areas where you have literally dozens of releases being (inaudible) going back and forth between care providers in a particular community. The legal issues and really the time constraints that it places on people who are trying to get access to care is a real issue. That is SAMSA and that is going to be the information sharing pieces with HIPAA which has current RFI outstanding, I think closes next month on that and SAMSA, which so Office for Civil Rights is overseeing HIPAA

and then SAMSA oversees 42 CFR Part 2 and they're going to stand out their own proposals on the information sharing side and so, I think we'll be able to address those a little bit. We may have another session on a sprint and another set of presentations on the sprint, but on that side of the information sharing side of the house as opposed to be affiliations and structural reform that we're dealing with on the Stark and Anti-kickback side. So, it'll have to wait to on that one, but we know -- we've heard the concerns certainly. Yeah.

MS. SIMON: Hi, I'm Rasha Simon and I'm a consultant and do most of the work in this town, I think, on non-emergency medical transportation. So, I was very pleased to hear you mention it twice in your remarks. And could you talk a little bit more about transportation because it does seem that the agency's moving in a lot of different directions, both with respect to, on one hand, moving to allow states to drop the benefit from Medicaid, at the same time, CMMI's looking at it and ambulance contacts and elsewhere and the program integrity contacts trying to get people going for dialysis out of ambulances.

MR. HARGAN: Right, so transportation is obviously a live issue in this area that covers a lot of different -- we cover a lot of different areas. I mean, we're aware of -- we're going to try to make sure we thread the needle so we don't have conflicts between the different initiatives that we're moving forward in the same area. Again, there is a certain underlying desire as you've seen the administrator at CMS has talked a lot about state flexibilities paired with accountability. That's kind of one of the themes underlined a lot of the reforms that she and the Medicaid team at CMCS is undertaking at that agency. So, they're trying to allow there being a lot more flexibility. That's obviously and it goes in a different way than private actors offering transportation, but it's not in conflict. I mean, those two things are not in in conflict by saying state may or may not, a private entity may or may not. Those aren't in conflict. They're simply allowing more freedom for innovation. In some ways, the idea that we cover transportation, again, I'm not going to second guess where the administrator or the states go in terms of offering those particular services. I'm anticipating

there's enough public support behind some of these things that I don't know where the states, any particular state would go if they rocker the flexibility. I think though you can see that there is a theme there. They're not necessarily in conflict, although I think -- I get your point. That they're people who want to get more transportation. See --

QUESTIONER: That's a social determinant.

MR. HARGAN: Yeah, and social determinants of health again, it can encompass a whole host of things. I mean, as I say, anything from the huge issue which I've had -- I had stakeholders in to talk to me about the very broad issues which deal with communities, families, social structures and sort of general social dysfunction, which is certain social determinant. They say, then you pack of down to transportation, nutrition and a whole host of issues that surround health care but aren't necessarily seen as health care per se and aren't covered in a health care services program, but which people say, this is important. Or they're matters of public health generally that broadly conceived. Those are -- that's another pack. Again, the Secretary's spoken on that, on the issue of how we thread those things, which Florida calls it no wrong door. There are other states that have initiatives where you're trying to make sure that programs that are intended to help the same person don't end getting -- yeah, you have 20 different numbers for same person to access 20 different programs they don't know about. Those are other initiatives. Some of which are harder to solve than others. Yeah, I can go on and on, but I'll stop there. Yep.

MR. COORS: Hi, there, my name is Rachel Coors, I'm a reporter with Inside Health Policy.

MR. HARGAN: Sure.

MS. COORS: So, we're talking about reforms to Stark and Anti-kickback. Senators Cassidy and Warner introduced draft text, they were released yesterday on talking about how they want to uni-reform or makes changes to Stark and Anti-kickback to facilitate outcomes-based or value-based contracts for prescription drugs. Is that something that you're also looking at?

MR. HARGAN: So, again, I'm not on the legislative side for this and so that kind of analysis, we really are focusing on to get this done, kind of Capitol Hill and the legislative side will be a totally different set of reforms and hopefully, they'll all be in accord with what we do on the sprint. That the kind of things that we end up reforming in this space will be completely in accord with a general, tone and tenor, where I think everyone wants to go in this space. Not everybody, but a significant number of people want to go by the majority of people that work in this space want to go here. So, hopefully that's additive to what we're doing here on the services side. Yep.

QUESTIONER: (Inaudible) NIH. How do you deal with mal (inaudible) of health care. You know, 60 years ago, Louisiana -- 60 years ago Louisiana had the highest, the worst outcomes in the country. Today, Louisiana has the worst health outcomes of a country with maternal, mostly mortality three times higher than the average and worst much for the African-American community. Are you, how do you -- if you have transportation, you'd like to get -- have doctors to go to and facilities to go to. So, how do you deal with that? There has not been a change for 60 or more years.

MR. HARGAN: I don't know that what will be discussed, I'll discuss here. The panel will deal with kind of maldistribution of health care. I mean, I hope that whatever we do in reform will help health care generally speaking, so, but I think that would be a topic for a completely different panel about that issue. Yep.

QUESTIONER: (Inaudible) Secretary, can you talk a little bit -- you mentioned in the -- whoop, thank you. Hi, Riley Swinehart with AdvaMed. My members are primarily interested in Anti-kickback Statute reform and we understand that there because there's a criminal law component to that, that there needs to be coordination with the Department of Justice. You mentioned in you remarks rulemaking that you are looking to coordinate with other agencies. Can you talk a little bit about any steps you've already taken with regards to DOJ?

MR. HARGAN: We have round everybody -- well, part of it is just generally.

The government is going to undertake once we send it to OMB. They will undertake to hand it around officially to the other departments that have equities in here. Pretty obvious DOJ has equities in something here as an enforcement agency, however, we also have an internal enforcement agency, the Inspector General who is actually looking and helping formulate drafting these sections. So, I know that DOJ and the IG have close relationships and I believe they've been talking to each other, not like, here's a draft to make comments yet, but the idea of like an overall formulation, I think we've been coordinated just internally and also, to some extent, externally. Although, there's a lot of work to be done here and a lot of it, I think requires the people involved to be sitting down and working through it. But there has been some coordination done, but there will be official coordination done at the end of this. So, when OMJ gets it, they farm it out to everybody who has equities, I'm going to say probably, DOJ is probably the largest player for this particular project that's outside HHS. So, we'll hear from them. I can pretty much guarantee that for sure. Okay, I think we're -- I think maybe done here but thank you all. Thanks for the good questions and wish us luck. (Applause) Thank you.

MS. YOUNG: Great, okay, good morning everybody. I am Christen Linke Young. I'm a fellow here at the USC Brookings Schaeffer Initiative for Health Policy and I am delighted to introduce our panelists this morning.

First, we have Kevin McAnaney. He's a lawyer in private practice. Earlier this morning, he was referred to as the world's leading Stark expert, which was meant as a compliment, so he's certainly in the right room today. He previously served as the chief of the Industry Guidance Branch of the Office of the Inspector General where he focused on industry guidance on Stark and the Anti-kickback Statute and we're delighted to have him with us here today. Kim Brandt is the principal Deputy Administrator for Operations at CMS. She focuses there on program and management on CMS programs and implementation of strategic priorities and cross-cutting initiatives. Previously she was the Chief Oversight Council at the Senate Finance Committee and the Director of Medicare Program Integrity at

the Medicare Integrity Group within CMS.

Dr. Bobbie Gostout joins us this morning. She's the vice president of the Mayo Clinic. She's the physician leader for Mayo's Community Practice in the Midwest, which includes Iowa, Minnesota and Wisconsin. Earlier she was dismissing all the fuss about the negative 30-degree temperatures of her homeland, so we know she's a real warrior. Better you than me. She's trained as an OB/GYN and a former head of the OB/GYN Department at Mayo.

And finally, Tim Gronniger serves as the president of Caravan Health. Previously, he was the chief of staff and director of delivery system reform at CMA where he worked on a variety of issues including creation of new payment models and other issues we've been talking about today.

So, with that, we'll go ahead and dive in. Panelists will each deliver remarks and then we will have some time for questions. So, Kevin is going to kick up off with a little bit of an overview of these laws and some of the legal foundation that we've been talking about today.

MR. MCANANEY: So, as a lawyer, my job is to be boring, so I will, just so we have it clear, so, I want to give a brief view of the laws and why they are so problematic for value-based arrangements. The Stark Law prohibits physicians from referring Medicare and Medicaid patients to any designated health entity, but primarily, hospitals are all designated health for services if they have a financial relationship which does not fit into a specific exception. It's a blank prohibition. It was originally -- its intent was to prohibit financial relationships that incentivize physicians to refer to particular entities. One thing that's important is Stark is basically a payment regulation. It's not a criminal -- it basically says, if you have a financial relationship that triggers the prohibition, you can't submit a bill to Medicare and Medicare can't pay. So, in that respect, CMS has a fairly broad authority to create exceptions to the law. The second thing is, virtually all the exceptions for compensation arrangements and that's really what we're focusing on here, have two major

components. One is, that the payment to the physician be fair market value for the services performed and second, that the payment not be determined in a manner that takes into account the volume or the value of the referrals. And those two requirements have problems.

So, the problem with the value-based payments in Stark is, virtually all value-based payment methodologies depend on creating networks of provider across the care spectrum and who were committed to high-quality cost-effective care and to get that you try to keep those referrals within those networks, within people that are guaranteed. Well, I mean, that's a problem because you're obviously directing referrals. The second thing is, is that even things like payments for reducing unnecessary care or duplicative care potentially trigger the prohibition on the value on payments taking into account the volume on referrals. Why? Because a service is less expensive to deliver by eliminating unnecessary care, is lower cost, but it's also therefore, higher profit, so it's a more valuable referral and so, therefore, even paying for reducing unnecessary costs may trigger this.

Then, the fair market value, unfortunately a lot of the court cases and the interpretations of what's the fair market value for physicians' service looks to sort of the time the physician spent in using a typical thing. That it's very hard to ascertain and prove the fair market value of a physician's service, its contribution to a greater team effort to reduce care that his piece may not directly reflect in a particular patient for a particular care. Another problem is any investments in the system, so to create these things, you have a very high IT to coordinate the care. You have a very high -- you want care coordinators. You have these investments in the system infrastructure. Physicians don't want to pay for that. I mean, they don't have the money especially on something that is unproven. They don't want to do it. Under Stark, if that's a benefit to them they have to pay fair market value and that becomes a very hard problem.

The last thing to point out of about Stark is any financial relationship between the hospital and the physician creates that financial relationship. Whether it

involves Medicare patients or not, so it stifles innovation by commercial insurance trying to develop these because that creates a financial relationship, that financial relationship has to fit in an exception.

The Kickback Statute -- and this is all obviously very high level. The Kickback Statute broadly prohibits any person from paying, offering, soliciting, or receiving anything of value in exchange for or to induce the referral federal health care patients or business. Unlike Stark, the ACS is a criminal statute. So, it's basically enforced by the Criminal Division of DOJ. These are people that are not regulators. And what it says is DOJ has actually the ultimate authority. Having written safe harbors on the HHS side, I can tell you, yes, we can do them, but ultimately, the Justice Department is the 500-pound gorilla and they have a lot to say.

The second thing is, criminal prosecutors are risk-averse. They would rather chill a hundred people that are okay than let a bad guy go. And that's just -- and you can't blame them because the people they see, the actors they see are typically pretty bad guys. So, they have this world view that these people are all out to rip us off and it may be skewed, but that's what you have to deal with. Now, the problems with the Kickback Statute are similar to Stark. One is its payments to induce the referral -- well, as I said, most of these systems are trying to keep patients within a referral network. So, by definition, they are really treading close to the line in any -- under the Kickback. The second thing is, these investments become very hard because even if the investment -- so, if you're giving a physician IT that coordinates care, physicians tend to have a single way they practice. If they think it's good, they're going to send all their patients that way, not just commercial. And so, t here's this sort of tagalong effect. So, even if you're doing it for a commercial, or if you're in a one of the waivered programs, those benefits will also accrue to fee-for-service patients and Medicare fee-for-service will tend to use them. That's a potential kickback. So, those are the two statutes.

The last thing to know is the enforcement of these statutes is not the

government -- that the fear here if you're in this sector is not the government. It's the False Claims Act. And a False Claims Act case can be brought by anybody in the name of the government. We call them whistleblowers, some call them bounty hunters, but anyway, they can bring these cases in the name of the government. The penalties are three times the amount of the claim and a mandatory, I think it's $15,000 per claim now. So, if you're looking at a value-based system, which is basically going to have almost all of your key physicians are going to be in that. You're talking a potentially a huge number of claims, a huge number of referrals that this is an existential threat and so on account of that, any ambiguity here is what is going to be resolved against going forward. So, it really is a significant chill on a health system that's really trying to implement these programs. So, with that, I will stop.

MS. YOUNG: Great. Thanks so much Kevin. Kim, why don't you take over from there and talk a little bit about some of the work you've been doing at CMS.

MS. BRANDT: Sure, thank you so much. The disadvantage of being the only government person on this panel and having your boss go first is, you're not left with a lot to say. You've heard a lot of it, but I want to reiterate a few of the key points that he made and maybe go over a couple of additional things.

First of all, as the Deputy Secretary mentioned, a big part of this effort, particularly when we look at it from a Stark perspective, is how we can focus on value and healthcare and really the shift from fee-for-service to value-based care. The reality is, as they say, it's not your father's Oldsmobile anymore, but we're kind of moving into a new payment model, in a new world and we really understood that we needed to think about how we can use our regulatory authority to make those changes.

The challenge is that while we have a pretty wide swath to make changes within the Stark Law, we also can only go to a point. As was evidenced by one of the questions earlier, there are legislative changes and statutory changes that only Congress can make. For instance, we cannot do away with the Stark Law. Only Congress can do

away with the Stark Law. Only Congress can make certain changes to really broaden some of the applicability of certain parts of the Stark Law, but within the confines of the current statute, we think that we've got a wide flexibility and there were a couple of reasons why we decided with the Deputy Secretary's leadership that Stark was a good place for us to really take a hard look.

The first was, as he mentioned, in our payment rules last year, the administrator was really interested in hearing about regulatory burden. So, in every single one of our payment rules last year, we put out a request for information asking for people to give us comments on where they thought the greatest amount of regulatory burden was. The number -- one of the top four things we got and sort of one of the biggest areas of comments that we got was related to the Stark Law. There were a lot of people who felt that the amount of burden and the amount of uncertainty and lack of clarity and just sort of lack of just direction generally, with respect to the Stark Law was a real impediment to them being able to provide value-based care or value-in-care generally. It was also stated in the way of their ability to coordinate care. And that is something that to make sure our beneficiaries are getting the care that they need and make sure we're providing the best value in health care was really something the Administrator thought we needed to think about.

So, as a result we went and as the Deputy Secretary mentioned, put out a request for information specific to the Stark Law last June and received 375 comments, totally about 3,500 pages. Yes, I have read them all as a team of ours and some of our OIG colleagues as well. So, many of us had to upgrade our prescriptions on our glasses as a result of all that. But I will say that the comments that we got as the Deputy Secretary mentioned, were extremely thoughtful and really gave us a great insight into where it is that people were having the impediments to value-based care and where they were care coordination issues.

When I was at the Senate Finance Committee, we did a similar type of

outreach, where with the Ways and Means Committee, we asked for people to send in comments on how we could change the Stark Law. A number of those were very good as well, but a number of them were unrepeatable because they used certain language, such as, get rid of the whole blanket-blank law and things like that.

These were a little more substantive and the average length was about 50 pages, but what I really thought was so striking about them was the number of very specific examples that people gave us, such as we would love to do this type of value-based arrangement or we would love to think about how to integrate social determinants of health, or do certain types of things to really be able to better serve patient populations and move towards more value-based types of arrangements, but we don't think we can because we have these impediments. And this is where the Stark Law is not serving its purpose.

We also had a number of commoners who wrote in and really stressed the need for the balance. They were concerned that we would go too far and that we would no longer have the appropriate guardrails or the parameters around it to ensure that there would be some sort of check against unnecessary referrals or unchecked types of care coordination where perhaps people would be able to skirt the law and hopefully wouldn't have quite the same level of bad actors that Kevin was referring to that DOJ deals with, but you know, it is the sort of thing that if you give people an inch, sometimes, they'll take a mile. So, we really needed to think about in the commoners told us, really try and make sure that you're hitting that balance between how it is that you can be more flexible and think more innovatively as you move towards the value-based care and care coordination, but at the same time, make sure you're still keeping those safeguards because we think those are really important to make sure people aren't going to go forth and just take unnecessary advantage of this.

So, I think when it came down to it, we really ended up with about six buckets that really are aware, hopefully as the MPR interim comes out later this year, you'll be able to see the types of things that we've been really trying to focus on. The first area

that we heard a lot about as I mentioned, was on the alternative payment models in care coordination. People asking for, should there be specific exceptions; what types of exceptions; how would those exceptions work; how do those work with existing exceptions. Now, exceptions are a popular theme here. There was a lot of discussion about how that all plays out and sort of what should stay and what should go and how we should think about that in the new world order.

One of the things that came up, which was something that we hadn't really thought of and the OIG heard quite a bit about this and then Anti-kickback solicitation as well, was in the area of being able to donate cybersecurity technology. To be honest, it wasn't really something we had thought a lot about at CMS. Obviously, cybersecurity is a big issue for everybody right now. Nobody wants a data breach; nobody wants that to happen, but we hadn't really thought about how that works in systems where a hospital system has asked a physician's office to put a certain type of cybersecurity software in place. Are they allowed to give that to them or not? How does that work? We also had a lot of questions about that with electronic health records and that kind of technology, particularly in coordinated care types of settings. So, those were really good comments because they were things that I think conceptually we knew were potential issues, but we hadn't really thought about the practical impact of those. And it was really good for us to hear about those.

I would say the number one thing that we heard, and this was not a surprise to me because Kevin pretty much calls me on this every week is clarity. They really -- the commoners were very clear that they wanted clarity in the definitions. Commercial, reasonableness, fair market value and volume over value. Those types of definitions have consistently been less than clear and have been things that have really caused a lot of constructive debate in the industry and have been things that people have felt that without clarity in those definitions has really held them back from being able to know where the line is and then puts them at great risk for those enforcement actions that Kevin was talking

about with the Department of Justice.

The last two things were sort of again, sort of making sure that any new exceptions that we got in would not exacerbate the ability to basically have over utilization or other types of harms to the program. So, again, we wanted to have that balance. And then finally we just got a lot of feedback on technical types of issues, signatures when signature requirements should be in place; what type of compensation is okay to be able to do in cash versus in kind things that ultimately impact a lot of rural facilities in particular. They were very concerned that they weren't getting caught and kind of a Gotcha game just by trying to do business and they didn't really have Stark experts on staff to be able to tell them, is it okay if we provide pizza to our attending doc who got caught because it's minus 60 outside and he couldn't get home.

So, those are the types of things that we looked at. Just real quick to finish up because I'm over time, but I really wanted to stress in finality that one of the things that we have been doing, and I think that you'll hopefully see the outcome of when both are in PRM in the Anti-kickback in PRM from LIG come out, is that we have been coordinating extremely closely with the Inspector General's office. We've had extensive conversations. Both teams have read each other's comments. Both teams have been coordinating throughout and we understand the need to make sure that there is good coordination and that we are thinking about the impact each of our particular regulations have on the other. Because we know that's one of the things that really came out loud and clear too, was that people were very concerned that we were kind of operating in autonomous universes without talking to each other, evidenced by the fact, not to pick on Vicky, but Vicky Robinson from the OIG's office is here today, but we have been working very closely with them and I hope you'll see that in the comments. So, with that, thank you.

MS. YOUNG: Great.

MS. GOSTOUT: Good morning. I will be addressing you from a very different perspective as a practicing physician and as a leader in in Mayo Clinic. So, many

these terms and details about the Stark Law are not all that familiar to me, but I can feel the chilling effect and I think I prefer the cold thermometers in Minnesota, the chilling effect of some of this regulation. But let me tell you a little bit about, first of all, Mayo Clinic, who we are. We are an academic, a not-for-profit medical center. We are known for our unique place in the nation, in the world as a place for serious and complex illness. We have three destination medical center sites, Rochester, Minnesota, Phoenix, Arizona, and Jacksonville, Florida. We serve more than a million patients a year and see them for a wide variety of concerns. We have about 65,000 staff members who come together to care for these patients. They come from all 50 states and they come from 140 or more different countries on an annual basis in order to get care at our unique site.

Now, unless you are from the Midwest, you may not have ever known that Mayo Clinic also has the health system, the part of our enterprise that I oversee, which serves for a community care network in a range in a 120-mile radius around our Rochester site. So, the aspects of longitudinal care and keeping people healthy over a lifespan is something that's very real to me. That means I get to live kind of in both worlds. My practice as a gynecologic oncologist is in the destination medical center, complex care world. And my leadership role is in the community practice with that longitudinal care. And it gives me a great chance to see health care in both of those -- through both of those lenses. At Mayo Clinic, our primary value is the needs of the patients come first and we really tried to live up to that with every encounter and it in the way we structure the care that we provide and the teams that we form.

Another thing that's very dear to us is teamwork and collaborative care. So, Will Mayo, one of the founders was famous for having said in order to get the best care to our patients, a union of forces is required. And that was very prescient when you think of him saying that 150 years ago at a time when most people were practicing in individual silos. But the value-based world that we're moving to really does require that we get very, very good at this union of forces. And that partnerships and collaborative networks is really what

it's going to be all about in order for us to achieve our goals as a nation in providing the best care to our people.

So, what does value based care mean? And how does it translate if you're a clinician? It starts with the real fundamentals of saying, get the right diagnosis the first time. It means don't do unnecessary procedures or have unnecessary care delivered. It means keep people out of hospitals and emergency rooms by keeping them healthy enough that they don't need that site and it means making sure that our population has got access to the preventive services they need to stay healthy. So, each aspect of that has to be in place in order for us to really work toward our dream of the highest value care that we can offer to Americans.

Let me give you one example of the weird interplay that this can mean sometimes we created a clinic called a complex diagnostic clinic and the purpose of this clinic was to take patients from around the globe who are just having trouble getting an answer or getting a diagnosis, but everybody knew something was wrong and saying, we'll form a network around these people and we'll work very hard to say with intensive work over the course of usually a week, we will strive to get answers.

So, in the first year of this clinic, we served 286 patients and 88 percent of those patients left with a new or refined diagnosis. Now, that time in the complex care clinic was a very resource intensive time. Might sound like, is that value? But the important point is if we don't get the fundamentals right, if we don't have the right diagnosis, we're going to be wasting a lot of time, effort, and resources in giving the wrong care rather than getting people better. So, it's really important that we understand value and that we continue to drive toward it.

As I said, I'm a clinician. I was in the clinic last week and then in the operating room on Friday, I'm in close touch with my team and in close touch with my colleagues at Mayo Clinic. And importantly, I also have a strong network of associates and colleagues across the nation and I feel very much in tuned to what it means to have chosen

health care as a field. And one of the things I know for sure is nobody decided to go into medical school or nursing school or physical therapy school because they wanted to really focus on process and policy. We all chose this because we want to get people better. We want to make a difference in their lives. And by nature we are collaborative, we are good listeners, we are innovators and we are passionate on behalf of helping our patients. So, if as policymakers and leaders of the nation, you're able to really focus us on what is the vision and I will say high value care is an exceptional good vision for us. If we can focus on the vision and then focus on getting out of the way, then this team of people that I know so well who come to work every day to serve our patients will have the best chances to use their passions in order to make this the healthiest nation that we can be. Thank you.

MS. YOUNG: Thank you so much, Tim.

MR. GRONNIGER: Thank you. And I'm really happy to be here on this panel and I appreciated the remarks from Secretary Hargan earlier. And I want to start -- I'm going to make some comments that two main buckets, drawing on my time at CMS, how to think about some of the policy issues at play here. And I now work at a company called Caravan Health. We support 225 health systems serving about a million Medicare beneficiaries working in ACOs across the country. So, I'm going to provide some anecdotes from my --- how these issues come up when I talk to hospitals and physician leaders sort of on the ground day-to-day level.

First, I want to commend Administrator Brandt and a Secretary Hargan on the process they're following here, going through an RFI, collecting comments, then getting into rulemaking, coordinating with law enforcement is agency's is one of the hardest ways to make rules in a CMS land. And you end up in the weirdest places sometimes. You find out that they have -- and I'm just certainly not speaking from any inside knowledge on this, but perhaps they have cases in the pipeline that are implicated by policies that you're making. Perhaps they have longstanding interpretations, so it's really hard to go through this process and -- but that you're -- I think you're following the right

approach here. And I also want to second that idea that whatever we do, having clarity around the rules is really important and we don't have clarity at all right now in a lot of these contexts and that's what causes a lot of the confusion and a lot of the lawyer -- the expensive lawyers' bills for systems that often don't, can't afford it. And I say that advisedly on a panel with three lawyers. But the reality is there are a lot of lawyers involved in this conversation.

So the, the first place I want to start is just around the policy issues around patient protection. So, these rules are old. They came about at a time that is not that far from today where there are very strong fee-for-service incentives to provide unnecessary tests and procedures that can be very harmful to patients. You don't have to look very hard to find examples of combination of hospitals and doctors trying to do unnecessary implants and cardiac defibrillators or do unnecessary spinal fusion surgeries and these laws are one set of brakes on some very strong fee-for-service incentives. They're not the only set of breaks, but it's really hard to catch perpetrators of those in real time. And so putting some brakes on responsible actors in the system, which are often health systems and their team of risk averse managers, it makes sense to have some self-vigilance in the industry here and to be cautious in how we go about creating new exceptions in safe harbors and the like to protect against really egregious behaviors. Not that those are really the new norm, but they are real and something that really needs to be caught off for beneficiary protection concerns. That said, in practice, I think it's clear that we probably haven't gotten the balance of protection and reasonable regulation right here. The fear of Stark and Anti-kickback color is basically all conversations between doctors and hospitals and I think is one contributor to unhealthy relationships between physicians and hospital leaders in a community. Physicians do not -- nobody understands these rules, even experts, except for possibly Kevin, but basically, no one else in health care does and even ones who work on this stuff for years at CMS and elsewhere view this is sort of the underbelly of payment reform where yes, we need to do something about it. But man, I'm really not sure what. And so, hospital

administrators, physicians, when this comes up in their world, it's their lawyers telling them, no, you can't do that because you might go to jail. And that's sort of the end of a conversation around a whole bunch of potentially worthwhile innovations. You never really know what innovations are not happening, but I think that the, the penalties are substantial enough here that they're probably real.

Interestingly, the Innovation Center at Medicare Shared Savings Program Waivers are the only game in town around this and a lot of cases. And those are very useful. Most of our clients rely on those to fund investments in certainly information technology, but also investments in a management structure to support working in an accountable care organization without those waivers. None of the ACOs -- we would have a ACO program that's 10 percent of its current size, probably composed only of health systems that employ their own physicians and very small physician led ACOs. So, those waivers are great and they're important. But I think that you could probably make an argument that they sort of unfairly prefer a CMS directed models, which I again love and have been involved with in many cases, but I think there's probably some innovations that could be driven by the private sector here that are just not even contemplated because of the structure of the waiver policy that we have today.

And so on the third hand, I think that we have to keep in mind that the risk bearing is not that widespread at this point in time. Despite, as Secretary Hargan said, you can see the light at the end of the tunnel and we need to lay the tracks there. We can't forget about the other pieces of the engine here. If you create a system that allows the hospital or a physician group to reflect lower cost to themselves, there is no guarantee that those are going to be passed onto other actors in the system, whether they're private payers are Medicare and so, policy and market structure is ultimately going to determine how patients and the government can benefit from these changes. And so, it's really important to continue and even accelerate efforts to reform the underlying fee-for-service system, which is still the majority of payments here.

I think it's also worth talking about that Congress likely needs to be involved here. I don't want to get into that in great detail now, but I'd be curious to hear what others on the panel think about that. I think that this is really hard to tackle just from an administration perspective and so some statutory involvement here is likely to be necessary at some point.

MS. YOUNG: Great, thank you. And actually why don't we start by picking up on the thread that Tim just introduced, which is how much can be done through administrative action versus what will ultimately require legislation and what the prospects are for legislation given that there seems to be widespread bipartisan agreement that reform is needed and sort of a sense of what sorts of reforms are useful. So, Kevin, do you maybe want to start us off and then folks can jump in as they have thoughts.

MR. MCANANEY: I think legislation would clearly be most useful in the Kickback Statute because that's a criminal statute. We don't do a lot of regs around criminal statutes. And so I think if Congress has the authority to create a very broad exception that -- and basically if Congress speaks justice has to listen to. So, I mean with the rest of us talking, justice doesn't have to. So, I mean that's clearly the single most important legislative piece. I think -- I mean Stark, there are pieces that that could be clarified, that could be fixed a legislatively. I think there are regulatory work arounds, but clearly the volume and value, some of the definitions in terms of when they apply to a bundled payment I think could be fixed in a way that would be simple, but I think the big change that Congress could do would be the Kickback Statute would be by far the most important.

MS. BRANDT: And I'll jump in, I think -- I won't speak that Anti-kickback because that's outside of CMS' purview, but with respect to Stark, we believe that we've got a fair amount of flexibility within the confines of the crime statute, but obviously it's always helpful if Congress takes a legislative action. So, if for instance, we would do a proposed rulemaking or even final rule making which had clear definitions in it that Congress would then want to codify into statute or things like that. It's always helpful because if you've got

something in statute, it's a little more permanent than it is with regulation. That the flipside of that is, regulatorily, we can always make tweaks and changes where it's much harder to do that with statute.

As to what the prospects are on that, I think there has been a little bit of interest as evidenced by the question earlier and starting to introduce some legislation related to this. There was legislation the last couple of Congresses around certainly technical violations of the Stark Law and how to handle those. I expect to see something like that backing in this year. So, we'll just see. But our goal is to work very closely to make sure whatever we do does not sort of go at odds with whenever Congress would intend to do.

MS. YOUNG: Great. All right. I'm going to ask one more question and then we will open it up to the audience. But I heard a lot about sort of two different themes from you all from the Deputy Secretary. The first is the need for clarity, that there are enormous penalties here. Stakeholders need clear, bright line rules about how they should be behaving. There was also a lot of talk about innovation, we have a set of laws that was written in one environment, we are now in a different environment and there's sort of a need for updating and for allowing continued innovation in this space. Do you see a tension between those values, between providing clarity and certainty about what we are doing now, but also not stifling additional innovation and putting us back where we are today with rules that don't work for the existing models five, 10, 15 years in the future. And if there is a tension, how do you think it can be resolved?

MR. HARGAN: Tim, do you want to take that? You've looked at it more?

MR. GRONNIGER: No, I mean, I think that it is a tension. I think that it's -- this has been a laggard parts of payment reform I would say. And it's been dealt with initially by waving big pieces of it, but not really trying to reconcile them the multiple versions of payments that Medicare and other payers have out there. So, this is why I think having Congress involved at some level is important. Congress has been involved in payment

reform pretty extensively and I think clearing up criminal statutes that really get into Medicare payment policy prerogatives is also a place where only Congress can really play. So, I think that ideally we would have -- this would be sort of a low enough wattage issue that it could be dealt with iteratively and not something where it's like you get one bite at this, so every 10 or 15 years, because I don't think that it's a clear enough set kind of policy solutions where you can -- where you'd want to do this in a big bang approach.

MR. MCANANEY: I would just say I don't think they are that much in conflict. When people talk about clarity, they're really talking especially about Stark about the current regulations and the definitions of what triggers it. In terms of an exception, I do think that that the exception needs to be broad and flexible. The problems with whether it's the Stark exceptions or the Kickback safe harbors. They've been so narrowly written that there are so prescriptive that, in fact, they don't really succeed that they're too prescriptive, they become too restrictive and they don't promote real innovation in the delivery of care.

MS. YOUNG: Questions from the audience. Right over here.

QUESTIONER: Hi. Well, first I'd like to thank you all for your perspectives and obviously, thanks to Brookings for hosting event. Maybe just sort of following on that last part of the conversation. It seems like we're talking about a range of different Stark in Anti-kickback problems and in terms of maybe what new legislation could do, is it maybe more beneficial to separate out some of the issues relating to kickback and program integrity that might be made more straightforward, like medical products and how they might be used in kind of unique value-based arrangements versus some of these other areas that still seem to be kind of very undefined. Like when we talk about integrating social determinants of health. So, kind of thoughts from the panelists about if separate safe harbors are exceptions would be better, or if it would be maybe more expedient to roll it all up into one.

MR. MCANANEY: I don't I -- yes, there are clearly some specifics in terms of value-based payments between device manufacturers in pharma that that can fit into the existing -- I mean, there are existing discount exceptions and safe harbors that could be

fixed, but in terms of these value-based arrangements among providers, I think a broad, flexible regulation should -- is an easier way to go. I think, as Kim just pointed out, regulations allow some flexibility. I think they should go as far as they think they can go and then they can dial it back. I frankly think the risk to Medicare and Medicaid now, is greater from the increasing costs then than it is from so called abusers' overutilization. I think that in fact, there's a lot more money to be saved by promoting a cost -- value-based arrangements then is it risk really from doctors overutilizing doing bad things? I mean, not that we shouldn't go after them, but I think the greater risk is not trying to get system reform.

MS. BRANDT: And I think that that's what we're really trying to go at and why we're working so closely with the OIG to make sure as we look at these exceptions, that we're sort of a coordinating with each other to make sure that they will allow the greatest flexibility because again, from a programmatic perspective, we want to promote that value, as you heard that's one of the Secretary's top four goals. That's certainly a key goal of the administrator and we want to promote that value and so if we have things like the Stark Law which are stopping people from going to those models, as Tim was out and some of the other panelists have mentioned, I think that's something that we really are trying to take into account as we look at how we update the Stark Law.

MS. GOSTOUT: I'll just comment also. I think you raised such a good question because you describe two very different realms where these same principles can play out and as a leader in health care, I think the question we ought to ask in answer to yours is, are we going to get the most precise guidance by separating those because the language and the content and the context are different, or are we going to be able to simplify and have one, but if separating is saying there's more than one domain here and the concerns are different in those domains, if separating give us more precise language, I'm all in favor of it because right now, I've got finance people and legal people and compliance people all running in the background trying to figure out does this work, does that work? Are we close? We don't want to be anywhere close to the line because the hazards are so great

for our organization and we intend to thrive as an organization and keep helping people who need health care. So --

MS. YOUNG: And that's you don't want to get in the way of being able to provide that care.

MS. BRANDT: That's right.

MS. YOUNG: Yes ma'am.

QUESTIONER: Again, thank you for being here. I just have a question. Since the laws are quite old and they were made so long ago and obviously, now we have new issues, so we have a more of an issue with prescription drugs over prescription. So, how is any reforms going take that into consideration? Also in the sense of doctors being I guess influenced or having incentives by pharmaceutical companies with prescribing of a particular kind of drug because for example, with opiates is a big problem and it's sort of like a follow on effect if you over prescribe opiates, it's putting more cost on the system of Medicare and stuff like that.

MR. HARGAN: So I'm just, I'll give a quick response. I mean, most of what we're talking about is it about relations between providers. I think that a lot of the concerns around pharmaceutical companies, sponsorships and consulting fees is something that is real and it's something that I've worked on in past lives and there's now Sunshine Act that require disclosure of that information. But I don't know if there's any real Anti-kickback Statute implications at this point in time.

MS. BRANDT: And I would just say just that jumping on, I help oversee our opioid efforts at CMS and we have been very focused on, as Tim mentioned, not only looking at Sunshine, making sure that people are reporting their relationships, we enforce that at CMS, but then also on the opioid side, we've been very focused on over prescribers and high utilizers and making sure that we do identification of them and make sure that we flag them and make prescribers aware that they're being watched so that we're hopefully curbing those types of behaviors as well.

MR. MCANANEY: And I would just say the False Claims Act, there have been -- there are a lot of people that have -- are keeping close watch on the pharmaceutical companies. They've been sued for and settled cases for virtually every kind of physician interaction action they've got. So, I think you've seen a lot of self-policing, again, for the same reason that we said before. So, I do think that the Kickback Statute has been an effective deterrent in that regard, at least going forward.

MS. YOUNG: Great. Well, I think we have time for one more. Yes sir.

MR. VOMET: My name is Kane Vomet. I just have a quick question for what does the panel think of the providers who are currently pursuing the direct primary care models and some of them are currently in between primary care, didn't want to take Medicare. The current legislation, how do we provide for those, especially like the technology back ventures and they still want to refer their patient to the hospital.

MR. GRONNIGER: So there are a lot of models out there, right. And I know the Innovation Center has expressed an interest in furthering a direct contracting model and there've been a lot of rumors about what that's looked like. There's been a lot of listening on that. We are anxiously waiting with everyone else to see what that is going to turn into a and direct primary care specifically has been an innovation in a number of pockets around the country. And I haven't heard of any legislation that's moving on it anytime soon. We view it as a closely related to ACO work from our perspective at Caravan, but I don't know if Kim, you want to say anything about innovation center work?

MS. BRANDT: No, I would just echo what Tim said in that it is something. We have a number of models that are under development at CMMI. We've been talking about a lot of ones that would involve primary care. We've done some requests for information and got a lot of good feedback and so I think we're constantly trying to figure out how we can make them as efficient as possible. I'm not aware of anything legislatively moving on that either but stay tuned because we're constantly issuing new models and constantly having new things coming out at CMS.

MS. YOUNG: Great. Thank you so much. Well, please join me in thanking our panelists this morning. (Applause)

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