Hearing on Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program

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HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES

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Hearing on Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program

U.S. House of Representatives,
Subcommittee on Human Resources,
Committee on Ways and Means,
Washington, D.C

WITNESSES

Eric Hargan
Deputy Secretary, Department of Health and Human Services
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Gary M. Kirsh, M.D.
President, The Urology Group
Witness Statement

Mike Lappin
Chief Integration Officer, AdvocateAuroraHealth
Witness Statement

Brian DeBusk, Ph.D., M.B.A.
President and Chief Executive Officer, DeRoyal
Witness Statement

Claire M. Sylvia
Partner, Phillips & Cohen LLP
Witness Statement

WAYS AND MEANS
CHAIRMAN KEVIN BRADY

Chairman Roskam Announces Hearing on Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program

House Ways and Means Health Subcommittee Chairman Peter Roskam (R-IL) announced today that the Subcommittee will hold a hearing on "**Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program."** The hearing will examine the need for and possible solutions for modernizing physician self-referral law, or "Stark Law," to increase the ability of the Medicare program to successfully move to a system that rewards higher value, coordinated health care over volume. **The hearing will take place on Tuesday, July 17, 2018 in 1100 Longworth House Office Building, beginning at 2:00 PM.**

In view of the limited time to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit written comments for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, http://waysandmeans.house.gov, select "Hearings." Select the hearing for which you would like to make a submission, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, submit all requested information. ATTACH your submission as a Word document, in compliance with the formatting requirements listed below, **by the close of business on Tuesday, July 31, 2018**. For questions, or if you encounter technical problems, please call (202) 225-3625.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve

the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission not in compliance with these guidelines will not be printed but will be maintained in the Committee files for review and use by the Committee.

All submissions and supplementary materials must be submitted in a single document via email, provided in Word format and must not exceed a total of 10 pages. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. The name, company, address, telephone, and fax numbers of each witness must be included in the body of the email. Please exclude any personal identifiable information in the attached submission.

Failure to follow the formatting requirements may result in the exclusion of a submission. All submissions for the record are final.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202-225-1721 or 202-226-3411 TTD/TTY in advance of the event (four business days' notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Note: All Committee advisories and news releases are available at http://www.waysandmeans.house.gov/

MODERNIZING STARK LAW TO ENSURE THE SUCCESSFUL TRANSITION FROM VOLUME TO VALUE IN THE MEDICARE PROGRAM

Tuesday, July 17, 2018
House of Representatives,
Subcommittee on Health,
Committee on Ways and Means,
Washington, D.C.

The subcommittee met, pursuant to call, at 3:43 p.m., in Room 1100, Longworth House Office Building, Hon. Peter J. Roskam [chairman of the subcommittee] presiding.

Mr. Smith. [Presiding.] The subcommittee will come to order.

Good afternoon. Since we had a later start than originally anticipated, let's go ahead and get started.

For quite some time now there has been a discussion around D.C. about moving the Medicare program toward a value-based system as opposed to the volume-based system that the traditional fee-for-service system has lived under for over 50 years.

During the last 20 years there has been some movement in this direction -- on a bipartisan basis, no less. A revamped Medicare Advantage program, a new prescription drug benefit in Medicare, and the start of Medicare's Shared Savings Programs, known more colloquially today as accountable care organizations or ACOs now, were each one additional step towards achieving higher value and coordinated care for our seniors.

Fast forward to 3 years ago when we passed the MACRA law that repealed the onerous sustainable growth rate, another legacy law of a different era that was creating undue yearly burdens on both our Nation's clinicians and, in turn, patients. MACRA implementation is well underway, encouraging providers of all types to work together to reduce costs and to increase the quality, value, efficiency, and coordination of care steps further.

However, there are certain laws that have long been in place to protect the program and patients but now stand in the way of making real progress toward the goal of value over volume.

Today we are here to talk about the physician self-referral law, or Stark law, and have an intuitive discussion as a first step towards what I know to be a needed modernization of the law.

Stark Laws were and in many ways still are necessary to ensure patient safety and a safeguard over taxpayer dollars. These laws essentially prevent physicians from making referrals to entities that provide certain services if they have any ownership or financial stake in that entity.

Now, understandably, that is an oversimplification, particularly now that the web of regulations borne out of the laws are nearly impossible to navigate without legal assistance.

In a world where we are now pushing our providers to work closely together to bring down costs and in many cases share in the savings that they create, we need to update the laws to give providers an easing of burdens and give the Centers for Medicare and Medicaid Services more flexibility to supply waivers to these providers to get into these high value arrangements.

For the sake of avoiding getting repetitive I will say just one more time, the goal here is shared by all: better care for Medicare patients. We will hear from the Department of Health and Human Services today and then from providers who will share their knowledge and experience to set the table for what I hope will be an ongoing and robust discussion going into next year.

Without objection, we are going to move to 4-minute member questions today in the interest of finishing up before votes.

Without objection, so ordered.

Let's get right to it. Let me just welcome the ranking member, Mr. Levin, for purposes of his opening statement.

Mr. Levin. Thank you very much.

As I know firsthand, and as do my colleagues who worked with us together on healthcare reform, at the heart of ACA was a recognition that we must transform how we pay for and deliver healthcare in this country.

The law gave providers tools to establish accountable care organizations, bundle payments, and other groundbreaking ways of paying for care. It also created the Center for Medicare and Medicaid Innovation, which tested many value-based payment models under the leadership of the Obama administration.

These reforms have ushered in an evolution in healthcare delivery that we are witnessing unfold every day in our districts.

As we enter this new landscape we have begun to hear calls to revisit certain other laws that have been in existence for many years. Today we are discussing whether several laws that prohibit physician self-referrals in Medicare, collectively known as the Stark law, with whom a number of us served, should be reexamined in the light of our shift to a value-based payment system.

On this issue we must proceed with care. The Stark law is an important tool that for nearly 30 years has protected Medicare beneficiaries from inappropriate referrals and overutilization of care. Despite its complexity, the core principle of law is a simple one: The physicians should not make referrals to entities in which they or an immediate family member have a financial interest.

Evidence continues to document that these self-referrals have a detrimental impact on care. For example, a series of reports by the Government Accountability Office found that an exemption in the law permitting self-referrals for in-office and select services has directly increased overutilization and raised Medicare spending by billions of dollars.

However, the incentives that exist in a fee-for-service healthcare system are not the same as those in a value-based system. Integration of care may in certain instances involve financial arrangements that do not violate the basic spirit of the Stark law.

We recognized this fact when we passed the Affordable Care Act, providing waiver authority to allow for providers to establish ACOs and other arrangements.

In addition, the Obama administration provided leeway through the regulatory process to facilitate new payment models. More recently, an ongoing request for information will provide additional information as to what may be done using existing statutory authority.

Before considering legislative action I hope that this committee will proceed with a process that befits an issue of such sensitivity and complexity. Unfortunately, no witnesses from the Office of the Inspector General or the Department of Justice were invited by the majority to join us this afternoon. It is critical that it be corrected soon.

Finally, it is ironical that this subcommittee is considering the impact of the Stark law on the value-based approach of the ACA at the same time the Trump administration continues to raise costs and reduce access to healthcare in its never-ending zeal to sabotage the law.

In the last few weeks it has refused to defend protections for Americans with preexisting conditions, stop risk adjustment payments to health plans covering sicker patients, and again slash payments to the navigators that help people access health insurance.

These and many other misguided efforts are raising costs for those Americans who need healthcare the most.

We should be examining and responding to this growing threat to affordable healthcare. Instead this subcommittee has exacerbated it through its silence in the face of regulatory sabotage and its own legislative efforts to rip coverage away from millions of Americans.

I yield back.

Mr. Smith. Without objection, other members' opening statements will be made a part of the record.

I would like to introduce our first witness today, as we are fortunate to have him. He is leading the administration's efforts to modernize the Stark Laws on the regulatory front: Eric Hargan, deputy secretary of the Department of Health and Human Services.

Thank you for being here. And you may begin your testimony.

STATEMENT OF ERIC HARGAN, DEPUTY SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Hargan. Mr. Smith, Ranking Member Levin, it is great to be here today.

As many of you here know, Secretary Azar has outlined four priorities for HHS: reforming the individual market for health insurance, lowering the price of prescription drugs, taking on the opioid crisis, and putting in place a healthcare system that emphasizes value and outcomes over procedures and spending.

The aim of all of these priorities is to provide quality care for the American people.

Regulations, especially ones like the physician self-referral law, commonly referred to as the Stark law, can hinder the development of newer and better ways to help Americans live healthier. These regulations affect at least one-sixth of the economy, and just as important, often directly affect family doctors and nurses who consult with us during some of life's most challenging moments.

HHS is determined to give healthcare providers space, not just to provide quality care and to really listen to patients, but to innovate as well.

When enacted in 1989, the Stark law rightfully addressed the concern that inappropriate motives could distort decisionmaking in healthcare. It recognized a worry that some physicians might order services based on their financial interests and service providers, rather than the good of their patients. And in a largely fee-for-service context this made sense. Congress intended to protect the American people and the Medicare program from abuse.

The law did it in two specific ways. 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.

Second, it prohibited the entity from filing claims with Medicare or billing another individual entity or third-party payer for those referred services. These restrictions are absolute, with certain enumerated exceptions, and the law grants HHS the authority to carve out exceptions for financial relationships that do not pose a risk of program or patient abuse.

But what made sense for the healthcare system of the 1980s does not necessarily translate to the modern healthcare system. The President's budget called for a modernization of the Stark law. That is why last month I asked the Centers for Medicare and Medicaid Services to take the lead on the task of

reexamining the Stark law by issuing a request for information to obtain public input on ways to address any undue impacts and burdens that the law causes.

The Stark law, which, as I noted, is designed for a fee-for-service model, does not always work in a system transitioning and moving to value-based payments for healthcare. It may unduly limit ways that physicians and healthcare providers can coordinate patient care by restricting ways that physicians can organize and work together and with others.

In considering changes to the Stark law we must be cognizant of the need to preserve competition in the healthcare marketplace where such competition achieves the goal of patient-centered quality care while also controlling costs. So we have asked CMS to consider input from stakeholders and to focus on how the Stark law may impede care coordination, which is a key aspect of systems that deliver value.

Through a request for information published toward the end of June, CMS requested additional feedback from stakeholders and the public on the structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements, as well as the need for revisions or additions to exceptions to the Stark law.

HHS is also looking at the anti-kickback statute and its intersection with the Stark law to see if either law, or the interactions between the two, is stifling innovative arrangements that could result in better outcomes for patients.

Throughout this process we will be consulting with our enforcement partners in the HHS Office of the Inspector General and the Department of Justice.

As shown by the President's budget request and the range of information sought from the healthcare community in the Stark law request for information last month, the Department is open-minded about the types of changes that may be needed to make the Stark law more compatible with the push toward integrated care and alternative payment models.

HHS looks forward to working with this subcommittee to find the best path to modernization, and I personally am looking forward to discussing the Stark law today and working with this committee to find a balanced way that leads to coordinated care and better outcomes for American patients.

So again, thank you for having me here today. I look forward to discussing the issue and taking your questions.

Mr. Smith. Thank you. Thank you for sharing your perspective and insight.

We will now proceed to the question-and-answer session, and I will begin by recognizing Mr. Johnson from Texas.

Mr. Johnson. Thank you, Mr. Chairman.

You know, this hearing is focused on finding ways to modernize the Stark law, and as I am sure you know, ObamaCare effectively bans the expansion of physician-owned hospitals, as well as banning the construction of new ones.

This means ObamaCare is preventing some of our best hospitals from expanding so that they can better serve our communities, and I think you will agree with me that is just wrong.

Deputy Secretary Hargan, would you agree that the ObamaCare ban on physician-owned hospitals limits competition, yes or no?

Mr. Hargan. Mr. Johnson, obviously, HHS has to enforce the law the ACA put in place, which was a ban on physician-owned hospitals, the expansion of them, the construction of new ones. Obviously, prohibiting any new entrants into the healthcare marketplace is going to reduce competition. It is going to make sure that there aren't as many hospitals, many places for patients to go.

Mr. Johnson. Well, thank you.

And would you agree that physician-owned hospitals are some of our Nation's best-quality hospitals, yes or no?

Mr. Hargan. I believe surveys have shown that physician-owned hospitals have good results.

Mr. Johnson. Wouldn't you agree that this ban is wrong, and I think you just said it, unfair?

I strongly believe that expanding physician-owned hospitals can increase patient access to affordable, quality healthcare. And will you commit to working with us to address the ObamaCare ban on these hospitals, yes or no?

Mr. Hargan. The Department stands ready to provide any technical assistance that the subcommittee needs.

Mr. Johnson. Thank you, sir.

As this committee moves to modernize the Stark law, I hope that in doing so we once and for all address the unfair ObamaCare ban on physician-owned hospitals, and I hope you agree with me.

I yield back.

Chairman Roskam. [Presiding.] Mr. Levin.

Mr. Levin. Welcome. And I think your testimony is sensitive to the issue, and I think your answer to our distinguished colleague from Texas also was appropriately cautious.

The issue of physician-owned hospitals has been a controversial one, and there were major abuses and problems. And I think your willingness to give technical assistance was well said.

Let me ask you, in view of your position in HHS, I want to ask you, because we are not going to have any other opportunity to ask about the stopping of the risk adjustment payments. That follows a decision that was taken by one court in February. Now, 5 months later, we have this action that is rippling through healthcare and the industry and threatens people with their payments.

Could you please tell us within your knowledge who was responsible for making that decision?

Mr. Hargan. Yes. The Department filed a motion for reconsideration with the court after the court made a decision to prohibit the risk adjustment that the Department had put in place.

In late June, the court ruled against the motion, and so at that point HHS had to make sure that the provider community was aware that the court had imposed what turned out to be a nationwide ban on the risk adjustment.

The court's decision was not limited to New Mexico, which is where the court sits, but was applicable nationally. And so the risk adjustment that had been undertaken had to to obey the court order, and that means that we had to make sure that the provider community knew of the court's decision as of that time.

Mr. Levin. Did you, HHS, consult the White House on that?

Mr. Hargan. I can find out about the ins and outs and get back to you, sir.

Mr. Levin. Could you not issue immediately an interim rule so that payments could continue? Don't you have that power?

Mr. Hargan. We are looking at all kinds of potential responses to the court's decision that obviously vacated our rule on risk adjustments. So we are taking a look at all kinds of different options.

Mr. Levin. You had 5 months. Why weren't you looking at those options before you issued this policy change that threatens dramatic change? Why didn't you take that time? It is a real problem, isn't it?

Mr. Hargan. It is a real problem for some parts of the healthcare community, yes.

Mr. Levin. So why all of a sudden after 5 months you act when you didn't take action during those 5 months to try to rectify the situation? I don't understand it. And the public doesn't understand it. And the industry doesn't understand.

Mr. Hargan. As I noted, sir, we were undertaking to convince the court through a motion for reconsideration to go back and reconsider its decision on that.

Ultimately, the court decided to reaffirm the decision it had originally gone with, and so at that point we had to, in the interest of prudence, make sure that we alerted the provider community that the court's decision stood --

Mr. Levin. You can do two things at once, you know.

Chairman Roskam. The gentleman's time has expired.

Mr. Nunes.

Mr. Nunes. Thank you, Mr. Chairman.

Deputy Secretary, welcome. I just have one question for you.

As we look for ways to modernize Medicare, I know that you are trying to do the same as Congress has struggled with this for many years. And healthcare continues to shift from fee-for-service to value-based care. I am interested in the thoughts that you may have, if you could kind of lay out just maybe one,

two, or three concepts or ideas on changes to the Stark law and how that would help Medicare beneficiaries.

Mr. Hargan. So changes to the Stark law, as I mentioned, the kind of way the Stark law now is, although fee-for-service is still definitely a part of the healthcare landscape and so the Stark law still applies to that part of the healthcare system, and right now we still have a majority of the system that is in fee-for-service.

However, the transition to value-based care, the Stark law is already in many cases, as we hear from our stakeholders, standing in the way, creating friction about the move to value-based care.

Some of the things that we have heard about already from stakeholder engagement on this front is that they believe that it is standing in the way of innovative models of care coordination, providing incentives between doctors and hospitals that could be very valuable that are going to enable better quality patient care so that patients aren't required on their own to coordinate their own care between them and their loved ones. And the Stark law in many ways can prohibit models or discourage models of coordinated care that would enable that --

Mr. Nunes. Those models would be models that would include new technology, being able to --

Mr. Hargan. Exactly.

Mr. Nunes. Telemedicine, things of that nature?

Mr. Hargan. There are many elements to that. In other words, the Stark law applies very broadly with regard to physicians.

So anyone a physician could interact with, whether it is a medical product provider like a device, dealing with devices, whether it is a hospital, or really anyone in the system, could be subject to the Stark law and effect the ability of physicians to coordinate care and of patients to receive coordinated care.

Mr. Nunes. Well, I encourage you to do all you can.

And I hope, Mr. Chairman, that we can act as soon as possible. And I yield back.

Chairman Roskam. Thank you.

Mr. Thompson.

Mr. Thompson. Thank you.

Thank you, sir, for being here today.

Last week we had a markup in our committee, and we spent a lot of time and were able to discuss a number of the things that the majority party and the administration are doing to undermine the current healthcare law and to sabotage the Affordable Care Act.

According to PricewaterhouseCoopers, Republicans are going to be responsible for as much as a 24 percent overall rate hike in healthcare.

Many of us raise the issue of efforts to discriminate against our constituents who have preexisting conditions, and the administration has been front and center in this effort. You have expanded access to junk healthcare policies that don't cover essential benefits, charging more for preexisting conditions, charging more for older people for their healthcare.

And this is going to have an effect where millions of people are going to be hurt and leave the individual market and will not be able to spread the risk out. So we are going to have sicker people trying to get coverage, and it is going to be a real disaster. And I think this is a problem that we need to deal with.

One of the things that has happened that I have concerns with is the cut, millions of dollars in cuts for enrollment grants that have taken place this year. And we know that this type of grant system helps. We have good evidence in California where they have been able to expand the market, they have been able to drive down the price, and they have lowered premiums this year by 3 percent, and that is better for everyone.

And the moneys that you are cutting aren't even -- they are not general fund moneys. These are moneys that are paid for by user fees.

Can you tell us how much of these user fees you are going to collect this year?

Mr. Hargan. I can get that information back to you, sir.

Mr. Thompson. So you don't know what that number is? Does a billion dollars sound close?

Mr. Hargan. We can get back to you with that exact information.

Mr. Thompson. The number that I have heard is roughly a billion dollars in the fees that you are collecting, but you are not spending much of them. About $870 million of that billion won't be spent. Is that correct?

Mr. Hargan. Sir, we can get back to you with that information.

Mr. Thompson. So the difference between whatever you collect and what is being funded after the cuts will not be spent, right? You don't have to get back to me with that information, that is just a fact. If you collect it but don't spend it, you are going to have money in reserve.

Mr. Hargan. That sounds logical to me.

Mr. Thompson. What are you going to do with that money?

Mr. Hargan. Again, I will get back to you with any information about the user fee and how much is being spent.

Mr. Thompson. When can we expect that? About $870 million -- $870 million -- and we have no idea what you are doing with it. When can I expect to hear from you as to where those dollars are going?

Mr. Hargan. We will get back to you as expeditiously as possible.

Mr. Thompson. Thank you. I yield back.

Chairman Roskam. Mr. Buchanan.

Mr. Buchanan. Thank you.

Mr. Secretary, thank you for being here today.

Let me ask you quickly, when you look at the Stark law and anti-kickback law, how do you compare the difference and the overlap, just from a general educational standpoint? How do you define the difference? Do they work together on certain scenarios?

Mr. Hargan. The two laws do not necessarily act in concert. They address a lot of the same issues, but they don't act together. They are overseen by two different parts of HHS, Centers for Medicare and Medicaid Services in the case of the Stark law and the Office of the Inspector General with regard to the anti-kickback statute.

They have significant differences in that one is really oriented toward civil penalties. One is a criminal statute dealing with intent. One is a strict liability statute where if you violate the law you are done in a sense because if you have violated it you don't get to prove whether you had a good intent or a bad intent in doing so. In the Stark law you have exceptions created by CMS. In the case of the anti-kickback statute you have safe harbors by the inspector general.

Even though in many cases they cover the same general areas, they are worded in different ways, they haven't been coordinated over time, and so it leads to a situation where the provider community that is trying to create a system of coordinated care really finds it very difficult, if not impossible, to understand the whys and wherefores of why these two systems are operating so differently over the same exact area.

Mr. Buchanan. Let me ask you also just in terms of not only in our region, but I think across the country, and I would say in the last 7 years, but in my experience the last 20 years, the huge raising cost in healthcare in general for a family of four is surging.

The Stark law was put in place in 1999. I am not sure on the other law. But by modernizing or looking at them, will it do anything to help lower costs in general? Because I can just tell you people are drowning in the cost of healthcare today.

And, again, this isn't something that's new in the last couple of years; this has been going on for 20 years. I just have seen it as a business person.

So what might it do or what can we expect might happen?

Mr. Hargan. Well, we have articulated value-based care as one of the cornerstones of what we are going to be driving towards. That is something that has been a goal of past administrations, as well.

One of the cornerstones of value-based care that we see is coordinated care. And to be able to coordinate care we need to modernize Stark and the interrelation between the Stark and the anti-kickback laws.

And so we anticipate, because we are going to be able to allow more coordinated care, getting both better quality of care and we believe lower cost. When we allow there to be more different models of coordination, that means that we will be able to allow there to be more experimentation, innovation --

Mr. Buchanan. Time is running out. Let me ask you one more question.

Just in our region in Florida, in the Sarasota region, there is a lot of consolidation with hospitals and others buying up practices. I am not saying it is good or bad. But how does this impact these laws, because a lot has changed in 20 years or so.

Mr. Hargan. We have heard back from stakeholders that the consolidation in the provider community in many cases is being driven by considerations of the Stark law. And so, in other words, the law is actually driving a lot of the business transactions and the consolidation that is happening in the industry.

Now, that itself, the fact that a regulation that is intended to prohibit physician self-referral is actually driving the way that we are structuring the entire industry and driving the patterns of consolidation, that I am not sure was intended.

Mr. Buchanan. Thank you. I yield back.

Chairman Roskam. Thank you.

Mr. Kind.

Mr. Kind. Thank you, Mr. Chairman.

Mr. Hargan, thank you for testifying here today.

Last fall Mr. Marchant and I teamed up to offer a Stark simplification law to try to further clarify and define what constitute technical violations and more egregious violations. It was made a part of the budget. You guys are now in charge of implementing. I was hoping to get an a little feedback from your office as far as the implementation of that and how it has been working.

You have also been tasked to receive public feedback as far as what Stark law changes need to be made. And I think we are all in agreement that with the move now towards greater care coordination, value, quality, outcome, the 1989

Stark law perhaps doesn't work so well in the modern era of where healthcare reform is going.

And I am confident that if our former colleague Pete Stark were here in front of us today he would admit the same thing, that we are in need of it. But we need to do this carefully so that we don't fall into the trap of self-dealing again out there, which was the whole premise behind Stark to begin with.

But the question I want to ask you here today, and you can take a moment to think about it, is whether or not the administration is working on a Plan B on replacing the Affordable Care Act.

You guys took a run at it with the complicity with the Republicans in Congress last year. You pulled up short. In fact, the bill that was before us under consideration would have driven up the uninsured by 25 million and would have given tax relief to Big Pharma companies and insurance companies to the tune of $800 billion.

Thank God the American people knew what was trying to be pulled on them because they rejected it, and it was one of the reasons why it went down in Congress.

Now, I don't know if the administration has a plan to try to resurrect that again at some point or if you have a whole new plan that you are working on to replace the Affordable Care Act, because from my perch and my perspective all the efforts that the administration is doing to undermine the Affordable Care Act are leaving more and more Americans behind, whether it is the elimination of the cost-sharing reduction payments that is creating unhealthy insurance pools right now.

You mentioned, Mr. Levin, the risk adjustment payments. I am not aware of the administration coming to Congress with any proposed fix to that court decision, but that is something you could easily do by bringing that our attention and saying: This is what we need to do in order to fix that right now.

But the elimination of the individual responsibility component, which was a part of their tax plan last year, is going to create again unhealthier markets.

But don't take my word for it. Your former boss, Tom Price, former HHS Secretary, was quoted as saying, and I quote: "There are many, and I am one of them, who believes that that actually will harm the pool in the exchange market because you will likely have individuals who are younger and healthier not

participating in that market, and consequently, that drives up the cost for other folks within that market."

And this is just self-evident. I mean, you don't have to be a rocket scientist to know that that was going to be the consequence of that shortsighted decision.

But beyond that, today we are living in a country where under this administration 4 million more Americans are uninsured, and the premiums and the exchanges are going up. In Wisconsin they are projected to go up by about $1,500 -- again, directly related to the action that this administration and this Congress is taking to try to undermine it.

So if the goal is to expand affordable quality healthcare coverage to more Americans, we have taken a drastic U-turn under this administration.

And the one phone call that I took repeatedly last year in the midst of their repeal-and-replace effort were from young mothers with children with preexisting conditions. They were scared out of their minds that their kids now were going to be left out there without adequate protection if they lose the protection of people with preexisting conditions. And now this administration has joined a lawsuit challenging the constitutionality of that.

I am not sure where the politics are going to lie, but my guess is it is going to be scaring a lot of Americans where well more than half of Americans have what constitute a preexisting condition in their life.

So again, I ask you, is the administration working on a better Plan B or are we stuck right now with this effort to just undermine the effects of the Affordable Care Act?

Chairman Roskam. The gentleman's time has expired, so it is a rhetorical question.

Mr. Smith.

Mr. Smith. Thank you, Mr. Chairman.

And thank you, Mr. Hargan, for your presence here today. I think we have a great opportunity to work in a bipartisan fashion on these issues that you are addressing, and I hope we take advantage of that.

I certainly appreciate your efforts to modernize the system. We know that we have some laws on the books that did not anticipate various technologies. And I would hope that we can, again, work together to address this so that we can help the American people.

We heard a while back from Zocdoc who explained that there are obstacles that stand in the way of adequately helping the American people. I know that, representing a very rural constituency, issues can be a little different than more urban areas, and as services are rolled out and fee structures and so forth that might be required under existing regulations, that may not be the best business model to reach folks in more rural areas. And so we need flexibility.

And when you look into the delays currently in place that stand in the way of patients receiving timely healthcare, I would hope, again, that we can work together to address this ultimately, I think, from certainly addressing regulations that are on the books. And I am glad that already you and the administration are looking into that.

But if you could perhaps elaborate on what is the administration's plan to account for the technological advances in healthcare relating to Stark law and Federal anti-kickback statute.

Mr. Hargan. So first of all, I want to say that I am also from a rural community, a town of about 800, tip of southern Illinois, called Mounds. And I grew up underfoot in a rural hospital where my mother worked.

So you can rest assured that we will be sensitive towards the issues faced by rural healthcare providers at HHS. We take it into account. Obviously, there are a lot of challenges facing rural and remote healthcare providers that are unique to them.

And, again, the Stark and anti-kickback statutes also make it more difficult in many ways. It creates a special problem for areas where there are few providers that aren't actually connected with one another.

In other words, when you only have one person that you can affiliate with in a community it becomes kind of a difficult issue to say: I can't affiliate with this person because the law prevents me from doing so. In other words, you can be driven to either remain completely isolated from anyone in the community, because there are relatively few providers, or you are violating the law.

So in other words, a rural community can be particularly effected by the Stark and anti-kickback statute as it is often implemented. So that is a particular issue.

With regard to, I believe you mentioned, technological issues, in many cases the Stark and anti-kickback statutes create, again, a problem where people can't get access to technologies as quickly as they otherwise should be able to.

And that is particularly an issue within rural communities, because they often lag urban communities in being able to get access to technology as quickly and being able to implement it for the health of the people in those areas. So you have both lower quality of health, you have fewer providers, and you have more restrictions on them being able to coordinate with one another due to, in many cases, older regulations interpreting these laws.

Mr. Smith. Thank you. I yield back.

Chairman Roskam. Ms. Sewell.

Ms. Sewell. Thank you, Deputy Secretary, for being here today. I am extremely interested in your personal testimony with respect to rural health, since I represent a district that has a hybrid. We have Birmingham, Alabama, which has some of the most sophisticated regional medicine providers in the Nation; and then I have rural parts of my district.

I am from the rural part, Selma, Alabama. People know it because of the civil rights movement, but it is a small town of 19,000. And frankly, there are a whole bunch of rural communities around it that depend upon the healthcare that is provided in Selma to help provide for them.

So my question really goes back to a question that was raised by Representative Kind. The reality is that if this administration doesn't have any plans to repeal and replace the Affordable Care Act, but only to work towards efforts that undermine the ACA, how are rural providers especially going to survive?

I have 14 counties, and the majority of my counties the rural hospitals actually have upwards of 90 percent of its patients depend upon Medicare or Medicaid or TRICARE or some Federal assistance. And several of the hospitals in my district have, like I said, 90 percent of the patients dependent upon Federal Government medical assistance.

Our rural hospitals are especially vulnerable to the sabotage that we are seeing, especially when you think about the fact that we are no longer paying for cost-sharing subsidies. And the only way that so many of my constituents can actually afford healthcare insurance at all is through this assistance.

And so I really want to understand, first, whether or not this administration has a plan to replace it or are we going to continue to see sabotage efforts that only sabotage some of the benefits of the ACA. And I would love to know your thoughts on that. You weren't able to answer Mr. Kind.

Mr. Hargan. So the ACA is the law, and we in the executive branch, have a duty to execute the law, faithfully execute the law as it stands. So the ACA is the law of the land, we are working to faithfully execute that law.

Ms. Sewell. Yes, but are you saying that the funding stream, the fact that this administration has cut the subsidies, which actually provide the financial assistance for people to actually be able to afford healthcare insurance, that that, yes, it is the law of the land, but are you denying that this administration has cut the budget for the subsidies?

Mr. Hargan. Which subsidies are you referring to?

Ms. Sewell. I am talking about the cost-sharing reductions.

Mr. Hargan. Okay. In that case we have had -- I mean, obviously, as you may know, there were court cases involved in those, in the decisions as well, that are in the background of that where --

Ms. Sewell. I am running out of time, sir. And they have been cut.

I have to also say that the cuts and slashes to the navigators also undermines the ability of constituents that I have that do want to get healthcare insurance from actually being able to understand what is out there and what is available in the marketplace.

I have one constituent by the name of Hank who, literally, when I asked him about the Affordable Care Act was very interested in getting healthcare insurance, but, when he heard it was ObamaCare, wasn't.

Thank God he had a navigator who helped him get healthcare insurance, because 6 months after not ever having healthcare insurance -- he was a farmer in a rural part of my district and had never had healthcare insurance, and his

hand got caught in one of those grinders. And thank God he had healthcare insurance because he not only didn't lose his hand, but he also didn't lose his farm.

So I guess I just really want to reiterate at this hearing, because we haven't had an opportunity to have a hearing about the sabotage on ACA, that the Affordable Care Act is the law of the land. And we should be doing everything we can to encourage Americans who need healthcare insurance to actually get healthcare insurance.

Thank you.

Chairman Roskam. Just for the record, the administration is responding to litigation. So CSRs and risk adjustments are the result of litigation. So I take the secretary at face value in terms of enforcing the law.

And with that, I recognize the gentlelady from Kansas.

Ms. Jenkins. Thank you, Mr. Chairman.

Thank you, Mr. Secretary, for joining us.

Today we are here to discuss the Stark law and possible solutions for updating the physician self-referral law to continue moving the Medicare program toward being a system that promotes better coordinated care.

The Stark law was intended to reduce fraud, waste, and abuse related to physician referrals in all healthcare settings; however, the law is outdated and needs to be modernized.

By looking into updating this statute we have got the opportunity to discuss the way care is delivered today and how we can better serve Americans, as modernization will ensure that we are creating easier access to care for people across the country while also rewarding value within our healthcare system.

For rural districts like mine and Mr. Smith's -- I represent eastern Kansas -- the Stark law does present a disproportionally heavy regulatory burden for our hospitals, as you have acknowledged. These rural hospitals have limited patient volume that at times may necessitate the need to share a specialist with nonaffiliated hospitals.

Additionally, there are fewer employees in rural areas, which increases the probability that a physician or a family member may work with an employer that triggers Stark implications.

In both of these examples the risk of potential financial relationships that have Stark law implications is high, generating significant additional legal effort needed to document and ensure compliance with the mandate.

Mr. Secretary, removing unnecessary government obstacles to care coordination is a key priority for the administration, and you have even stated in your comments we need to change the healthcare system so that it puts value and results at the forefront of care, and coordinated care plays a vital role in this transformation. HHS is responsible for removing regulatory barriers to help providers deliver the best team-based care.

Do you think these are all changes you can make administratively or do you believe Congress may ultimately need to intervene in order for physicians to deliver value-based care?

Mr. Hargan. Thank you.

We are going to do what we can from an administrative point of view based on the stakeholder feedback that we get. So we are currently through the RFI process going to get as much feedback as we can from the stakeholder community on where we can go, where they think they have good ideas, and where they think we should go in terms of that. We are going to reflect on that with our experts at HHS and then come out with an administrative proposal to address the regulatory side that we can affect within the strictures of the law.

I think when we go where we can go and where we think is going to be a positive place from the point of view both of the reflections we have from the community as well as our own, I think we would be happy to work with you all, provide what assistance we can in where it seems likely that there could be legislative changes that would be positive here.

That would sort of preserve the core good part of the law, the part that is kind of animating the issue that it was originally intended to fix, which is that where we have undue issues where providers are incentivized to kind of enrich themselves in an inappropriate way and to maintain that focus on value.

Because obviously we are moving to a system of value-based care, and that is what we are trying to do, and so it means that we need to keep our eye on all

the elements, including the heart of the Stark law and what it is intended to achieve.

So we look forward to working with you all as you make plans, if that is where you are going, in terms of modernizing it from a statutory point of view.

Ms. Jenkins. All right. We will look forward to working with you.

Thank you, Mr. Chairman. I yield back.

Chairman Roskam. Ms. Chu.

Ms. Chu. Deputy Secretary Hargan, this is a rare opportunity for me to ask a question directly of an HHS deputy secretary. So I wanted to ask a question on a different issue that is on my mind, which is the healthcare of children and parents separated at the border.

I want to read you a letter from Henry, a constituent who wrote the letter I have here in my hands. He wrote to me in pink marker and asked me to please reunite the children with their families.

I take letters from my constituents very seriously, and that is why I am going ask you a few questions today that might get us closer to finding answers.

This weekend there were a number of disheartening reports of children who were separated from their parents at the border and have been recently reunited with them. According to a story from The Washington Post, a 10-year old said she did not wish to remember her time spent in detention and recounted watching an out-of-control kindergartner get injected with something after he misbehaved in class.

Sandy Gonzalez, a second grader from Guatemala whose mother fled the country to get away from her abusive husband, was reunited with her mother after 2 months in detention, but told the newspaper that, "They told us to behave or we would be there forever." She cries when other children try to hug her because they always kept the boys and girls separate and "they punished us" if we tried to be near each other.

Another young boy, named Diego, a 9-year-old from Brazil, reported falling on a concrete court while playing and hearing his arm crunch. No doctors or medical professionals attended to him and he was given a temporary cast by the

shelter's employees.

Next, I would like to enter the following article into the record: "Pregnant Women Say They Miscarried in Immigration Detention and Didn't Get the Care They Needed."

Chairman Roskam. Without objection, so ordered.

Ms. Chu. It was published by BuzzFeed on July 9, 2019. The article describes a number of disturbing practices, including pregnant women being detained well into their third trimester, being shackled across their belly, and even going through a miscarriage without being given any medical attention.

One of the women in this story is quoted as saying that when she arrived to alert authorities she believes she was losing her baby. She says, "An official arrived and they said it was not a hospital and they weren't doctors. They wouldn't look after me."

While the woman quoted in the BuzzFeed story was in adult detention, I am concerned about the condition of pregnant young women who are under the age and 18 and are therefore in custody of the Office of Refugee Resettlement.

Deputy Secretary Hargan, how many pregnant young women are currently under ORR's custody?

Mr. Hargan. We can get back to you with that exact number, Congresswoman.

Ms. Chu. I would definitely appreciate that.

It is my understanding, based on a deposition taken by the ACLU, that ORR Director Lloyd receives a spreadsheet each week of the number of pregnant young women in ORR custody and the gestational ages of their fetuses. If this is correct, I imagine it would be easy for you to determine the number of pregnant women in ORR custody.

Last month I joined my colleagues, Congress Members Dingell and Kuster, as well as 60 other signatories, in asking the Department of Health and Human Services how many pregnant young women were in ORR's custody and what ORR is doing to ensure that these young women are receiving adequate medical care. We have not yet received a reply to this letter.

So I would like to ask you, what is ORR doing to ensure that pregnant teenagers in ORR's custody are receiving adequate prenatal care? Have any young women given birth in ORR custody? What is being done to ensure that they and their child receive adequate medical care?

Mr. Hargan. So the mission of HHS and the ORR is the safety and health of the children that are given into our care. And so that is the primary focus of that, whether or not they are young women who are pregnant, children, and any

of the other children that are in our care. And that is the utmost importance for the program, and that is what we intend to carry out.

Chairman Roskam. The gentlelady's time has expired.

Mr. Secretary, if you could respond in writing appropriately and promptly.

Mr. Hargan. Absolutely, Chairman.

Chairman Roskam. Mr. Marchant.

Mr. Marchant. Thank you, Mr. Chairman.

Earlier this year our committee, with Mr. Kind's assistance, passed Stark simplification legislation. I, for one, believe that the Stark Laws need to stay in effect for the private practices. And in terms of the whole kickback scheme, I don't think anybody on our side believes that we should go back and remove all of that.

But for my constituents that don't know what value-based treatment is, could you just describe a typical procedure or a typical situation that a patient would find themselves in where our current Stark Laws and the way they are written would either prohibit them from getting the right care or would prolong their care or would make their care much more expensive?

Mr. Hargan. Sure. So an example of sort of uncoordinated care, right, so right now the Stark law can prohibit different groups of doctors and other types of providers from affiliating with each other, from having relationships with each other. The Stark law makes it much more difficult. So when you have a situation where you have, say, a primary care doctor, who is often the first person that a patient sees, is their primary care doctor --

Mr. Marchant. I think everybody on this panel understands that. But if you are talking to somebody back in my district and you are going to talk to them about, say, a knee surgery.

Mr. Hargan. Sure. So, say, a knee surgery, you have an orthopedic surgeon who is going to be involved in the knee surgery. They may have a lab that they order lab tests from, a pain center that they refer them to, a rehab center where the patient would go for rehab with physical therapy, primary care doc who is the original person involved in this, a hospital that could be doing something, could have a role to play on the side. Any number of organizations that could

be involved in this. Right now the Stark law can prohibit a lot of the relationships that can develop among those different kinds of providers.

Mr. Marchant. And when you say value-based, you mean pretty much we are going to pay you this much money from the first visit to the last visit?

Mr. Hargan. Right. So that is certainly a common way of looking at value-based care. Value-based care means really paying for outcomes and for the value in the procedure. And many times that is seen as a bundled system or you can call it any number of things. But a bundle or a single payment that you were mentioning, those are examples of value-based care.

Mr. Marchant. So an insurance carrier could look at that and say, "Here is our maximum exposure on that procedure," and theoretically back into either a lower premium ultimately or keep costs from escalating.

Mr. Hargan. Any payer could do that, could say, "I am going to pay a single bundled payment for an episode of care." That is a common way of looking at it.

Mr. Marchant. But under our current law and the way the Stark Laws are written, a lot of that can't happen simply because to achieve that bundled number you have got to have some affiliation and some association.

Mr. Hargan. That is certainly an easy way to do it. There are certain types of entities that can coordinate that care right now. A hospital could have everything in-house. But it is not necessarily the case that a general hospital is always going to be there able to do, perform from A to Z a particular episode of care.

And you may want to create affiliations between groups of providers that aren't necessarily commonly owned together or they are not necessarily affiliated in a certain way. To be able to create those relationships among one another, the Stark law is often seen as acting as a barrier.

Mr. Marchant. Thank you. Thank you very much.

Chairman Roskam. Mr. Paulsen.

Mr. Paulsen. Thank you, Mr. Chairman.

And, Deputy Secretary Hargan, I want to thank, first of all, CMS for issuing recently the Stark law RFI that came out actually just a few weeks ago to get public input on ways that we can better, more responsibly modernize Stark and then promote that shift towards value-based care.

But now the Stark law isn't the only law that is designed under fee-for-service that has been an obstacle in this shift to value-based care. You have got the anti-kickback statute, as well, which is also meant to protect against fraud and abuse by limiting certain types of financial arrangements.

But equally, I would say we are probably losing opportunities for better support for coordinated care, for innovative care delivery, and for new payment models for the benefit of different providers and patients.

And now under this value-based payment arrangement or the opportunity for it, you are going to have goals of the parties, of the providers and the payers and the medical technology manufacturers, others, et cetera, that can all use their data, all the information they have collected to help better financially align and incentivize each other, right, to coordinate care and improve outcomes.

Would you agree that it is also responsible to analyze or look at the anti-kickback statute, as well?

Mr. Hargan. Yes, absolutely. And so I have sponsored what I have called the Regulatory Sprint to Coordinated Care within HHS.

So I brought together CMS, the Inspector General's Office, the Office of Civil Rights, which oversees HIPPA, and SAMHSA, which in the opioids area overseas 42 CFR Part 2, which is another rule that has been seen by stakeholders as blocking some kinds of coordinated care, particularly with regard to substance use disorder and opioid issues. That is, obviously, of vital interest to this administration and the President.

So we brought together actually four different agencies to be able to coordinate amongst themselves so that they can align with each other to create a system of coordinated care so they don't act against each other and that we end up with kind of a reform that we can do, within respecting the law and respecting the goals of the laws, but that we believe we can reduce some of the duplication, the overlap, and the contradictions among the different regulations that our agencies have come up with on their own.

So the first part was Stark, because when I launched this regulatory sprint the staff at CMS were ready to go. They had seen a lot of the issues that had arisen on their watch over time and were ready to go. But the inspector general is also on board with this, as are our other agencies, in order to achieve this coordination.

So the anti-kickback is absolutely being looked at in this area. Obviously, the inspector general is going to enforce the anti-kickback statute, but they are fully in line with the idea of value-based care and with the notion that they need to be talking to one another, the agencies of HHS need to talk to one another and make sure that they are not sort of strangling innovation and new models of care, they are going to be for the benefit of the American people.

Mr. Paulsen. Will there be a similar situation where you do an RFI on anti-kickback, for instance, for that input?

Mr. Hargan. Yes, exactly. So that is what I am asking the agencies to do.

Mr. Paulsen. Got it. Okay.

Thanks, Mr. Chairman. I yield back.

Chairman Roskam. Mr. Reed.

Mr. Reed. Well, thank you, Mr. Chairman.

And thank you, Mr. Secretary, for being here today.

I kind of want to follow up on what my colleague from Texas Mr. Marchant was kind of getting to. And I always try to ask these questions from the perspective of a constituent, from an actual patient perspective. So I am a patient who is in Medicare. I am not that old yet, but the hair gives it away.

The question I have for you, with the Stark Laws on the books today, and as we go to a capitated, value-based type of reimbursement model, what kind of care do I potentially not have access to? What would be my experience under that if the Stark rules are not modernized like I believe they need to be done?

Mr. Hargan. Right. Sure.

Well, put yourself in the perspective of a patient. We are all patients of the American healthcare system. We are all patients and potential patients of the

system. I have the perspective of a patient, everyone here does potentially. So we are always going to try to maintain a focus on the patients as the center of care for the system.

What can't you get right now? You might have to in some circumstances be responsible for knowing every single element of the chain in medicine. When you are diagnosed with something, the doctor that diagnoses you might not know the right specialist. They might not know the right provider.

When you go to that specialist, that specialist might not know the right lab, they might not know the other right providers that are needed, the physical therapist. I will just take the orthopedic, going back to the orthopedic example. They might not know the physical therapist.

You might have to find in a moment of sickness, in a moment when you are trying to get care, when you are under pressure, you are going to have to know all that yourself.

Mr. Reed. As a patient, from a patient perspective.

Mr. Hargan. As a patient, from a patient perspective, you --

Mr. Reed. That is the scenario we are looking at if we do nothing.

Mr. Hargan. You have got it.

Mr. Reed. Where a patient would have the obligation and responsibility potentially to know exactly who is going to run afoul of this Stark law, who is going to run afoul of these procedures.

Mr. Hargan. Right. In other words, the providers in many ways are not incentivized to talk to each other. They are not incentivized to coordinate. They can't coordinate in many cases because this is going to cause a big problem for them --

Mr. Reed. Because of the Stark law.

Mr. Hargan. Because of the Stark --

Mr. Reed. Because of the way it exists today.

Mr. Hargan. Exactly. And so you in many cases are on your own. It is much harder to coordinate in the system that we have now.

Now, there is a lot of information out there and people do coordinate, and there are systems, big provider systems, that are all owned by the same owner, and they coordinate and there are exceptions here and there.

But what we have done is we have created 40-plus exceptions to the Stark law to address this. It is a Swiss cheese in many ways. And at this point we are decades down the road in interpreting the Stark law, and that is why we are trying to kind of look at a revamp, to be able to reform this law from a regulatory point of view, to create a better way for patients to be able to get coordination.

Mr. Reed. So that way when I am a patient walking into a physician's office or a provider's office, I don't have to take on that responsibility, or know where I have to get my cancer treatment, my rehab, my counseling, mental health counseling, and all that because now, under the new model, with the modernized Stark law, that can be driven from the patient advocate, the patient provider, who then would be able to have seamless care from my perspective as a patient.

Is that what we are trying to achieve?

Mr. Hargan. Exactly. The idea is to be able to have more seamless care within the system and better coordinated care overall.

Mr. Reed. And I truly appreciate that. I think from the perspective of a patient that should be the joint goal we achieve through this process. Thank you.

Chairman Roskam. Mr. Kelly.

Mr. Kelly. Thank you, Chairman.

Secretary Hargan, thank you very much for being here today.

You know, the Chairman has been, over the past year or so, working on this Medicare red tape relief initiative. And over the past few months, we have brought in dozens and dozens of doctors and providers to discuss ways we can make the system better.

Your department has also undertaken a similar project, appropriately named the Patients Over Paperwork Initiative. And some of the main points we hear again and again is how outdated government regulation gets in the way of innovation in the doctor-patient relationship. This feedback also included how Stark law is adding to the growing administrative burdens.

I can just tell you from being in the private sector my whole life, being in compliance requires so much nonproductive labor in order to get up-to-speed with this, along with constantly checking and rechecking and making sure you are in the right position. I think the same thing has happened with the healthcare system. It is incredibly difficult to keep up with all the compliance issues.

Now, I think the idea behind all of this is: how are we going to make this easier and not harder for doctors to take care of their patients? And if you can, just share a few ideas from HHS, on how you can streamline this process, get rid of all the red tape that really, I don't know at the end of the day, if people will say, "Yeah, this is really great that we do this, and we are making sure all of this is taking place," but does it actually add value to the American people's healthcare system?

So some of the ways you can streamline it and taking a lot at it from a private sector initiative of how you would handle it as opposed to how government does it.

Mr. Hargan. Sure. So, to go back to the Patients Over Paperwork Initiative, that is obviously an attempt to kind of, again, elevate that over the huge amount of regulatory red tape that has been allowed to kind of encrust the healthcare system over time.

We are broadly attempting to reform our regulations and the processes that we have in place in order to liberate those resources in terms of time and in terms of money so that we can dedicate more resources to patient care. You know, there always does have to be accountability.

Obviously, Medicare and Medicaid are funded by the taxpayers, and so we have to focus on that to make sure that, again, it is value-based care, right? We want to make sure that the money that is being put in through these programs and our stewardship of that money that has been entrusted to these programs is being spent on patient care.

In many cases, many well-meaning attempts to provide oversight and to be able to see exactly what is going on in the system has resulted in overlap, duplication, the proliferation of measures that have not advanced patient care or good stewardship of the taxpayer dollars but have, instead, resulted in kind of a negative effect on all of that.

So we are attempting to address that. I think that is what CMS is trying to do with many of the initiatives that are going on there, including initiatives that we are packing into the new Medicare rules that are coming forward. So we are sort of continuously trying to reform this system.

Mr. Kelly. I just think, you know, if we can model the government the way the private sector works, we have become more effective and efficient; that way you get a better result. What we are looking at here is for outcomes for the American people.

I thank you for the work that you are doing. And it is a large, large challenge, and we have to get some kind of a sense of control over it.

Thank you very much.

I yield back, Mr. Chairman.

Chairman Roskam. Mr. Blumenauer.

Mr. Blumenauer. Thank you, Mr. Chairman. I apologize for the delay. I was defending the honor of the Ways and Means Committee before rules on H. Con Res --

Chairman Roskam. God bless you, my friend. God bless you.

Mr. Blumenauer. -- 119 about condemning a carbon tax.

And I want you to know that you can rest easy tonight that the resolution doesn't mean anything. It doesn't relate to any specific carbon tax proposal. There has not been a single hearing on a carbon tax in our committee or any place else, and so you don't have to have your people do a real deep dive on their sense of Congress resolution.

And in fact, it is going to be a nothing burger, but I made the case for the committee for you on your behalf.

Chairman Roskam. Hear hear.

Mr. Blumenauer. Mr. Chairman, I would, with your permission, request that we enter into the record a statement. This is the 398th hearing that we have had since Republicans took control of the Ways and Means Committee. And in that time, we have had one 5-minute witness testify about meeting our responsibilities for infrastructure finance.

And as the Health Subcommittee, I would just say, this makes a difference for the health of Americans. In 2016 alone, 37,461 Americans were killed in fatal automobile crashes. One every 14 minutes. More than 2 million Americans are routinely injured in traffic accidents. The health impact of a long commute, traffic congestion, it is rather substantial.

It has a significant impact on the health and well-being of our communities and our citizens. And our failure to meet our responsibility to help fulfill opportunities to deal with an infrastructure crisis I think impacts our health. And I hope that at some point in the near future, we will be able to address that.

Chairman Roskam. Is there a statement for the record? Is there something you want to --

Mr. Blumenauer. I do actually have a statement for the record, Mr. Chairman --

Chairman Roskam. Without objection, so ordered.

Mr. Blumenauer. -- which I would like to enter in.

Chairman Roskam. So ordered.

Mr. Blumenauer. Thank you. You are very kind.

Mr. Chairman, I would like to identify myself with the concerns that were indicated by my friend and colleague from California, Ms. Chu. These are issues dealing with the treatment of these children. We hear really rather grotesque stories.

I hope that most of them are not true or that they might be exaggerated, but they are frequent enough from a variety enough sources that gives us all

pause. And so we really would appreciate being able to dig in and provide some information.

I have just one question to you. I am unable, nor were two senators from my State nor other Members of Congress, able to meet, to be able to visit one of these centers, which is five blocks from my office.

But instead of being able, as we do routinely, in terms of oversight and inspection, to be able to show up and look at true conditions. There is sort of this elaborate process we have to go through other committees.

Is there some reason why Members of Congress are unable to be able to visit these facilities, to be able to understand the conditions and satisfy for ourselves in a timely and orderly fashion?

Mr. Hargan. Sir, Members of Congress are absolutely allowed to visit these facilities. In fact, we have already organized tours that over 70 of your fellow Members of Congress have come to all of our shelters and have been able to --

Mr. Blumenauer. These are orchestrated in advance. We don't have an opportunity to show up and actually look to see how they are, not being staged for tour.

Chairman Roskam. The gentleman's time has expired.

Could I suggest that you respond to Mr. Blumenauer's inquiry?

Mr. Hargan. Yes.

Mr. Blumenauer. Thank you, Mr. Chairman.

Chairman Roskam. Dr. Wenstrup.

Mr. Wenstrup. Thank you, Mr. Chairman. Thank you for the opportunity to be here with everyone.

You know, it seems to me as a doctor when the Stark laws came about, there was an idea that there are some people that are acting out of greed and that we should probably do something about it. But from my standpoint, what it ended up doing is where you have some bad actors, we made everyone stay after school and have to be subject to a lot of things that made it more and more difficult to take care of patients.

And one of the things you talked about today was coordinated care, and I agree with that. How can you coordinate care more expeditiously and in a better manner for patients? But the laws made it very difficult and challenging and nerve-racking.

In our group of orthopedic surgeons, we had one doctor who was an orthopedic oncologist. He was really the only one in town. And so, if I had a patient that I saw that had a bone tumor, that is who I want them to see. But since he was in my group, we had to be concerned, can I actually refer to him, because that is part of my group, and it is like a self-referral. And we worry about that. And, of course, we have waivers, and we all know that can be okay.

But then we went through with physical therapy. So you have your own physical therapy, which is great, because it is right down the hall. You can keep track of the patient's progress. But we are operating under the assumption that you only referred them to physical therapy, not because they needed it, because there is some revenue for you. And then so we had to get rid of our physical therapy, because we were worried about Stark laws, and sell it off.

And then we realize: Well, you can have your physical therapy. And then we bring it back. You know, this is years later. This does not make patient care better. And that is really what it is about.

And I just want to say, as a doctor, I sit here, a large majority of doctors are worried about quality and outcomes for their patients as well as being efficient and affordable. That is really what we are trying to do. And then you have all these laws that sort of assumed you have done something wrong.

And so, as we are talking about this, and I think you are probably on the same page with us, how do we modernize this, that we are able to see who bad actors are and address that situation, and at the same time let doctors take care of patients and let patients being taken care of in a smooth, coordinated way?

Mr. Hargan. Thank you. Yes. I mean, I think that we share those same goals. And we hear a lot. We have been hearing already a lot from the stakeholders that we have reached out to with the RFI. It is identified as one of the top -- I mean, if not the top -- issue on which we have heard feedback from stakeholder community, particularly from providers, physicians, that this is one of the main areas that they urgently seek reform from us, for the reasons that you articulated, similar reasons, where the patient is not getting the smooth coordination of care.

And that, in many ways, the law -- which, again, well-intentioned -- and there is a core element of it that, I think, everyone knows is necessary -- but that over time there has been interpretation of the law and regulations that have perhaps produced results that aren't optimal for the patients and for their care.

Mr. Wenstrup. And as an aside to that, if a patient said, "Look, you know, I drive 50 miles to see you, but physical therapy twice a week or three times a week is too hard; can I see someone near me," absolutely.

We will work with it. Whatever is going to be best for the patient. That is really where we want to go.

Thank you. I yield back.

Chairman Roskam. Thank you. Well, Mr. Deputy Secretary, thank you for your insight this afternoon. I think we have all benefitted from it.

It is interesting, too. You can listen to sort of the subtext of the discussion. And the subtext of the discussion was a lot of common ground on Stark. A lot of recognition that what we have is a legacy that, in its current form, is not serving us, is not keeping us safe from things that threaten us anymore. And now it has become actually an obstacle.

And so the big question is, how do we move forward and modernize this? How do we update this? And many times, this is just sort of the nature of legislation and regulation. And regulation and legislation tends to lag, just sort of the nature of the system.

Now, we have recognized that, with this transition, we have got to update this. And, you know, notwithstanding some of the, you know, partisan sort of comments here and there -- and that comes with the territory -- I think there is a real desire on the part of this subcommittee to try and modernize and update this.

So, without objection, I submit an article that was written this afternoon by kind of an odd couple of healthcare politics. And that is former Secretary Tommy Thompson and Kathleen Sebelius regarding the importance of moving away from traditional fee-for-service and modernizing laws like Stark to achieve higher value.

So let's close this out. Stretch your legs a little. What would you want us to be mindful of as we transition and basically begin to think about what this could be like?

What do you want us to know about?

Mr. Hargan. Yes. Well, I think that, just to reiterate what we have been talking about all together, to sum up, I think that it is great to see that you and the subcommittee have recognized broadly that this is a real problem for us as we try to make, as a Nation, a transition from the fee-for-service system to a system of value-based care that I think is going to result in higher quality, can result in higher quality and lower cost for the American people, and a lot less stress and anxiety for them as they are able to have better care coordination and be able to be taken care of from the beginning to the end of their interactions with the system.

So, you know, I look forward both to working with you, to keeping you all apprised of what we are doing in terms of trying to undertake regulatory modernization, to the extent that we can, respecting the law as it stands today, and then providing you with whatever information we have, both from outreach to the stakeholders, to the provider community, and then the results of the regulatory reforms that we are making to help inform you as you all move forward with perhaps modernization efforts of your own that you undertake here from a statutory or legislative point of view.

Chairman Roskam. Very good.

Secretary Hargan, on behalf of the subcommittee, thank you for your time.

And if you could respond to the other members who had other questions -- you can respond to them directly, at this point, we will dismiss you and thank you. And we will welcome the second panel to assemble at the witness table.

Mr. Hargan. Thank you.

Chairman Roskam. Okay. While people are gathering, I am going to take advantage of the time.

We have agreed to move witness or member questions to 3 minutes. So let's move some traffic. What do you say?

I am going to recognize Mr. Wenstrup for the purpose of introducing one of our witnesses.

Mr. Wenstrup. Thank you, Mr. Chairman.

I am pleased to recognize and introduce Dr. Gary Kirsh, who is a longtime friend and colleague from the Cincinnati area, where we practiced in the same circles for many years.

He is from a 35-urologist group in Cincinnati, Ohio. It is an independent urology company serving all regions of the Cincinnati metropolitan area. And I can tell you, they do a great job, and they really try to coordinate care for patients where they operate and own their own surgical, imaging, laboratory, radiation and clinical research services, which has been a large asset to our community.

He has been instrumental in founding the Large Urology Group Practice Association that has been involved with legislation and health policy for many years, and we appreciate that. And he got his medical degree in Chicago, did his residency in Cleveland, and we are glad that he chose Cincinnati to practice. So thank you. And I yield back.

Chairman Roskam. To round out the rest of our witnesses, we have Mike Lappin from Chicagoland. He is the Chief Integration Officer at Aurora Advocate Health. Brian DeBusk, president and CEO of DeRoyal. And Claire Sylvia, attorney-at-law at Phillips and Cohen.

You each have 5 minutes.

Dr. Kirsh, you are recognized.

STATEMENT OF GARY M. KIRSH, M.D., PRESIDENT, THE UROLOGY GROUP

Dr. Kirsh. Thank you, Mr. Chairman and Ranking Member Levin. And thank you, Congressman Wenstrup, for the generous introduction, and it is great to see you here again.

I am a practicing physician, a urologist. I am president of The Urology Group at Cincinnati, as the Congressman mentioned. I also represent an organization called the Large Urology Group Practice Association, known as LUGPA. And

we represent the independent freestanding urology group practices in the country, collectively providing about 35 percent of the Nation's urology services.

Our commitment to value-based care predates the ACA and MACRA, and LUGPA heartily embraces the Congress' vision of value-based care.

Unfortunately, it is my duty to tell you and to report to you today that the vision of MACRA and value-based delivery is in serious jeopardy.

According to CMS, currently only 5 percent of U.S. physicians are even participating in alternative payment model arrangements.

More troubling, there are almost no APMs in the pipeline. In the 2 and a half years that PTAC has been operational, only 26 APMs have been submitted for review. Of these, only four have been recommended for implementation, and six for limited scale testing. Moreover, not a single PTAC-recommended APM has been enacted by CMS.

Last month, PTAC had a regularly scheduled meeting for hearing APM proposals from the medical community. The meeting was canceled due to a lack of submitted proposals. The Stark and associated fraud and abuse laws are one of the principal barriers to the development of alternative payment models. The Stark law was written nearly 30 years ago, as you know, and it has not been substantially modified since 1993.

Congress recognized long ago that the Stark law was an obstacle to care coordination and value-based delivery when it authorized the Secretary of HHS to waive the self-referral and the anti-kickback prohibitions for accountable care organizations, yet independent physician practices were left behind.

Congress needs to, in our judgment, level the playing field to provide the same protections for independent physicians to test and participate in APMs that were offered to ACOs.

While HHS can grant waivers to approve APMs, it is important to understand that organizations and practices wishing to engage in APM development find themselves in a catch-22.

We cannot test in APM in the real world without financial waivers to Stark and anti-kickback laws, yet these waivers cannot be granted unless there is an approved APM.

Organizations such as ours, frankly, may spend years of work and substantial investments designing an APM, but it remains a theoretical, mathematical model whose actual impact on patient care and healthcare financing is unknown without testing in the clinical environment.

Moreover, case-by-case waivers granted by HHS are also typically narrow and cannot foresee real-world circumstances, such as evolving standards of care or new innovations, or other circumstances that affect physician behavior and require modification of waivers.

Stark law additionally represents a barrier to APM adoption in that it prohibits compensation to physicians who receive revenue from designated health services based on the, quote, "volume or value" of their referrals to these services. While this makes sense in a fee-for-service model, and we do not dispute that, it is not relevant in alternative payment models under which practices accept risk and financial exposure to Medicare is limited. The volume or value prohibition prevents practices from utilizing revenue from designated health services to financially reward or penalize physicians for adherence or deviation from clinical best practices standards.

Our ability to financially incentivize physicians for clinical pathway adherence is crucial to success in a value-based construct. Eliminating volume or value from Stark prohibitions for the testing and operations of APMs would result in a clean, targeted, modernized version of the Stark and anti-kickback statutes.

We must be able to pay for value, frankly, on a value-based arrangement. To be unable to pay for value in a value-based arrangement is sort of a nonstarter, frankly. These are the reasons why LUGPA and 24 other diverse physician organizations have endorsed the Medicare Care Coordination Improvement Act, H.R. 4206, which eliminates the volume or value prohibition in APMs and also provides a means for HHS to grant waivers to test a proposed APM when it is submitted in writing and approved by the Secretary.

Importantly, these waivers are not indefinite. They must be recertified on a semiannual basis until the APM is approved or denied.

We fully recognize there is no panacea that would transform healthcare delivery into a value-based system overnight. We do not advocate modification of the Stark law as it relates to Medicare fee-for-service.

That said, Stark law must be modernized to allow for the creation of alternative payment models. These models represent innovative delivery systems that will increase care coordination, improve outcomes, and decrease costs.

I thank you for the attention, and would be happy to answer questions, Mr. Chairman.

Chairman Roskam. Thank you.

Mr. Lappin.

STATEMENT OF MIKE LAPPIN, CHIEF INTEGRATION OFFICER, ADVOCATE AURORA HEALTH

Mr. Lappin. Thank you, Mr. Chairman, Ranking Member Levin and distinguished members of this subcommittee.

Thank you for convening this important hearing and allowing me the opportunity to share some of the more significant barriers we have faced under the Stark law and other laws as we have moved towards a value-based care delivery model. I will also suggest some solutions that Advocate Aurora Health urges Congress to consider.

I am the Chief Integration Officer of Advocate Aurora, the tenth largest not-for-profit integrated health system in the United States. We serve nearly 3 million patients annually in Illinois and Wisconsin across more than 500 sites of care.

Our system is committed to the delivery of value-based care and participating in innovative reimbursement models intended to improve outcomes and better control costs. Roughly 50 percent of our patients are in some type of value-based payment model.

We have also operated one of the largest ACOs in the country and have achieved millions in cost savings for taxpayers while remaining among the highest in national quality results.

Dr. Lee Sacks, our Chief Medical Officer, testified at a roundtable of hospital providers held by this subcommittee in April on value-based care, during which he mentioned the need for Stark modernization. I welcome the opportunity to continue this important discussion with the subcommittee today.

While our system has been successful in driving care delivery improvements and cost savings in the provision of value-based care, the Stark and fraud and abuse laws in their current form are stymying our efforts and our ability to drive future success.

Here are a few examples:

Gain sharing. We only pursued a test of a gain sharing system in which we aligned some physician compensation to outcomes by sharing a portion of the savings generated under new care models and standardization with physicians on a much more limited basis than desired, although it met OIG guidance, because we were not comfortable with the risk posed by not having a clear Stark exception.

Data analytics. We would like to share our analytics platform being developed and other innovative technologies with physicians that are closely aligned with our system, as we did with our Electronic Health Record. But there is no exception to Stark for the analytics tools or other technologies like there is for our EHR. This data analytics platform will guide clinical decision making in a value-based environment. We have already experienced several successes, including dramatically reducing the number of high-risk heart failure patients presenting for admissions in our hospitals and emergency rooms.

Innovation. Ironically, in many situations, it is riskier for us to work with a new business venture started by a physician who cares for our patients, our greatest source of innovation, rather than a physician who does not, because making an investment in or providing other support to a venture started by one of our physicians implicates Stark.

Here are three solutions we propose to help modernize the existing Stark law:

Provide exemptions for participation in value-based arrangements. Properly structured APMs typically have built-in safeguards, such as the careful monitoring by CMS and a payment system that rewards value and inherently protects against inappropriate self-referral and overutilization. Existing waivers only provide limited protections.

Make Stark intent-based; make penalties proportionate to the violation. A major problem with the Stark law is that it is a strict liability statute. Penalties are disproportionate to the violation and intent to violate the law is not considered. And all noncompliance, however minor or innocent, constitutes a violation of the law potentially resulting in severe penalties.

Finally, reduce confusion in the application of Stark and other laws. Clarify the requirements for key terms used in Stark, such as fair market value, which have been interpreted by courts differently, and seek to reduce overlap between Stark and other related laws, which creates confusion and burdens us with our efforts to comply with these laws and to manage the care of our patients.

We urge Congress to provide HHS and OIG with greater rulemaking authority to align the Stark law exceptions and other laws' requirements to create a cohesive regulatory regime that protects patients while still allowing for innovative care arrangements.

While we have achieved significant success to date, we feel strongly that there are additional opportunities to unlock the full potential of innovative APMs from improving care quality and reducing cost for patients, taxpayers, and the Nation.

If we had a clear exception authority or assurance that certain high-quality initiatives would not run afoul of existing Stark requirements, we believe we could take on more risk and move more quickly to implement a truly value-based healthcare system.

The Stark law needs to be modernized to meet patient needs and expectations.

Thank you again for this opportunity to testify on the Stark law and recommended reforms. I am happy to answer questions that the subcommittee has on this topic.

Chairman Roskam. Thank you.

Mr. DeBusk.

STATEMENT OF BRIAN DEBUSK, PH.D., M.B.A., PRESIDENT AND CHIEF EXECUTIVE OFFICER, DEROYAL

Mr. DeBusk. Chairman Roskam, Ranking Member Levin, and members of the subcommittee, thank you for the opportunity to testify.

My name is Brian DeBusk, and I am the president and CEO of DeRoyal, a medical device manufacturer with approximately 2,000 employees worldwide.

I appreciate the opportunity to speak with you today about ways to improve the delivery of healthcare through better physician provider alignment.

Medicare Stark law plays a critical role in ensuring adequate financial separation between doctors and providers to whom they commonly refer patients. Induced utilization created by potential conflicting interests places beneficiaries and taxpayers in harm's way. Therefore, I would like to emphasize the need for caution when considering ways to make significant changes to amend the Stark law in an unfettered fee-for-service environment.

Yet, to date, physicians and providers are being encouraged to align their activities to be more patient-centric, improve care coordination, and facilitate delivery system change. And to support this transformation, the Stark law should be modernized.

Waiving certain elements of the Stark law is not without precedent. Even in its earliest form, the Stark law exempted what we now refer to as the Medicare Advantage program for many of its provisions.

Policymakers recognize that in a capitated risk-borne environment, checks and balances exist to curtail the risks of induced utilization the Stark law set out to prevent.

Similarly, when providers share risk in a fee-for-service environment, there is diminished upside to increasing utilization through referral as it diminishes potential shared savings.

To that end, Congress has further encouraged care coordination by giving Medicare providers new tools for managing cost and quality through programs like the Medicaid Shared Savings Programs, demonstrations managed by the Innovation Center, and MACRA's payment incentives.

Many, but not necessarily all, of these alternative payment models incorporate some form of downside risk. While the financial constraints aren't as direct as the risk-borne capitation found in Medicare Advantage, they do represent a significant weigh point between unmanaged fee-for-service and private plans.

Many of the APMs already include Stark law waivers. However, it appears these waivers are not used to their fullest. Why?

One is an issue of past practice. For the last few decades, the Stark law has cast a long shadow over physician-provider financial arrangements and, as intended, has served as a strong deterrent.

Of the current initiatives in my view, accountable care organizations, ACOs, represent the most promising platform for moving Medicare toward a managed fee-for-service model. ACOs already have generous waivers that exempt them from major portions of the Stark law.

For example, the next generation ACO model waives most of Stark's financial arrangement provisions. Again, it appears these waivers are not used to their fullest. I believe the reason is twofold.

First, because the waivers are issued on a case-by-case basis, there is an inherent uncertainty as to their evolution over time. Codifying these waivers into law would give physicians and other providers the certainty they need to invest in and support the transition to value-based care.

Second, we need to strengthen ACOs themselves, particularly models that incorporate downside risk.

ACOs serve as the substrate for the transition to value-based care, which is the underlying driver for these hearings on Stark modernization today.

I commend policymakers for the improvements made in terms of beneficiary attribution and spending benchmarks within the ACO programs, but more needs to be done to provide certainty and encourage physicians to become active participants in these models.

It is safe to say that the issues of Stark modernization, the proliferation of successful ACOs with downside risk, and the successful implementation of MACRA, are all inextricably linked.

In summary, there is an exciting opportunity to modernize the Stark law so as to support the transition from volume to value.

Thank you for allowing me to testify today. I look forward to answering my questions you may have.

Chairman Roskam. Thank you.

Mr. Sylvia.

STATEMENT OF CLAIRE M. SYLVIA, PARTNER, PHILLIPS & COHEN LLP

Ms. Sylvia. Thank you. Thank you, Chairman Roskam, Ranking Member Levin, and members of the subcommittee. Thank you for the opportunity to testify this afternoon.

My name is Claire Sylvia, and I am a partner in the law firm of Phillips and Cohen, which represents whistleblowers and False Claims Act cases. The False Claims Act is one of the primary ways the government enforces the Stark and anti-kickback laws.

I am offering this testimony on behalf of Taxpayers Against Fraud, education fund, a nonprofit education that provides education and supports the Federal and State False Claims Act and laws intended to protect taxpayer funds.

The president and CEO of Taxpayers Against Fraud, Bob Patten, is here with me today.

I have submitted written comments for the record, and I won't repeat them here this afternoon. I want to address just three general arguments and respond to them that have been made about the need to reform Stark.

This afternoon's hearing is to address ways in which the Stark's self-referral law hinders the development of value-based coordinated healthcare and provide possible solutions to this concern.

We believe, really, the threshold question for this subcommittee is to identify specifically what, if any, problem exists related to the development of value-based care that needs to be rectified and can't be addressed within the existing Stark framework.

Stark is a critical tool for the government in checking conflicts of interest and in the delivery of federally funded healthcare and ensuring that patient needs, rather than financial interest, are the focus of medical decisionmaking.

Proposals to eliminate or substantially curtail application of this important antifraud law to broad undefined categories of arrangements should be approached with caution.

I will touch briefly on several arguments that have been advanced about the need to amend Stark, many of which predated the move towards value-based care: first, that the law blocks or restricts innovation; second, that the law is too complicated; and, third, that the penalties and the complying costs are too high.

With respect to innovation, it sounds like something we can all support. The case hasn't been made that the law as it exists and the ways of providing for regulations and advisory opinions stand in the way of innovation.

To a degree, all ethics laws restrict the ability of persons or industries to innovate, but they do that because there is some important value that we place above unrestrained innovation.

Here, that value is ensuring that financial interest doesn't skew healthcare decisionmaking that affects patients. And this is particularly concerned where the government subsidizes those healthcare decisions on a vast scale and cannot easily evaluate each transaction to determine if it is compliant with patient needs.

If there are specific arrangements that do not present a risk of conflicts of interest, there are existing mechanisms to propose them and have stakeholders opine on how those arrangements may or may not implicate conflicts of interest. Those mechanisms may not work as quickly or efficiently as the regulating community may want, but taking the time to evaluate competing claims is necessary to help avoid unintended consequences.

We have also heard the law is complicated. But it is important to remember that the basic idea of the Stark law is pretty simple. Regulations that expand on the exceptions to the law provide flexibility in a changing environment.

As we have heard, laws can sometimes not keep up with developments in industry, but the regulations allow for flexibility to address those changing environments.

Regulations allow providers to structure arrangements in ways that do not violate the broad prohibition on self-referrals. We have heard a lot this afternoon that people find it difficult to comply, but there are many

circumstances where they can comply. There is no necessary indication that the law itself needs amendment.

The regulatory process provides the flexibility to address changes in healthcare field without undermining the basic premise of the statute, which has stood the test of time.

The penalties for violating Stark are high, but there is a reason for that. Without high penalties, violating the law can be just the cost of doing business. The purpose of high penalties is to ensure that providers take this prohibition very seriously. What is at stake is taxpayer money is spent on individual patients who are affected by those decisions. These are not minor issues.

According to the GAO report that was issued this month, the Federal Government spent $700 billion in 2017 on healthcare. Requests for blanket exceptions to the fraud laws that prevent those funds from being expended inappropriately should be approached with extreme caution.

I thank you, and I look forward to the opportunity to answer any questions that you may have.

Chairman Roskam. Thank you all very much.

I think we all learned and I know I greatly benefitted from each of you in your perspectives.

I yield to Mr. Paulsen.

Mr. Paulsen. Thank you, Mr. Chairman.

And we have had a very good, healthy discussion and testimony, which we appreciate today. Let me just follow up. Maybe Dr. Kirsh or Mr. DeBusk, if you can answer.

So, as part of the committee's Medicare Red Tape Relief Initiative, which has been ongoing -- Chairman Tiberi started this before Chairman Roskam continued the effort -- we actually received dozens and dozens and dozens of comment letters from a multitude of all of these healthcare providers complaining about the burdens that were associated with the Stark law.

And that includes burdens that get in the way of coordinated care, burdens that get in the way of these confusing documentation requirements, actually. And the violations that are associated with documentation requirements can then lead to the severe penalties.

And I am wondering if you can just maybe provide some examples of what are some documentation examples that could be identified where this is distracting from patient care and is leading to violations of Stark?

And any of you can comment.

Mr. DeBusk. One example that immediately comes to mind is the documentation necessary, for example, to do fair market value estimates any time you are trying to enter into a direct or indirect compensation arrangement with physicians. I know that providers and physicians experience a lot of angst and a lot of legal work just trying to get these, basically, quotes to determine fair market value.

Mr. Paulsen. Anyone else?

Dr. Kirsh, anything to add?

Or Mr. Lappin?

Dr. Kirsh. Well, the genesis of your question is related, I think, toward the fee-for-service system that we are currently operating in. And we do operate in that system, and we do have burdens with Stark, with complying with Stark.

I do agree that Stark has done its job. It has curbed fraud and abuse. Within the fee-for-service context, it does make it very difficult for us to structure relationships with other provider entities that we would want to provide care for the beneficiary.

This is actually more important in an alternative payment construct, which is the emphasis of my comments today. But even in the fee-for-service environment, if, for example, a urology group wanted to coordinate care with an oncology group in the community to provide a comprehensive suite of services to patients with prostate cancer, we have lots of barriers in doing that.

And I understand testimony here regarding the severity of the penalty being important to guard against abuses, but when the penalties are so severe that you are afraid to even enter any arrangements to care-coordinate with other physicians, then you really can't get anywhere.

I want to emphasize, though, that that is in the fee-for-service construct. And the focus of our argument, at least for me today, is that we really need much more reform in the alternative payment world.

Mr. Paulsen. Thank you. Thank you, Mr. Chairman.

Chairman Roskam. Mr. Levin.

Mr. Levin. You know, as I have listened to this, I am really saddened that the focus in this Congress has been to dismantle the Affordable Care Act. What we should have been doing is discussing issues like this. Instead, it has been this negative effort to rip up what has provided healthcare coverage and insurance for the first time for millions of people. And I think that is a sad commentary on what has been the focus of the majority here. We should be discussing issues like this instead of being destructive.

I was on the committee during, putting together much of the Stark law. The focus then was something very different. We didn't have these new models. And the problem was we saw abuses where people, physicians and providers, were referring people to entities that were owned by the person who was making the referral.

I don't remember discussing this issue hardly at all. So now it has changed. And I think the challenge is this: How are we going to make sure that within this new model that so many of us work for in the Affordable Care Act, value-based, that there aren't new problems and new abuses?

We don't want hospitals paying physicians to refer patients to their hospitals, right? And we don't want companies that make medical devices paying physicians to use those devices. That is a somewhat different set of problems.

And so, Mr. Chairman, I think what we need to do is now to shift our focus entirely and to make sure that, as we move to a model, that we have a structure that alerts ourselves to new problems and new potential abuses and not simply sweep aside a Stark structure that worked fairly well -- though there was endless controversy for fee-for-service -- and make sure it works as we move to a value-based system.

And, again, it is really sad that the focus these last years have been 50-60 bills to destroy what has brought healthcare to millions of people.

So I hope, Mr. Chairman, from here on in, there can be an emphasis on a constructive discussion like the four of you have presented

Chairman Roskam. Mr. Kelly.

Mr. Kelly. Thank you, Mr. Chairman. Thank you all for being here.

I know you leave your private lives to come here and testify in front of us and to give us some look into the way we could make the healthcare system something that is actually better for the patients and actually more affordable for taxpayer whose subsidize quite a bit of this.

I am interested though, Dr. Kirsh, when you talked about, was it alternative payments? I come from an altogether different world. I know it rankles some members when I talk about how the automobile people handle warranty work. But I got to tell you, there are so many times that we do work, we base it on three things: Number one, we establish a repair order. An owner comes in with a complaint. We try to determine the cause of the complaint. And then we come up with the correction. So we call it the 3C's. But what you are looking at though, aren't we looking at how do we drive -- how do we look at innovation and technology today to collect data that would show you exactly where things are trending?

The only thing I find wrong with the Stark piece -- maybe not the only thing -- but is the assumption that somehow these doctors are working in collusion with their groups or with other people in order to run the costs up so they can pad their own pockets.

I just think that is awfully difficult to sit there and assume that everybody is in that ballpark. And I am not saying that is what everybody thinks, but that seems to be the way the Stark law works -- but alternative payments is what I am looking at.

So, when you talk about that, Doctor -- anybody else can weigh in on this -- listen, we have a huge challenge in front of us. But my assumption is most of these people spend all their time in med school, and they go and they do their internship, and they come out because they want to help people.

And I think we are making it so hard for them to make that decision. A lot of them opt out early on and say, why in the world would you incur all that time and all that debt and come out and not be able to have a sustainable business model?

So if you can, talk to me about the alternative payment model. I asked Dr. Wenstrup what that meant. So if you can just kind of walk me through that.

Dr. Kirsh. Well, I will be happy to, Congressman. Thank you for the question.

In the transition to value-based care, the concept is that we are going to create new payment models, whereby the payer -- in this case, Medicare -- is going to compensate a group of providers for achieving a certain health outcome for a certain population of patients.

And in the proper payment model construct such as that, the volume of referrals to any particular service really become somewhat irrelevant. And what is needed is the ability to have win-win scenarios between the patient, the provider, and the payer, such that if we work together we can decrease cost and improve quality.

And in fact, this is the vision of the value-based care. It is the vision of the ACA and of MACRA, and we are falling very far behind because we are not making much progress in American medicine in providing value-based care.

I hope I explained that adequately what an alternative payment context is.

Mr. Kelly. No, I get that. We are on limited time, but thank you all so much for being here today. It was very valuable. So thank you.

And, Mr. Chairman, I yield back.

Chairman Roskam. Dr. Wenstrup.

Mr. Wenstrup. Thank you, Mr. Chairman.

And thank you again for being here, all of you.

You know, I think one of the frustrating things for physicians today -- you know, I can remember practicing, eighties and nighties, and the headlines every day were Greedy Doctors This and Greedy Doctors That. And I was so far in debt that, as I am starting up in my practice, I was like: You have got to be kidding me. Do you know how many years went into this debt, and while my friends were out making money and having a good time, as their careers were starting off, I was further and further in debt?

And that is where doctors are today: $200,000 in debt, and all this stuff, and then, you know, you come out into an environment where you must be out to try and rip people off.

And the fact of the matter is: You set aside and work very hard for 7, 10 years, sometimes more, depending upon your specialty, and this is what you face when you get out. And I don't think that is going to help the future of medicine. And that is why you see so many doctors today telling their kids: Don't go into medicine.

I went to court one time in 27 years of practice, and that was to testify against another doctor because what that doctor was doing wasn't just bad outcomes; it was bad things. And we want to police our own. And so, when you get into all this and everybody is guilty until proven innocent of something, we have really harmed our system.

And I think with the way you can collect data and outcomes today, you can come up with alternative payment models, and you can look at trends.

The community knows who is not doing things right. I promise you. As a doctor, I never felt I needed Washington to tell me if I was doing a good job. I needed my referring doctors to tell me that. I needed my patients to tell me

that. And that is how I kept my doors open, and that is how I was able to put a roof over my head.

So we are going in the wrong direction here. I am all in favor of going after bad actors, but don't make everyone a bad actor. And our system is in that situation today.

And so I kind of addressed that to you, Ms. Sylvia, because, you know, you are in that arena, aren't there ways we can do this better where we can -- you know, like I said, communities know who the bad actors are. I think we can cut your agency down considerably and do more -- yeah, if you don't mind addressing that, please.

Ms. Sylvia. Yes. Thank you, Congressman Wenstrup.

I think we would all like to live in a world where all doctors are as you described. And I do believe that there are many such doctors who go to medical school and try to do the right thing by their patients. But if the Department of Justice were here today, I think they would give you many, many examples of doctors who don't fit into that category.

There are doctors who violate of the anti-kickback statute. There are doctors who engage in abusive practices or hospitals that engage in abusive practices. And the Stark law isn't assuming that everyone is a bad actor, but it is directing all healthcare providers to stay away from an area which is prone to abuse.

The anti-kickback statute is designed to ensure that people who actually have the intent to influence decision making are covered. So, you know, we would like every one to be appropriate, but the laws are designed for those who are not.

Mr. Wenstrup. The anti-kickback statute, I get that, but at the same time, I think with today's ability to collect data and watch things, we can watch for trends and then go after the people that are abusive.

Chairman Roskam. Thank you. On behalf of the subcommittee, I thank all four of you for your testimony today.

I just want to hit just a couple of quick points.

Ms. Sylvia, I hear what you are saying. So I know you are the minority witness, and you feel like: Oh, golly, you know, 3 to 1 and all that. But I hear what you are saying. And at least my attitude -- and I think I speak for most folks on the committee – is that there is not this disposition that says, "Let's just sweep this away," like it is all a foregone conclusion. But it really does feel like we can improve this. And I would be interested in your thoughts in terms of improvement, and for example, Mr. DeBusk's suggestion on codification of the exemptions, and so forth. That seems to me pretty rational.

So I think that there is some very good work that we can do here. My view, you and I would probably differ in terms of strict liability. You have articulated a reason for it. I think it may be yesterday and moving more into intent is the way to go. And I get it; reasonable people can differ.

The harmonization, and this was the testimony of Secretary Hargan, the harmonization essentially of the anti-kickback statute with Stark, you know, these things should be -- the term of art should be overlapping; they should be interactive and so forth. And I think this is something that we can take up.

The final point is there is good work that we can do here. So God bless my friend Mr. Levin. But when Mr. Levin says, "I am so disappointed and bummed out that we are having this conversation now as opposed to previously," it is like, okay, I get that, but we are having this conversation now. And I think that that is a good thing.

And notwithstanding some of the other disagreements we have about the ACA and so forth, I think that this subcommittee can do really robust, solid work that can take into account the critics, like Ms. Sylvia, who are basically urging to pump the brakes here, don't go too fast, and yet, at the same time, are sensitive to the changing nature of things.

And I think that we can perform at a higher level on a bipartisan basis, and I am looking forward to fruitful work.

And I sense I have provoked Mr. Levin, and I will yield to him.

Mr. Levin. I fully agree.

Chairman Roskam. I continue to yield to him.

Mr. Levin. I just regret it so much that it is July and we are now discussing this constructively when we should have been doing it all along. But I agree

completely that this is an example of where we need to sit down and to exchange ideas. I agree completely.

Chairman Roskam. Well, I am not going to improve on that closing.

And as a reminder, any member who wishes to submit a question for the record will have 14 days to do so. Any member submitting questions after this hearing, I ask that the witnesses would respond in a timely manner, to the extent that you are able.

And, with that, again, thank you to our witnesses.

The committee stands adjourned.

[Whereupon, at 5:41 p.m., the subcommittee was adjourned.]

MEMBER QUESTIONS FOR THE RECORD

Questions for the Record
Hearing on Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program
July 17, 2018

Representative Kind (D-WI)
Question: As you know, the Stark law prohibits a physician from making referrals for designated health care services to an entity with which he or she (or an immediate family member) has a financial relationship. There are statutory and regulatory exceptions such as the In-Office Ancillary Services Exception (IOASE) and waivers granted for CMS led models. The IOASE includes physical therapists even though physical therapy is not a same-day service. Under Stark, claims for services resulting from a prohibited referral may not be filed with Medicare, and Medicare cannot pay any such claims.

How should the Stark law's self-referral prohibitions be modified so as to respond to the goal of coordinated care and payments based on value? In order to reflect the current way in which medicine is practiced and health care delivered, should that tailored approach also include revision of the In-Office Ancillary Services Exception to remove physical therapy and other services which are not same-day services?

Response: To achieve a truly value-based, patient-centered health care system, doctors and other providers need to work together with patients, and Medicare's regulations must support this close collaboration. Over the past year, the Centers for Medicare & Medicaid Services (CMS) has engaged with providers in a discussion about regulatory burdens. Through these discussions, one of the top four issues raised by stakeholders was the burdens imposed by Stark Law compliance. Stakeholders said the Stark Law sometimes prevents doctors from participating in or considering integrated delivery models, alternative payment models, and arrangements to incentivize improvements in outcomes and reductions in cost.

This Administration is open-minded about the types of regulatory and statutory changes that may be needed to make the Stark Law more compatible with the push toward integrated care and alternative payment models. We note that the in-office ancillary services exception is statutory, and the President's Fiscal Year 2019 Budget includes a proposal to establish a prior authorization program for high utilization practitioners of radiation therapy, therapy services, advanced imaging, and anatomic pathology services. Under the proposal, CMS would re-evaluate annually to determine which physicians would be subject to prior authorization in the coming calendar year.

In June, CMS released a Request for Information (RFI) soliciting specific input on a range of issues identified with the Stark Law to help the agency better understand provider concerns and target its regulatory efforts to address those concerns. The President's Fiscal Year 2019 Budget includes a proposal that would establish a new exception to the physician self-referral law for arrangements that arise due to participation in Advanced Alternative Payment Models. HHS, including CMS, is always happy to work with Congress and provide technical assistance on any proposed legislation to revise the Stark law, including legislation related to the in-office ancillary services exception.

HHS is working hard to transform the healthcare system into one that pays for value, and we will continue to engage Congress, providers, patients, and other stakeholders across the healthcare industry as we examine ways to reduce regulatory burden while ensuring patient safety and holding providers accountable for improved patient outcomes.

Question: Thank you for your testimony on the need to modernize the Stark law in order to provide more pathways for the development of value based payment arrangements. We heard at the hearing from physicians and health systems that the Stark law needs updating if we hope to encourage the development of more innovative care delivery models. I believe Congress also has a role to play here. As you may be aware, I have introduced a bipartisan bill, H.R. 4206, the Medicare Care Coordination Improvement Act, that seeks to break down barriers to the Stark law to pave the way for independent physician practices to begin to develop alternative payment models. If we are going to succeed in promoting the success of MACRA and the development of value based payment models, we need to work together through both the legislative and regulatory process. Could I get your commitment to work with us in a more technical way to help advance our legislation, H.R. 4206?

Response: HHS, including CMS, is always happy to work with Congress and provide technical assistance on proposed legislation.

Representative Higgins (D-NY)

Question: I **appreciate the efforts of the Centers for Medicare and Medicaid Services to increase provider participation in Alternative Payment Models by studying whether changes to underlying laws, like the Stark laws, should be made to do so. Given that the GAO and several peer-reviewed journals have reported that the abuse of the Stark law's in-office ancillary services exception has led to overutilization, can you please describe how the department will address the valid concerns of cost, overutilization, and patient protections as it seeks to advance APMs via Stark law reform?**

Response: Across all of our programs, HHS is committed to being responsible stewards of taxpayer dollars. Millions of Americans rely on Medicaid and Medicare to meet their everyday healthcare needs, and together Federal health care programs comprise the largest portion of the Federal Budget.

This Administration is open-minded about the types of regulatory and statutory changes that may be needed to make the Stark Law more compatible with the push toward integrated care and alternative payment models. We note that the in-office ancillary services exception is statutory, and the President's Fiscal Year 2019 Budget includes a proposal to establish a prior authorization program for high utilization practitioners of radiation therapy, therapy services, advanced imaging, and anatomic pathology services. Under the proposal, CMS would re-evaluate annually to determine which physicians would be subject to prior authorization in the coming calendar year.

In June, CMS released a Request for Information (RFI) soliciting specific input on a range of issues identified with the Stark Law to help the agency better understand provider concerns and target its regulatory efforts to address those concerns. The President's Fiscal Year 2019 Budget also includes a proposal that would establish a new exception to the physician self-referral law for arrangements that arise due to participation in Advanced Alternative Payment Models. In addition, HHS, including CMS, is always happy to work with Congress and provide technical assistance on any proposed legislation to revise the Stark law, included related to the in-office ancillary services exception.

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Committee on Ways and Means

U.S. House of Representatives

1102 Longworth House Office Building

Washington, DC 20515

Dear Representative Kind:

Thank you for your question in follow-up to the Hearing on Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program, of July 17, 2018.

Question: Thank you for your testimony in support of H.R. 4206, the Medicare Care Coordination Improvement Act. I was pleased to introduce this bill with my colleagues Reps. Marchant, Ruiz and Bucshon and I'm pleased that my colleague from Washington, Rep. DelBene, has joined in cosponsoring this important legislation. In your testimony you referenced the slow pace at which independent physicians have been developing alternative payment models. In order for MACRA to succeed, we need to break down barriers and encourage more innovation and care delivery models to be put forward. Can you please give us an example of how, if we are able to modernize Stark law, an independent urology group like yours could improve patient care for prostate cancer?

Response: As I indicated in my testimony, the current APM development and approval process is dysfunctional. Several dozen APMs have been submitted to PTAC, but not a single one has been approved and implemented by CMMI. We should be seeing many more APM applications to PTAC (if anything, they have slowed) and at least some movement by CMMI in implementing submitted APM applications by now. Only 5 percent of physicians are currently engaged in an APM.

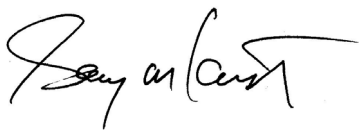
We are grateful for your introduction of H.R. 4206, the Medicare Care Coordination Improvement Act. The primary obstacle the bill would remove is our ability to test an APM while it is under review by CMS. Our trade association, LUGPA, which represents the majority of independent urologists in the US, spent large sums of money developing an APM to encourage adoption of active surveillance for prostate cancer (see below). The development phase included clinical protocols and complex economic modelling regarding physician compensation, but at the end of the day we do not know whether the APM will be successful in the real world unless we can actually test the APM in clinical practice. The bill would eliminate the restrictions imposed by Stark on "volume or value" and allow practices like ours to test APM models—only after the approval of the Secretary—during the submission and review process. This will inform both practitioners and policymakers of the viability of an APM and whether any adjustments should be made.

Without this testing feature in the legislation, physician practices are left to wait for CMS review and approval of their APMs, which can take a very long time and does not allow an evaluation of real world clinical and economic outcome after engaging in the treatment pathways envisioned by an APM.

LUGPA's APM on Active Surveillance provides a good example of how the law can improve patient care, which is the basis of your follow-up question. As the understanding of prostate cancer has evolved, urologists are better able to stratify prostate cancer patients by their risk of disease progression and to advise patients with low-grade or more indolent cancers to pursue "active surveillance" rather than immediate treatment for their cancer. Active surveillance allows men to safely avoid the inconvenience and side effects of surgery or radiation therapy for prostate cancer—a significant improvement in patient care—while at the same time achieving healthcare savings for the Medicare system and the beneficiary.

Under Medicare's fee-for-service system, physicians are largely compensated when they perform procedures such as surgery or radiation therapy. We would like to align the compensation system with current science and incentivize active surveillance in appropriate men with prostate cancer via the LUGPA APM. However, we have not been able to test the feasibility of adoption of active surveillance protocols, or the effectiveness of the APM's proposed compensation methodology due to current Stark restrictions. The Stark law prohibits the sharing of designated health service (e.g. pathology and radiation therapy) revenue amongst practice partners in ways that recognize volume or value. As a result, we are unable to implement protocols that that financially reward physicians for providing less volume of services and greater value. The bill, if enacted, would allow us to test the concept that alignment of financial remuneration with best practices can lead to meaningful and appropriate changes in practice patterns that both improve patient care and provide savings to the Medicare program.

Sincerely,



Gary M. Kirsh, M.D.

STILL PENDING ONE QUESTION FOR THE RECORD

PUBLIC SUBMISSIONS FOR THE RECORD

STATEMENT

of the

American Medical Association

to the

U.S. House of Representatives Committee on Ways and Means
Subcommittee on Health

Re: Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program

July 17, 2018

Division of Legislative Counsel
(202) 789-7426

STATEMENT

For the Record

of the

American Medical Association

to the

U.S. House of Representatives Committee on Ways and Means
Subcommittee on Health

Re: Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program

July 17, 2018

The American Medical Association (AMA) appreciates the opportunity to provide our views regarding today's hearing on modernizing the Stark law to ensure the successful transition to value-based care. We commend the Health Subcommittee for holding this hearing and urge Congress and the Administration to update Stark to remove the barriers that impede value-based care.

According to the U.S. Department of Health and Human Services (HHS), the fraud and abuse laws "may serve as an impediment to robust, innovative programs that align providers by using financial incentives to achieve quality standards, generate cost savings, and reduce waste."[1] While everyone wants fraudsters to face appropriate punishment, there also is widespread acknowledgment that the fraud and abuse laws, like Stark, can stand in the way of payment and delivery system innovation.

Significant changes in health care payment and delivery have occurred since the enactment of Stark. Numerous initiatives are attempting to align payment and coordinate care to improve the quality and value of care delivered. Delivery of care is going through a digital transformation. However, Stark—in its almost thirty years of existence—has not commensurably changed.

Stark was enacted in a fee-for-service world that rewarded the volume of services. The fraud and abuse laws act as a deterrent against overutilization, inappropriate patient steering, and compromised medical judgment with heavy civil and criminal penalties like treble damages, exclusion from participation in federal health care programs, and potential jail time. As the Subcommittee notes, the health care system is moving to a world that rewards the outcome of the care provided. An important focus of payment reform is changing reimbursement models to emphasize the value or quality of care provided. However, this emphasis can run afoul of the

[1] Department of Health and Human Services, *Report to Congress Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements between Physicians and Hospitals As Required by Section 512(b) of the Medicare Access and CHIP Reauthorization Act of 2015* (2016), *available at* https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Report-to-Congress-2015.pdf.

fraud and abuse laws. For example, even if the primary purpose of an arrangement is to improve patients' outcomes, as long as one purpose of the arrangement's payments is to induce future referrals, the fraud and abuse laws are implicated (e.g., an arrangement that pays for a nurse coordinator to coordinate a recently discharged patient's care between a hospital, physician specialists, and a primary care physician may induce future referrals to the primary care physician to avoid an unnecessary readmission to the hospital).

Fostering the shift from volume to value has necessitated reviewing and, in some situations, updating fraud and abuse laws to ensure that they do not unduly impede the development of value-based payment. Through specific statutory authority, both the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) have deemed it necessary to waive the requirements of certain fraud and abuse laws to test the viability of innovative models that reward value and outcomes.

Outside of those models, however, the fraud and abuse laws may still pose barriers to initiatives that align payment with quality and improve care coordination. Tying compensation to the value of care provided, equipping providers with tools to improve care, and investing in tools to clinically and financially integrate all may run afoul of Stark. For example, it remains unclear how CMS will view measures that promote value given its long-standing belief that rewarding physicians for meeting utilization targets or for reducing or limiting services generally violates Stark.[2]

Accordingly, the AMA urges Congress and the Administration to create a Stark exception to facilitate coordinated care and promote well-designed alternative payment models. This exception should be broad, cover both the development and operation of a model to allow physicians to transition to an alternative payment model, and provide adequate protection for the entire care delivery process to include downstream care partners, entities, and manufacturers who are linking outcomes and value to the services or products provided.

Flexibility is important for innovation. Yet flexibility in a new payment system also may raise fraud and abuse concerns. To help address these concerns, the Stark exception could incorporate provisions that increased transparency and accountability through a board of directors approval; require the arrangement to be tied to the goals of the alternative payment model; and allow freedom of choice for patients by prohibiting stinting on medically necessary care.

While participation agreements work well in the context of specific payment models, the AMA believes they would likely be impractical for Medicare generally. As an alternative, the parties to the arrangement could set forth in writing the specifics of the arrangement, such as their goals for patient care quality, utilization, and costs, and the items and services covered under the arrangement.

While the focus of today's hearing is on Stark, Stark interacts with other fraud and abuse laws that also need to be modernized, i.e., the anti-kickback statute and the civil monetary penalties law. The AMA asks that Congress and the Administration set forth clear and commonsense

[2] 69 Fed. Reg. 16054, 16088 (Mar. 24. 2004); 72 Fed. Reg. 51052; 51046 (Sept. 5, 2007).

exceptions and safe harbors concerning the formation of innovative delivery models so that physicians can pursue integration options that are not hospital driven.[3]

Physician leadership in these new efforts is instrumental to optimizing care, improving population health, and reducing costs. Physicians provide the care, take care of the patients, and see the cost inefficiencies and overutilization. Physicians should not have to be employed by a hospital or sell their practice to a hospital in order to participate in innovative delivery models. Ultimately, physicians should be able to maintain their independent practice while at the same time have access to the infrastructure and resources necessary to participate in alternative payment models.

The AMA applauds the Subcommittee's efforts to improve the Stark Law and appreciates the opportunity to provide our comments on this important topic. We look forward to working with Congress on ensuring that legal structures keep pace with evolving health care delivery and payment systems.

[3] Although OIG has the regulatory authority to create an anti-kickback safe harbor, CMS, by statute, must show no program or patient abuse in creating Stark exceptions. 42 U.S.C. § 1395nn(b)(4). This Stark standard is difficult for CMS to meet and has caused other proposed regulatory Stark exceptions to fail.

STATEMENT FOR THE RECORD

SUBMITTED TO THE

HOUSE WAYS AND MEANS
HEALTH SUBCOMMITTEE

Hearing on Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program

July 17, 2018

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Ascension is a faith-based healthcare organization dedicated to transformation through innovation across the continuum of care. As the largest non-profit health system in the U.S. and the world's largest Catholic health system, Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2017, Ascension provided more than $1.8 billion in care of persons living in poverty and other community benefit programs. Ascension includes approximately 165,000 associates and 34,000 aligned providers. Ascension's Healthcare Division operates more than 2,600 sites of care – including 153 hospitals and more than 50 senior living facilities – in 22 states and the District of Columbia, while its Solutions Division provides a variety of services and solutions including physician practice management, venture capital investing, investment management, biomedical engineering, facilities management, clinical care management, information services, risk management, and contracting through Ascension's own group purchasing organization.

We sincerely appreciate the Committee holding today's hearing. We applaud the Department of Health and Human Services (HHS) for taking bold steps to identify and address the regulatory impact and burden of the physician self-referral ("Stark") law, while maintaining appropriate safeguards against fraud, waste, and abuse, as well as strong beneficiary protections. Through the request for information (RFI) recently issued by HHS through the Centers for Medicare & Medicaid Services (CMS), this Administration has demonstrated a new and promising commitment to modernizing the Stark Law as part of its overarching "Regulatory Sprint to Coordinated Care." We look forward to submitting more in-depth comments on the RFI and working with HHS on this important issue. Our laws and regulations should support and protect clinical integration arrangements because ultimately they can lead to better care and lower costs. While having appropriate protections against fraud and abuse, healthcare law and policy should encourage integration among hospitals, physicians, and other providers that establish incentive payments or shared savings programs to: (1) promote accountability for quality, cost, and overall care for patients; (2) manage and coordinate care for patients; or (3) encourage investment in infrastructure and redesigned care processes for high-quality and efficient care delivery for patients.

Background

Today, hospitals, physicians, and other healthcare providers face unprecedented pressure to integrate, collaborate, and streamline their services to provide patients and payors more value per dollar, as measured in terms of both improved quality and greater efficiency. Despite the fact that alternative payment models rewarding quality and efficiency have become increasingly popular with payors and are being used to cover more patients, federal fraud and abuse laws have not been modernized to distinguish between alternative payment models and traditional fee-for-service (FFS) healthcare delivery.

Enacted several decades ago, federal healthcare fraud and abuse laws are all still aimed primarily at policing fee-for-service reimbursement. Because of this, their applicability to new and emerging value-based care models is unclear, at best. Combine this ambiguity with the potential for significant penalties (ranging from criminal charges, to financial penalties, to program exclusion), and the result has been that many providers find the risks of participating in value-based care models to be too high. The most onerous legal barriers today include, among others, the federal physician self-referral law, more commonly referred to as the "Stark Law." Originally passed in 1989, the Stark Law has, over time, evolved into a complex system of rules and regulations that prohibit a physician from referring patients to receive "designated health services" payable by Medicare or Medicaid from healthcare entities with which the physician or an immediate family

member has a financial relationship (unless an exception applies). A “financial relationship” can include ownership or investment in a healthcare entity as well as compensation arrangements. “Designated health services” are defined to include several categories of services ranging from inpatient and outpatient hospital care to medical equipment and prescription medications. For example, if a physician is employed by a hospital, the Stark Law states that the physician may not refer patients to that hospital for services paid for by Medicare (*e.g.*, radiology) unless the employment arrangement is structured to comply with an exception — the theory being that the physician would benefit financially from the hospital getting that referral.

The Stark Law was created with the intent of reducing physician financial incentives to send patients for unnecessary tests and procedures, which can be medically unnecessary and raise costs. Physicians and healthcare entities that violate the Stark Law must repay the government for all funds received under the improper arrangement, can be excluded from participating in Medicare and Medicaid, and can face substantial civil charges under the False Claims Act. The Stark Law is a strict liability statute, so a provider is subject to penalties for violating the law regardless of whether he or she knowingly or intentionally did so, or whether there is any intent to induce or reward referrals.

There are specific exceptions to the Stark Law that allow financial relationships between physicians and healthcare entities if the relationships meet strict requirements. For example, there are exceptions for employment relationships, personal services arrangements, office leases, equipment leases, and fair market value arrangements. Though each exception has its own requirements, the exceptions governing payments to physicians all generally provide that a physician’s compensation may not take into account the volume or value of services the physician refers to the healthcare entity, and that the compensation must be commercially reasonable and consistent with fair market value for the relevant services. These terms are complicated to interpret for purposes of value-based arrangements, their definitions have become outdated in the context of integrated care delivery systems, and the move toward value-based care is stymied by their blunt enforcement mechanisms.

As legislators and regulators have increasingly recognized the need to support delivery system reforms that promote greater reliance on value-based arrangements, Congress authorized—and the two most recent Administrations have both executed—limited waivers applicable to federal demonstration programs. These waivers are generally helpful in the context of the demonstration programs to which they apply, but offer very limited value outside of these specific models. Yet, the fact that the government recognizes the need for these waivers further demonstrates that the incentives in value-based arrangements are different than the incentives in a volume-driven system. The flaw in these waivers is that they are temporary and limited in their application, leaving the broader healthcare delivery system to operate in silos because of the restrictions imposed by ambiguously applicable federal fraud and abuse laws that carry the potential for significant penalties. While Congress and the Administration have taken some important steps to address these barriers, the transition to value-based care will require broader changes to existing fraud and abuse laws.

Because the technical requirements of existing federal fraud and abuse laws were crafted to regulate a volume-based payment system, new incentive arrangements that are necessary and appropriate for a value-based system frequently do not fit within the relevant Stark exceptions that are currently available. As a result, there are unmet opportunities to implement value-based arrangements that would improve the delivery of care and lower costs, because the financial incentive arrangements with physicians that promote the transition to value-based care cannot be implemented without very real exposure to compliance risk under current law. At the same time,

value-based arrangements put providers at risk for overutilization, structurally addressing incentives to commit fraudulent billing practices—driving up volume becomes self-defeating in a value-based arrangement where the provider is at financial risk for increased spending.

The Stark Law, along with other similar fraud, waste, and abuse laws and regulations, poses a barrier to numerous types of incentive arrangements that health systems and clinicians have expressed an interest in pursuing, including (but certainly not limited to):

Payment-Based Incentives	Infrastructure	Provider Collaboration	Member/Beneficiary Incentives
• Performance Incentives - Quality Metric Attainment and Adherence to Clinical Protocols • Shared Savings/ Gainsharing • Bundled Payments	• Providing EHR Systems and Other Technology Platforms • Care Management Services and Team-based Care	• Discharge Planning • Clinically Integrated Networks	• Chronic Disease Management • Treatment Plan Compliance

Congress and the Administration have made notable strides towards advancing value-based care. However, notwithstanding the overarching desire to transition towards a value-based system, FFS-driven federal fraud and abuse laws continue to inhibit this shift and remain impediments to bending the cost curve through innovative, comprehensive care models. To fully address the existing barriers, we strongly agree with HHS that it is time to modernize these laws to promote transformation by increasing the flexibility of healthcare industry participants to engage in innovative financial arrangements.

Conclusion

We reiterate our strong support for the Administration's efforts to modernize Stark as part of the broader Regulatory Sprint and we thank HHS and CMS for being strong partners in promoting transformation of the healthcare delivery system. These efforts demonstrate a unique understanding at HHS that certain regulatory requirements or prohibitions – well-meaning as they may have been when promulgated – can act as barriers to coordinated care in today's evolving healthcare delivery system. We appreciate HHS's thoughtful engagement with industry, patient groups, and other stakeholders to assess whether these regulatory provisions serve as unnecessary obstacles to coordinated care. While Stark and other fraud protection laws should continue to play an important role in protecting against fraud and abuse in the FFS context, we agree with HHS that the time has come to assess how we can modernize Stark to appropriately encourage and incentivize the transformation toward better-coordinated, higher quality, and more efficient care. We also sincerely appreciate the Ways and Means Health Subcommittee highlighting the Administration's efforts around modernizing Stark and laying the groundwork for any potential legislation that might also be necessary to accomplish these goals.

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Statement

of the

American Hospital Association

for the

Committee on Ways and Means, Subcommittee on Health

of the

U.S. House of Representatives

"Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program"

July 17, 2018

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 individuals who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to submit for the record our comments on the burden that the physician self-referral (Stark) law creates for patients and providers and the resultant cost increase visited on health care in America. We also discuss strategies to address those costs and ensure patients receive value and high-quality care.

The cost – and affordability – of health care in America affects stakeholders from across the community, including patients and their families, employers, policymakers and providers of care. Hospitals and health systems understand the importance of this issue, and of ensuring access to affordable health care.

We recommend two areas of action to address Stark law issues and improve care coordination: (1) legislative action, and (2) actions that the Administration can take without legislation.

LEGISLATIVE ACTION

As health care needs and experiences have grown increasingly complex over the past decade, hospitals are working to deliver more value-based care to patients, and to meet the demands of patients, other providers, the government, and other payers for accountability and affordability. However, the tools available to hospitals and health systems are limited – development of innovative payment arrangements have been greatly stymied by the Stark law. Hospitals and health systems are eager to work both within and outside our field with a variety of partners to deliver comprehensive, coordinated care to our patients.

The design of the compensation prohibitions and the strict liability standard of the Stark law are very problematic. Any violation is subject to the same penalty – return of any amount paid by the Medicare and Medicaid programs for services provided to a beneficiary based on a physician's self-referral – without regard to whether the services were, in fact, medically necessary or the nature of the infraction was highly technical, such as failing to sign a form. The Stark law compensation prohibitions also are at odds with Congress's goals for a value-based system, which only can be accomplished through teamwork among hospitals, physicians and other health care providers across sites of care. Instead, the Stark law compensation provisions drive providers in the opposite direction, keeping them siloed. An essential component for the success of value-based arrangements is aligned incentives – specifically, financial incentives to promote more coordinated care and improve the patient care experience. The Stark law compensation prohibitions do not support a value-based system.

We urge that oversight of compensation arrangements reside exclusively under the Anti-Kickback Statute (AKS) and that a new safe harbor designed specifically for value-based arrangements be created. Because the AKS provides oversight for compensation arrangements that cuts across all providers, professionals, federal health care programs and financial arrangements, it is the most logical place to create a clear and comprehensive statutory safe harbor.

We urge Congress to remove the compensation provisions under Stark – returning the law to its original purpose, prohibiting physician ownership of businesses that benefit from their own referrals. Oversight of compensation arrangements would be under the Anti-Kickback Laws (criminal or civil), which are best suited to combat payment for referrals. America's hospitals and health systems face numerous duplicative and excessive rules and requirements. The AHA suggests the following actions to reduce burdens immediately on hospitals and patients.

Create Anti-Kickback Safe Harbor for Clinical Integration Arrangements. **We urge Congress to create an Anti-Kickback safe harbor for clinical integration arrangements that establishes the basic accountabilities for the use of incentive payment or shared savings programs among hospitals, physicians and other providers and allows for the sharing of expertise in cybersecurity.** The safe harbor should include the following requirements:

- **Transparency:** Documentation of the use of incentives or other assistance is required and must be available to the Department of Health and Human Services (HHS) on request.
- **Recognizable improvement processes:** Any performance standards that providers use to govern their collaboration (e.g., required care protocols, metrics used to award performance bonuses) must be consistent with accepted medical standards and reasonably fit for the purpose of improving patient care.
- **Monitoring:** Performance under integration arrangements must be internally reviewed to guard against adverse effects and documentation disclosed to HHS upon request.

The safe harbor should not try to supplant, duplicate or recreate existing quality improvement processes or the mechanisms for monitoring quality of care in hospitals. Currently, there is both internal and external oversight. State licensing agencies and accrediting organizations have an ongoing role. Medicare Quality Improvement Organizations continuously review the quality of care for beneficiaries. Other Medicare program oversight includes the hospital inpatient and outpatient quality reporting programs, readmissions program and value-based purchasing program.

We recommend that the safe harbor cover arrangements established for one or more of these purposes:

- Promoting accountability for the quality, cost and overall care for patients;
- Managing and coordinating care for patients; or
- Encouraging investment in infrastructure (e.g., ensuring the security of information systems and information exchange) and redesigned care processes for high-quality and efficient care delivery for patients.

The safe harbor should protect remuneration, including any program start-up or support contribution, in cash or in-kind.

Create Anti-Kickback Safe Harbor for Patient Assistance. Hospital responsibility for patient care no longer begins and ends in the hospital setting or any other site of care provided by the hospital. Maintaining a person in the community requires more than direct patient care. It includes encouraging, supporting or helping patients access care, or making it more convenient. It would include removing barriers or hurdles for patients as well as filling gaps in needed support. However, current laws impede hospitals from providing such assistance. The general prohibition on providing anything of value to "induce" the use of services paid for by the Medicare program also applies to assistance to patients.

We urge Congress to create an Anti-Kickback safe harbor that permits hospitals to help patients achieve and maintain health. Arrangements protected under the safe harbor also would be protected from financial penalties under the civil monetary penalties (CMPs) for providing an inducement to a patient.

The safe harbor should:

- Protect encouraging, supporting or helping patients to access care or make access more convenient;
- Permit support that is financial (such as transportation vouchers) or in-kind (such as scales or meal preparation); and
- Recognize that access to care goes beyond medical or clinical care, and include the range of support important to maintaining health such as social services, counseling or meal preparation.

Additionally, attached is the report ***Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them (Wayne's World)***. This report describes the impact on a patient, as well as how specific actions taken above will improve care, reduce costs and make Medicare a more efficient payer.

ADMINISTRATIVE ACTION

There also are steps that the Centers for Medicare & Medicaid Services (CMS) can take to help minimize the difficulties created by their regulations for hospitals and physicians working together to improve and coordinate care. Our recommendations for changes to the Stark law compensation regulations are enumerated below. **No changes should be made to the regulations implementing the Stark law's ownership ban. The ban is a carefully crafted policy that is working as Congress intended.**

We recommend that CMS create a new innovative payment exception for value-based payment arrangements. The creation of this exception would present the field with a new opportunity to implement incentives that drive physician decision-making toward high-value care for each and every patient they see. We recommend that an innovative payment exception protect value-based incentive programs that promote: (1) accountability for the quality, cost and overall care of patients; (2) care management and coordination; and/or (3) investment in infrastructure and redesigned care processes for high-quality and efficient care delivery. The proposed exception should protect any remuneration that is provided and received pursuant to a clinical integration arrangement involving providers or suppliers of services and physicians or a physician practice. The exception also should protect incentive payments, shared savings based on actual cost savings, and infrastructure payments or in-kind assistance reasonably related to and used in the implementation of the clinical integration arrangement, and should be subject to objective, measurable and transparent performance standards. We believe this proposed innovative payment exception is essential to our ability to improve patient care.

We also recommend the agency provide clear, unambiguous definitions of critical requirements of the Stark law and exceptions to the law. Hospitals often are uncertain about what is acceptable under several Stark requirements; that uncertainty decreases the ability to innovate and undercuts care transformation. By offering guidance and clarity around the requirements with which hospitals need to comply in order to receive payment, CMS will enable the field to invest in integrated care and innovative payment arrangements in a manner that is compliant with the Stark law.

Compensation that does not take into account the volume or value of referrals. The volume/value element of the Stark law has created immense confusion in our field, thereby chilling the drive of hospitals and health systems to create innovative payment arrangements. To combat this chilling effect, **CMS should clarify that, for a fixed payment, the amount of compensation does not vary or take into account the volume or value of referrals if the amount is initially determined by a methodology that does not take into account referrals and is not subsequently adjusted during the term of the agreement based on referrals**. The volume/value element requires that the methodology used to formulate the amount of compensation paid must not take into account referrals. The parties' state of mind in arriving at the amount of compensation is not relevant; rather, the central question is whether the methodology actually utilizes a physician's referrals in determining the amount of compensation paid to a physician or an immediate family member. This clarification is essential to the field's ability to align the goals of an organization and of its physicians and to incentivize physicians to make value-based modifications on a patient-by-patient basis.

CMS also should clarify and reaffirm that the volume/value requirement is not implicated where the payment is based on physicians' personally performed services, even when those services incidentally increase or decrease the delivery of designated health services (DHS) by a hospital or other DHS entity. This clarification will reduce concerns that arise when hospitals engage in efforts to improve quality and efficiency through greater cooperation with physicians (such as quality bonus programs, shared savings arrangements, and provision of infrastructure or other assistance at no charge).

Fair market value (FMV). **CMS should restore the definition of FMV to the original language of the statute**. Doing so would rightfully de-couple FMV from the volume/value element of the Stark law, giving hospitals and health systems a chance to design incentives that may impact referrals but that do not drive overutilization nor undercut medically necessary utilization. **To that end, CMS should define FMV as the value in arms-length transactions consistent with general market value, and define general market value as the price of an asset or compensation for a service that would result from bona fide bargaining between well-informed parties to the agreement**. Whether or not the parties are in a position to generate business for each other is irrelevant (and the agency's addition of that language to the regulation has created needless confusion).

Commercial reasonableness. Despite guidance over the years on the definition of commercial reasonableness, there is still confusion on what is needed to satisfy that prong of various Stark law exceptions. **We urge CMS to clarify that commercial reasonableness is a question of whether the items or services being purchased are useful in the purchaser's business and purchased on terms and conditions typical of similar arrangements between similarly situated parties. As described above, asking whether the amount of the purchase is reasonable is the subject of FMV determinations, not commercial reasonableness**. This change will enable hospitals and health systems to clinically integrate with physicians for improved care coordination even when the purchase of a physician practice, for example, is a net loss to their system.

Referral. Because care coordination requires some degree of care management, hospitals and health systems need the ability to work together across their organizations, and even outside of it, to ensure patients get the right care at the right time. However, some hospitals' physicians' efforts to do so are considered "referrals" under the current Stark law, even if the referral presents no risk for increased payment to the organization. **CMS should clarify that a referral only implicates the Stark law when it results in an additional or increased payment from CMS to the DHS entity**.

The Administration also should address needlessly confusing and burdensome documentation requirements that expose hospitals to potentially catastrophic payment denials without protecting against problematic arrangements. An alternative method of compliance with documentation requirements should be created that focuses on whether there is a legally binding agreement between the parties. **This method should provide that an agreement enforceable under applicable state law will be sufficient to satisfy the requirement in any Stark exception that an arrangement be set out in writing and signed by the parties**.

Finally, in order to give effect to any modifications made to the Stark law, **the Stark law should be de-coupled from the AKS by eliminating from regulatory exceptions to the Stark law the requirement that financial arrangements must not violate the federal AKS**. This requirement is unnecessary and will be an impediment to comprehensive, coordinated care by, for example, placing an unreasonable burden of proof on entities seeking payment with no offsetting benefit or protection to the Medicare program.

CONCLUSION

We appreciate the opportunity to provide these comments and support the Committee's efforts and attention to examining the issues concerning the Stark laws. We are committed to working with Congress, the Administration, and other health care stakeholders to ensure that all individuals and families have the health care coverage they need to reach their highest potential for health.