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EXAMINING THE STARK LAW: CURRENT ISSUES AND OPPORTUNITIES

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EXAMINING THE STARK LAW: CURRENT ISSUES AND OPPORTUNITIES

TUESDAY, JULY 12, 2016

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:12 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Orrin G. Hatch (chairman of the committee) presiding.

Present: Senators Grassley, Burr, Coats, Heller, Scott, Wyden, Stabenow, Cardin, Bennet, and Casey.

Also present: Republican Staff: Chris Campbell, Staff Director; Kimberly Brandt, Chief Oversight Counsel; and Jill Wright, Detailee. Democratic Staff: Joshua Sheinkman, Staff Director; Elizabeth Jurinka, Chief Health Advisor; and Beth Vrabel, Senior Health Counsel.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The committee will come to order. As members of the Senate Finance Committee, we have a wide range of duties. In addition to drafting laws and overseeing their enforcement and implementation, we are also called on to assess the impact of existing laws to determine their effectiveness at achieving their intended goals.

When it comes to that last part, there is a quote from a well-known American business leader that applies—quote: "Good intentions often get muddled with very complex execution."

Today we are here to talk about the Stark Law, an important yet extremely complicated health-care fraud law that prohibits physician referrals under certain circumstances. This law is the embodiment of good intentions muddled with complex execution.

At its most basic level, the Stark Law prohibits doctors from referring Medicare patients to hospitals, labs, and other physicians for health-care services if the referring doctor has any direct or indirect financial relationship with that entity.

The sweeping nature of that prohibition makes vast swaths of medicine performed in the current health-care system potentially illegal. Anyone caught violating the law must give back all the Medicare reimbursements paid to the doctor, hospital, or lab under the tainted arrangement, even if the violations were unintentional, because the Stark Law is a strict liability statute that is indifferent to motive, knowledge, or state of mind.

When the Stark Law passed in 1989, the lawmakers believed that, given a bright-line rule, providers would self-police their arrangements with physicians. And despite this original intent, the Stark Law has become increasingly complex and created more and more challenges for legitimate health-care arrangements.

Today the health-care world is populated by scores of legal experts who strive to keep up with the sprawling compendium of statutes, regulations, and Federal advisories known collectively as the Stark Law.

The Federal Register contains hundreds, if not thousands, of pages of regulatory text drafted by the Department of Health and Human Services to improve compliance with and implementation of the Stark Law. Through these regulations, HHS has come up with more than 30 exceptions to the law, each of which carries its own detailed requirements. Even the original sponsor, the namesake of the legislation, Representative Fortney "Pete" Stark, recently lamented the Byzantine turn that the statute has taken, stating, quote, "It gave every shyster and promoter a loophole. We now have to keep rewriting the laws like the tax code."

Because it regulates physicians' financial relationships, the Stark Law has a significant impact on the structure and operation of the health-care delivery system. Therefore, as we have collectively worked to transition our Federal health programs towards more value-based payments and systems and away from fee-for-service models, one question keeps coming up. In its current form, is the Stark Law still necessary?

Last December, in an effort to answer this question and address long-standing concerns about the Stark Law, the Finance and Ways and Means Committees convened a roundtable discussion with stakeholders and legal experts to discuss these issues.

All three of the witnesses here today were part of that discussion. We received feedback on a number of issues related to the Stark Law, including the barriers it places on the implementation of health reform laws, stakeholders' frustrations with the difficulty and expense associated with compliance, and the problems created by the Centers for Medicare and Medicaid Services' limited authority to create exceptions and to issue advisory opinions.

Following the roundtable, we issued a broader call for comments by industry leaders, and we received almost 50 responses suggesting a variety of changes, including additional or expanded waivers or exceptions, enhanced authority for CMS to address specific needs on an ongoing basis, and repeal of the compensation arrangement prohibition.

In addition, some suggested that we repeal the law in its entirety. Commentators across the board expressed concern about the ambiguous way certain terms are defined under the Stark Law—terms like "fair market value," "volume and value of referrals," and "commercial reasonableness." They all have decisive impact on the application of the law, yet they are not clearly defined. And finally, virtually every one we heard from believes that technical violations of form rather than substance of the law should be subject to separate sanctions and limited liability.

If the aim of the Stark Law is to prevent physicians from inappropriately referring patients for medically unnecessary treat-

ments, it does so in a rather roundabout way, at least under the current structure.

If we really want to prevent inappropriate self-referrals and address the culture of overutilization, we have to do more than target specific relationships and practices prone to abuse. We must also realign the financial incentives created by our current payment mechanisms.

If, as some have claimed, the Stark Law is impeding the implementation of recently passed health reforms like the Medicare Access and CHIP Reauthorization Act and preventing better integration in the delivery of medical treatment, we should address that as well.

As a committee, we have a responsibility to explore potential changes to make the law more workable in terms of enforcement and compliance, in both fee-for-service and value-based payment models, as both are likely to be around for years to come.

We are here today to examine these issues and hopefully hear some potential answers to the questions that have come up. And I look forward to hearing the testimony of our witnesses and getting their input on all of these important issues today.

And with that, I will turn to Senator Wyden for any opening remarks.

[The prepared statement of Chairman Hatch appears in the appendix.]

OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON

Senator WYDEN. Thank you, Mr. Chairman; and, Mr. Chairman, thank you for scheduling a hearing on an important topic. Our country is beginning a major transformation in the way health care in America is paid for. We are moving away from an old system, fee-for-service medicine, which in effect opened the financial till for every visit, every test, and every procedure that was done in a doctor's office or a hospital.

Now, American health care is going to have a new focus: paying for the quality of care that our people receive, rather than the quantity. Even though the sea change is in the early days, already 30 percent of Medicare payments are going through the new system, focused on value and efficiency. Certainly that number is going to rise in the years ahead.

In my view, when you make a health-care transformation, particularly when you are talking about the system that we have where one out of every six dollars in the American economy goes to health care, there is no question that you are going to bump up against some very significant challenges, and one of those challenges is what we are looking at this morning.

Now, in my judgment, what this is all about is trying to balance two important priorities. On one hand, there is a drive toward bringing doctors and specialists together, promoting coordination, and making American health care as efficient as possible.

On the other hand, there is a longstanding protection that comes from what is known as the Stark Law. It says that financial relationships between providers must not influence a patient's medical care.

Some health-care providers in our country are concerned that parts of the Stark Law date back years or even decades and could be an impediment to treatment. For example, when fee-for-service was king, a jump in referrals from a doctor to a physical therapist would have probably raised red flags, if there were some financial ties.

Today, it is common for doctors and physical therapists to work in the same medical practice or hospital system, and the science has demonstrated that physical therapy is often exactly the right choice to keep a lifelong golfer with a bad shoulder or an older woman with a knee replacement healthy and out of the emergency room.

That means that in this day and age, an uptick in referrals for physical therapy in one medical practice should not automatically be declared a violation of the Stark Law. In effect, we are going to be looking at a variety of cases, because certainly different cases present different challenges.

In my judgment, the two important priorities—promoting coordination of care and upholding the principles of the Stark Law—should not automatically come into conflict.

As long as there are clear guidelines about what is fair game when it comes to patient referrals and the relationship between doctors, it ought to be possible to guarantee that patients are getting the care that is right for them and not just right for somebody else's pocketbook. In certain ways, it could be as simple as revisiting the rules that are already on the books.

So I look forward, Mr. Chairman, to having a productive discussion. I want to commend the staff on both sides for their effort to look at these questions. We appreciate our witnesses and look forward to hearing their testimony.

Thank you.

The CHAIRMAN. Thank you, Senator.

[The prepared statement of Senator Wyden appears in the appendix.]

The CHAIRMAN. Our first witness today will be Mr. Troy Barsky, a partner at Crowell and Moring in the firm's health-care group. Mr. Barsky counsels hospitals, group practices, and health plans on the Stark Law. He represents clients seeking reprieve from government health-care program overpayment issues, as well as fraud and abuse matters.

Prior to joining Crowell and Moring, he served in various positions, providing legal counsel and helping draft and implement policy at the Department of Health and Human Services and the Centers for Medicare and Medicaid Services for 11 years.

He provided counsel to his agency clients on a wide range of Medicare and health-care issues and managed Stark Law issues and those relating to Medicare payments, as the director of the Division of Technical Payment Policy.

Senator Burr will introduce our second witness, Dr. Ronald Paulus.

Senator Burr?

Senator BURR. Thank you, Mr. Chairman, for allowing me to introduce Dr. Ronald Paulus from Mission Health in Asheville, NC. My colleagues know I am not shy when it comes to highlighting the

great health care that we have in North Carolina, so I am pleased that one of our leaders is here with us today.

Dr. Paulus, thank you for traveling here and for your willingness to share your thoughts and your expertise. I know that today's discussion will be improved by Dr. Paulus's participation.

Dr. Paulus is the president and CEO of Mission Health, a health-care system with an impressive footprint in western North Carolina and, I would add, one of the most beautiful parts of North Carolina.

Mission Health Care has a network of more than 500 physicians, six acute hospitals, a rehabilitation hospital, inpatient and home hospice programs, a PACE program, and an Accountable Care Organization. In other words, under Dr. Paulus's leadership, Mission Health is meeting a range of health-care needs for a significant number of North Carolinians.

Prior to his work with Mission Health, Dr. Paulus was the executive vice president for clinical operations and CIO for Geisinger Health System, where he was responsible for managing the group practice of over 800 physicians as well as the system's hospital.

He is also the co-founder, president, and CEO of CareScience, Inc., a company that provided a web-based platform to improve quality and efficiency in health care, a product that is now used in health-care systems across the country.

As if this was not impressive enough, Dr. Paulus earned both his MBA and doctorate of medicine from the University of Pennsylvania.

I will end with taking the opportunity to publicly congratulate Mission Health for being recognized as one of the Nation's top 15 health systems for 4 years in a row. Dr. Paulus is a testament to the incredible work he and his colleagues at Mission Health do, day-in and day-out.

I thank you and look forward to hearing your thoughts on the challenges and opportunities we see for improving quality of care for patients in North Carolina and around the Nation, today and in the future.

And, Mr. Chairman, if I could say to the ranking member, his analogy of a golfer—a good golfer would never go to the emergency room, because I can assure you there is a doctor in their foursome. [Laughter.]

Thank you, Mr. Chairman.

The CHAIRMAN. Well, with that wisdom, I will finish introducing. Thank you, Senator Burr.

Our third witness is Mr. Peter Mancino, the deputy general counsel of the Johns Hopkins Health System Corporation. He serves as secretary to the boards of trustees for Johns Hopkins Medicine, the Johns Hopkins Health System Corporation, and for the Johns Hopkins Hospital.

He is responsible for the administrative management and supervision of the legal department of the Johns Hopkins Health System. He further manages legal matters involving the Community Hospital Division and Children's Hospital. He was previously a partner at a prominent New York law firm, Garfunkel Wild, and specialized in health law.

I want to thank all three of you for coming. We will hear the witness testimonies in the order that they have been introduced.

Mr. Barsky, we will ask you to proceed with your statement.

STATEMENT OF TROY A. BARSKY, PARTNER, CROWELL AND MORING, LLP, WASHINGTON, DC

Mr. BARSKY. Thank you, Chairman Hatch, Ranking Member Wyden, and distinguished Senators of this committee. I am honored and grateful for this invitation to speak to you about an issue of vital importance to the Medicare program and its millions of beneficiaries throughout the United States.

I am here today to share my past experiences as a CMS official who administered the Stark Law for 4 years and now is a partner at the law firm of Crowell and Moring, advising clients who must comply with this law.

I hope to provide my insight into current challenges posed by the Stark Law and how this law can be modernized to facilitate a new era of health-care reform.

The Stark Law came about from a simple concern that physicians with a financial interest in their referrals will corrupt medical decision-making. This law has evolved from this simple premise into a tortured web of confusing standards, ambiguous and conflicting definitions, exceptions to the rule—even exceptions to those exceptions—and volumes of regulations that require lawyers and valuation experts just to comply.

The problem is that the Stark Law is a strict liability statute. Intent to violate the law is not required. Therefore, as a health-care entity, if you fail to meet any of the technical requirements, you will inadvertently violate the law, exposing you to millions of dollars or potentially tens of millions of dollars in payments and penalties, program exclusion, and potentially False Claims Act liability as well.

As the committee is well aware and as has already been mentioned, even before the Affordable Care Act and MACRA, the health-care system has been rapidly changing. Health-care providers are focused on coordinated care, improved outcomes, and lower overall costs. The Affordable Care Act and MACRA have only accelerated this effort.

The goals of these new payment systems are diametrically opposed to the goals of the Stark Law. The new health-care payment models are designed to integrate providers clinically and financially, while the Stark Law is designed to keep parties financially separated.

So here are some suggested solutions and pathways to reform the law.

First, as we move away from a fee-for-service world, the need and utility of the Stark Law continues to diminish. Repeal in whole or in part of the Stark Law should not be off the table in these discussions. Instead, existing fraud and abuse laws that have an intent requirement, like the Anti-Kickback Statute and the False Claims Act, already exist to prohibit financial arrangements that incentivize referrals.

Next, absent full or partial repeal, there are other common-sense reforms that may be implemented.

First, change the proportionality of the penalty to the nature of the violation. The Stark Law has so many confusing technical requirements, either remove the technical requirements completely or impose a fixed monetary penalty for these violations, rather than requiring a full refund of all overpayments related to prohibited referrals.

Second, establish bright-line rules in the Stark Law that providers can follow and give CMS greater authority to provide guidance through advisory opinions and regulations.

Third, remove barriers to health-care reform. The Affordable Care Act allowed HHS to issue broad Stark waivers, and they have taken advantage of that authority. I recommend giving greater authority to HHS to continue and expand these waivers to encourage innovative payment models and allow for a unified approach to the provision of all fraud and abuse waivers related to alternative payment models, rather than the piecemeal approach that we now see developing.

Fourth, for those entities that are not yet participating in these alternative payment models but aspire to, we need to help them to innovate as well. They cannot be protected by Affordable Care Act waivers, and CMS does not have existing authority to create regulatory exceptions to protect these providers. Only Congress can create this pathway to innovation.

Last, limit loopholes that are contrary to health-care reform efforts. For example, the in-office ancillary services exception continues to incentivize in-office referrals and overutilization, making it less likely that the self-referring physicians will move to an integrated delivery model. Closing this exception will incentivize physicians to move to these new models.

Because the Stark Law has served to protect against overutilization and unnecessary services for Medicare patients, I recognize that this committee must move forward carefully and thoughtfully. But modernizing the Stark Law to allow and encourage innovation in the Medicare program and the entire health-care system will best serve the patients that this law was originally designed to protect.

I am happy to answer any questions that this committee has on this very important issue.

Thank you.

[The prepared statement of Mr. Barsky appears in the appendix.]

STATEMENT OF RONALD A. PAULUS, M.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, MISSION HEALTH SYSTEM, ASHEVILLE, NC

Dr. PAULUS. Mr. Chairman, Ranking Member Wyden, and members of the committee, thank you for the opportunity to testify today.

I am the CEO of Mission Health, and we serve the 18 most western counties in North Carolina. We are the region's only safety-net system, and our patients, more than 900,000, are older, poorer, sicker, and less likely to be insured than State and national averages.

More than 75 percent of all of our patients are Medicare or Medicaid beneficiaries or uninsured, and 10 percent of our babies are born addicted to narcotics.

Upon arriving 6 years ago, we began to transform Mission by establishing a culture of physician and clinician leadership and emphasizing value-based care. Why? Because it benefits our patients and local employers and it has the potential to provide needed financial stability, not only for Mission, but for the U.S. health-care system more broadly.

We have made real progress, including reducing an already better than average mortality rate by more than 50 percent, and achieving the lowest Medicare readmission rate of any general acute care hospital in the Nation.

But our crucial responsibility as the region's only safety-net system demands that we avoid unnecessary risk, and some of our most significant risks are the unclear boundaries in our fraud and abuse laws.

As a physician executive, I am absolutely convinced that it is simply not possible to transform health care without a strong partnership between health systems and physicians. The Stark Law makes this remarkably difficult, both by creating a thick fog of uncertainty and, at times, directly causing patient harm.

The committee's recently released Majority Staff Report provides an excellent summary of important comments, the weight of which makes clear that Stark has largely outlived its usefulness, given the broad reimbursement changes and the existing protections of the Anti-Kickback Statutes.

Stark has multiple problems that cannot be fixed just by tinkering around the edges, and a full repeal would not only help systems do what we need to do, but do precisely what you have asked us to do: focus on what is best for patients while leading the transformation of our antiquated fee-for-service system.

Let me describe a typical pay-for-performance problem at Mission. As you know, Stark prohibits linking payments to, quote, "the volume or value of referrals." So any Stark-compliant incentive program must be structured to distribute payments equally to all physicians, regardless of the effort or outcome.

A key focus for Mission and CMS is eliminating all hospital-acquired infections. Stark unnecessarily constrains what we can do in our hospitals because they include many physicians who are not part of our ACO. Under Stark, we have to reward a physician who had a dramatic increase in his infection rate exactly the same as a physician who eliminated all of her infections.

In most industries, shareholders and watchdogs are demanding outcome-based pay for performance. In health care, Stark specifically prohibits it.

As noted, under Stark payment to physicians must be, quote, "fair market value," unrelated to volume or value of referrals. Sounds all right, but those terms are not clearly defined, and they are fact-specific, meaning we can never ever be sure that any program will pass muster if scrutinized. And our risk of guessing wrong? All reimbursement from those physicians who are not employed by Mission is subject to repayment.

Beyond pay for performance, Stark also impacts patient care in significant and at times negative ways. Here is a real example.

For a number of years, a Mission geneticist has met with expectant mothers who have recently learned that the child they are carrying will die shortly after birth. The geneticist helps the mothers and fathers understand the child's fatal condition and what to expect during and after delivery. Our geneticists strongly desire to have this no-charge conversation with parents at the Ob-Gyn office so they can support them immediately and in a comfortable and familiar environment.

However, when brought to the attention of Mission's attorneys, they quickly and understandably became concerned that the service could be seen as providing something of core financial value to the Ob-Gyn's practice and, given no Stark exception, they rejected it.

Had we been only subject to Anti-Kickback, the service could have been provided, as the obvious intent is helpful and not abusive. Unfortunately, Stark's strict liability makes it so that we cannot take that risk, even during this difficult time in these families' lives.

Now, some have argued that Stark can be managed by CMS without action by Congress, and while improvements have been made, CMS simply does not have the legislative authority to go further, and they cannot resolve all the fundamental issues in Stark. It is too complex and too cumbersome.

Because of the extraordinary penalties involved, it freezes health systems in their place and impairs patient care. The stakes are simply too high and the need for health-care reform too great for our patients, our businesses, and, frankly, our Nation. Only Congress can remove those barriers.

I want to thank you truly for being willing to take on this very important issue. It has been an honor and privilege to share these thoughts with you. I appreciate your leadership, and I know together we can make the changes necessary to remedy these problems and succeed in the needed transition to a high-quality, efficient, and effective value-based system.

If I can answer any questions or provide any information, I would be delighted to do so.

The CHAIRMAN. Well, thanks, Dr. Paulus. That was a very good statement.

[The prepared statement of Dr. Paulus appears in the appendix.]

The CHAIRMAN. Mr. Mancino, we will take your testimony now.

STATEMENT OF PETER B. MANCINO, DEPUTY GENERAL COUNSEL, THE JOHNS HOPKINS HEALTH SYSTEM CORPORATION, BALTIMORE, MD

Mr. MANCINO. Chairman Hatch, Ranking Member Wyden, and members of the committee, thank you for the opportunity to be here today to discuss the important subject of the Stark Law.

Given the recent MACRA legislation, we believe that now is the ideal time to re-examine the Stark Law to ensure that it does not impede the goals of MACRA and health-care reform.

The Johns Hopkins Health System views the Stark Law as our top compliance risk, because it is so easy to violate Stark and the

penalties are so substantial. I would like to highlight three reforms in particular that would greatly improve the Stark Law.

Number one, eliminate ambiguities in key Stark terms; number two, make Stark penalties more reasonable; and number three, reform Stark to allow for innovative payment arrangements.

First, eliminate Stark ambiguity. When the Stark Law was created, the goal was to create a bright-line test to address overutilization of health-care services. The problem is that this bright-line test has been transformed over time into a complex, ambiguous, and highly technical rule that includes over three dozen exceptions. As a result, there is considerable confusion about basic Stark terms like "fair market value."

As a health law attorney for 20 years, I have been confronted with numerous transactions that raise Stark questions. No matter how much time, money, or effort is expended in analyzing the issues, there are often no clear or 100-percent safe answers. Subjective judgment calls are often required when entering into physician arrangements, contrary to Stark's original design as a bright-line test.

Further, the Stark Law is so rooted in a fee-for-service environment that it has become very difficult to adapt Stark to value-based health care. Stark's fair market value requirements, for example, have been applied to allow physician compensation based on productivity and work effort, but there are barriers to compensation based on value, clinical efficiencies, cost savings, and quality outcomes. We believe that the Stark Law should be modernized to make it easier to apply in a value-based industry.

Second, make Stark penalties more reasonable. The Stark Law's complexity and ambiguity have made it very difficult for even diligent health-care providers to comply. Failure to satisfy even one of its technical requirements can result in a violation, and, despite the best compliance efforts, unintentional mistakes occur.

Liability under the Stark Law can be staggering, even for minor violations. The potential liability associated with an alleged Stark violation creates an enormous barrier to a provider's ability to defend against a claim, even when there are valid defenses.

Most health-care providers want to be compliant and are willing to be accountable for mistakes. However, accountability should not entail ruinous penalties. Recent judicial decisions have had a chilling effect on the health-care industry, causing clients to be reluctant to try creative arrangements at a time when innovation is most needed. Accordingly, potential penalties associated with Stark violations should be more reasonable.

Third, innovative payment arrangements. Hospitals and physicians must work together like never before to reduce health-care costs, become more efficient, and improve patient quality and outcomes. Unfortunately, Stark is an impediment to this collaboration, because it has created an overly rigid structure for hospital-physician relationships.

For example, Stark restricts a hospital's ability to create gainsharing arrangements with physicians to incentivize cost-efficient, quality-promoting behaviors. It can also prevent hospitals from providing care coordination resources to keep chronically ill patients out of the hospital.

These types of team-based arrangements between hospitals and physicians are often problematic under Stark. However, these are the types of arrangements that Congress should support, because they promote the purposes of MACRA.

Therefore, we support reforming Stark to allow hospitals the ability to enter into innovative relationships with physicians.

Now is the time for Congress to modernize the Stark Law to promote fairness and further the goals of MACRA. Health-care providers have a reputation of being too slow to change and too expensive. The reality is that providers want to change, but we need the freedom and the tools to do so.

Stark has created an atmosphere that is antithetical to change. We urge Congress to act quickly to address our concerns so that the health-care industry can transform itself to meet today's challenges and the goals of MACRA.

I appreciate the committee's interest and look forward to answering any questions.

The CHAIRMAN. Thanks to all three of you.

[The prepared statement of Mr. Mancino appears in the appendix.]

The CHAIRMAN. Let me just start the question period by asking this question.

With the current Stark Law, based on your experience under the current waiver processes, either through the ACA or as set forth for new models developed under CMMI's authority, is there sufficient, quote, "safe space" for innovation in the development and implementation of alternative payment models? And which better promotes innovation—the current waiver-based system where the waivers are issued on a case-by-case basis, or a regulatory exception system where exceptions would be applicable to any organization that meets the requirements?

Let me start with you first, Mr. Barsky.

Mr. BARSKY. Yes. First, it was an honor for me to work on some of those initial waivers when I worked at CMS, and we were given the authority to exercise very broad waiver authority.

It is remarkable that for any new innovative payment model that was designed by CMS or mandated by Congress, in every single case the Stark Law needed to be waived in order for those programs to be successful.

So from my perspective, the waivers as currently drafted have provided that safe space, have provided and allowed for innovation within specific models, whether they be Accountable Care Organizations, bundled payment models, or many new and innovative payment models that are coming out of CMS.

The only danger that I see that is now developing is that with every new program that comes out, a new waiver comes out. So what we now find is that there are many different waiver authorities that are being developed, and health-care providers are forced to operate under multiple waiver regimes at the same time.

But overall, this is a successful effort, and I encourage Congress to continue to think about how this might be expanded to allow for innovation.

The CHAIRMAN. Dr. Paulus?

Dr. PAULUS. Thank you. I do not disagree with my colleague. On the other hand, I would note that despite the overlapping waiver scenarios, which absolutely, undeniably have been helpful, there is still a very large amount of uncertainty that permeates and is always present in any of our dialogue.

We do not have a single program worth thinking about where we do not go through a Stark analysis to figure out how we can do it, whether we can do it—look at the waiver, look at an exception, look at the pattern. And I think that is just too onerous.

And then I would add, and repeat from the testimony that I just provided, there are circumstances like our goal to reduce hospital-acquired infections where, because it does not fit into a waiver and because it includes physicians who are not part of the ACO, there is no way to manage that program.

So yes, it has been helpful. Is it sufficient? Not in my opinion.

The CHAIRMAN. Mr. Mancino?

Mr. MANCINO. So I would echo what was said, but I would also just add that, number one, given the impending MACRA deadlines, I do not think that the waiver process is going to be quick enough to implement the changes that need to be made in physician practices.

I would also say that the waivers do not cover enough, because they only cover Medicare. They do not cover Medicaid, commercial payers, and certain physician specialties.

And then finally I would say that, while the waivers are helpful, the problem is that again we have so many Stark exceptions, and then you layer onto that specific Stark waivers, and it creates all sorts of confusion in the industry about what you can do and what you cannot do, as Dr. Paulus suggested.

The CHAIRMAN. Well, thank you. I thank all three of you.

Let me just ask you this question, Mr. Barsky. Does HHS currently have the authority to create waivers, or to waive the Stark Law for alternative payment models, absent a statutory mandate?

Mr. BARSKY. I think the answer is, they do partially, but they do not have the authority to go far enough. As was already stated, they do have the authority to waive the law within certain Affordable Care Act-mandated programs. They do not currently have the authority to go farther and protect alternative payment models that are mandated by MACRA.

Further, there are many types of innovative programs that were already mentioned by my colleagues, both in Medicaid and especially in the commercial market, that still trigger Stark Law scrutiny.

And right now, CMS does not have either waiver authority or even the authority to create adequate regulations in order to fully protect innovative payment models.

Back in 2008, CMS did try, under their existing regulatory authority, without waiver authority, to issue exceptions to protect innovative payment models. This exception had 16 different requirements, with additional subsections, because they needed to meet their statutory mandate, which is to not create regulations that would cause any risk of program or patient abuse.

So CMS itself has proven that, without further authority, they do not have the ability to allow for innovation. They are getting part

of the way there, but the statute prevents them from going any further.

The CHAIRMAN. Well, thank you. And my time is up.

Senator Wyden?

Senator WYDEN. Gentleman, thank you, and this has been an excellent panel. I think if one were to listen in, you would say, boy, this is just about as fascinating as having prolonged root canal work. [Laughter.]

But the reality is the stakes here are enormously high, because what you are talking about is striking the right balance between encouraging these alternative payment models, which are so important in care coordination, and at the same time maintaining protections against the financial incentives for providing large volumes of unnecessary care, which is what Stark was all about.

I would be interested in having the three of you, because we have a number of members here, tell us in something resembling English what you think would be the best way for us to go about, in effect, modernizing how you strike that balance between two important causes.

Mr. Barsky?

Mr. BARSKY. I will make an attempt to speak in plain English. I think—a few specific recommendations. First, if you are not going to repeal the Stark Law completely, at least consider eliminating the compensation component of Stark.

Stark Law eliminates, or prohibits, both ownership relationships and compensational relationships. Keep the ownership prohibition, but remove the compensation prohibition.

There are very clear anti-fraud statutes—the Anti-Kickback Statute, the False Claims Act—that protect against bribes and kickbacks in the health-care marketplace. So there are still protections, getting to your point about balancing allowing for innovation and also protecting patients in the Medicare program.

I also would say, when you look at these new innovative payment models, the incentives within those models are completely different from the fee-for-service world, as you mentioned. So there is no incentive in those models to overutilize.

If you overutilize care, if you are providing unnecessary care, too much care, you will not be successful. Health systems will not make as much money as they otherwise would if they provide high-quality care, necessary care, but not too much care, which was incentivized in the old fee-for-service world.

So I would say removing compensation, allowing for the Anti-Kickback Statute and the False Claims Act to protect you, and allowing these new systems with the change in incentives to protect patients and to protect the program.

Senator WYDEN. Dr. Paulus?

Dr. PAULUS. Well, I guess as a physician and someone testifying on this complex of a law, I do not know if it is possible to speak in plain English. But with that caveat aside, I agree with Mr. Barsky that getting rid of the compensation arrangement components is the most important thing.

And I will note, and Chairman Hatch mentioned this, in 2007 Pete Stark wrote that he believed that, on balance, the law may have done more harm than good. And when you look at how much

has changed in terms of payment models and the shift that is occurring, I think we have to ask ourselves, how do we do more good than harm in eliminating the compensation arrangements, getting rid of that strict liability component?

And historically, courts were originally challenged to enforce the Anti-Kickback Statute because of the intent requirement. But now there are a series of cases and other factors that I think already provide belt and suspenders for the program.

Senator WYDEN. Mr. Mancino, let me modify the question a little bit, because time is short, and you and your colleagues made important points already.

Could you give us some specific examples of something your organization would like to do with respect to physician compensation that you believe you are not allowed to do because of Stark? Some specific examples and, I think, that plus the thoughts I heard earlier about striking the balance is about what I was hoping to pick up.

Mr. MANCINO. Sure. Literally every week I get questions from my clients about how we can do gain-sharing arrangements with physicians in our community hospitals and in our academic medical centers. And the answer is that Stark puts great barriers on our ability to do that.

So what I would recommend is that there be an ability to give bonuses and incentives to physicians to change their practices, to reduce costs—the types of devices they order, the types of products in the emergency room, et cetera.

And then I think also that quality metrics are important. We need to incentivize them to reduce infections, things like that. These are the types of programs that we need to be able to do and that Congress has been telling us to do with MACRA and other laws, and I think gain-sharing is an important tool in that regard.

Senator WYDEN. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Stabebow?

Senator STABENOW. Thank you, Mr. Chairman and Ranking Member, for holding this really important hearing, and thank you to all of you.

As we are making these shifts, as we have done from the Affordable Care Act and from the legislation that we passed in 2015, these are really important discussions. And I think for nearly 30 years the Stark Act has been focused on rooting out fraud and preventing overutilization and protecting the Medicare program financially—important things. And I think for equally long I have heard concerns, legitimate concerns, about stifling innovation and the kinds of things you are talking about today. And I think, as we are going to these new models, there is even more of a conflict.

So the question is, how do we address that? And so I think we have challenges and opportunities, depending on how we want to look at it right now, as we evolve and figure out how to address these issues.

Let me start with Mr. Barsky though and ask you, and then anyone—you are all welcome to respond. But when we look at the two payment models, one of the questions that I have is—we have two different approaches here now. We have MIPS, the Merit-based In-

centive Payment System, which continues fee-for-service, and then we have the alternative payment models.

When this fully takes effect, the change that we made, in 2019, as we know, we are looking at 4, 5, 6 percent of practitioners in that new alternative payment model. So we still have fee-for-service; we know where we want to go, but we will not be there yet.

So the question I have really relates to your thoughts on each of the payment systems and how we can, over time, bridge that gap. Because it seems that if we are suddenly saying we are not concerned about fee-for-service any more in terms of these issues, but yet most physicians are still on fee-for-service, I am not sure that that makes sense in terms of repeal. But at the same time, there is no question that we want collaboration, we want the incentives changed, we want innovation, we want all the things you are talking about to be able to happen.

So I wonder if you might provide your thoughts as to, overall, how we get there—in 2019, we are still not going to be there yet—and how we mesh those two.

Mr. BARSKY. Thank you for the question. It is challenging in that we want to encourage everyone to get all the way there, to get to these alternative payment models, but we will not be there for some time, and we will continue to have this fee-for-service world with the same incentives that the Stark Law was designed to prevent.

So if you are ultimately going to conclude that we are not going to repeal Stark at this point, I would make two different points here.

One is to allow for waivers, give CMS greater authority to create exceptions. When you do move to alternative payment models, when you see physicians trying to move to innovative payment arrangements, either inside or outside of MACRA, you are providing a carrot for physicians to have waiver authority if they move to these new programs.

But for those physicians, those health systems that are going to remain in this fee-for-service world for a few years to come until we move to a fully population-based payment model, I would say that we at the very least need to provide greater clarity for those hospital systems, for those physicians who are operating in this environment of Stark.

As we had mentioned, strict liability applies. False Claims Act liability applies in an environment where there are very few clear rules. So I would say——

Senator STABENOW. If I might just interrupt to ask, are you saying that the prohibitions on self-referral under Stark should continue under the MIPS system, or are you saying, are you arguing that they should not?

Mr. BARSKY. So to be clear, if you are operating under MIPS, which is still a fee-for-service system with incentive payments, as I said before, I would advocate to eliminate the compensation part of Stark but allow for the ownership prohibition to remain.

Senator STABENOW. I see. All right.

Mr. BARSKY. If you move to an alternative payment model, then I think Stark is not necessary at all and that you should eliminate it, provide for a waiver completely.

Senator STABENOW. Quickly, I do not know if anyone else wants to respond to this. I am about out of time here, but—yes?

Dr. PAULUS. If I could just add briefly—and I truly appreciate the concern that you have. And I would agree that the ownership restriction should stay in the fee-for-service world.

But again, you also need, I believe, to think about the balancing act. So just for example, for us to provide teaching for our medical students and our residents, we have over 90 contracts that have to be specified and arranged and renewed every single year. We spend millions of dollars just complying with all these technical restrictions that are not adding any incremental value that Anti-Kickback and False Claims do not already provide.

Senator STABENOW. Thank you so much.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Burr?

Senator BURR. Thank you, Mr. Chairman.

You know, what I have found is this issue is just as confusing as it was 22 years ago when I started on it. [Laughter.]

But I think what is different is that the health-care world has changed significantly since then, so let me ask the same question a different way.

Not repealing Stark will do what, Dr. Paulus, to Mission's ability in the future as it starts to transform to that future model of a health-care system?

Dr. PAULUS. I appreciate that. And the main concern, the main impairment, relates to how we can partner with our physicians who have chosen or understandably want not to be employed by us, right? So with our employed physicians, we have broad latitude. But we do not live in a fully employed world, and the majority of our physicians are not employed by us.

So with those individuals, each and every time we want to do something to improve care quality, we face barrier after barrier after barrier.

Number one, as I mentioned, all of the rewards have to be equal, no matter your performance. That does not make any sense to me. I should reward the people who perform and not reward the people who do not perform. That is not allowed.

And every single time we want to do something to improve the delivery, the compassion, the effectiveness of care, we have to do this Stark algorithm. And just like with the geneticists who are unable to go to the Ob-Gyn's office, and just like our neonatal palliative care physician who cannot do the things that he would like to do, we are impaired and held back every step of the way.

And when we look at the challenges that we face and the amount of improvement in quality and efficiency we have to create, we do not need these barriers.

And I will reiterate that the Anti-Kickback Statute and the False Claims Act, with a remaining ownership restriction, cover the bases.

Senator BURR. So in essence, what I hear is, we are spending a tremendous amount of money to have the comfort of knowing that

this self-referral process is not going to take place, though we are spending a multiplier times an additional cost that is not going into the delivery of quality health care for this assurance of knowing we have this provision out there. Forget for the moment that the provision is written in a way that is very difficult to understand; it is a moving target.

So I guess my point to my colleagues is, we are sacrificing the planning we need to do for the future as to how health-care systems should transform and what the relationship between physicians and systems are to keep a law in place, a statute in place, that really has been replaced with the Anti-Kickback Statute and other pieces that give us the same assurance that that same self-referral will not get out of control.

Mr. Barsky, I want to go to you just very quickly. Your testimony talked about Stark Law waivers, where the current workaround for alternative payment plans under the Stark Law is a waiver from HHS.

My question is this: even if a payment model is being tested and it demonstrates superior care and decreased cost, once the waiver expires, what happens?

Mr. BARSKY. That is an excellent question. And the law specifically says—the Affordable Care Act, which is what HHS uses to waive the Stark law—HHS does not have the authority right now to extend that waiver to protect those providers and those programs.

So you have an experiment that goes on for a few years, and at the end of that experiment, because there is no other waiver authority, everyone needs to unwind all of the good things that they did.

Senator BURR. So we do this tremendous workaround to find a successful route only to find out you cannot continue it without Stark being eliminated?

Mr. BARSKY. Exactly.

Senator BURR. Mr. Mancino, as Medicare payments move from volume-based to value-based care, will it be possible for health-care systems like Johns Hopkins to comply with Stark while utilizing the innovative payment models? And what barriers need to be removed to make this transition occur more easily?

Mr. MANCINO. Well, I echo what my colleagues here have said. I believe that the compensation aspect of Stark should be eliminated. I think that that would give a lot more clarity to the Stark Law.

I think that it really needs to be emphasized, the chilling effect the Stark Law has had on the industry. People are frightened; after the major judicial decisions that have occurred over the last few years, they are frightened to do anything, really, outside of employment arrangements. You are seeing a lot more employment than I think you would normally see because of it.

So I think that—I echo what has been said, and I think that that is the best way to go.

Senator BURR. Great. Thank you.

The CHAIRMAN. Thank you, Senator.

Senator Casey?

Senator CASEY. Thank you, Mr. Chairman. I want to thank the panel for this informative hearing, because this is complicated, and we are grateful that you bring your own experience and scholarship to this.

Dr. Paulus, we are certainly grateful that you went to Penn for—how many degrees, three degrees? We are not grateful that you left, so we are going to try to recruit you back. But thanks for your testimony.

I guess I want to start with one of the basic problems here, as you have outlined, that when we consider the interplay between Stark and this new so-called MACRA set of policies, part of what we are trying to do with MACRA is to encourage, on the part of physicians, both more collaboration and also the opportunity to modify your practice behaviors. And those efforts are obviously running into the problem that you highlight.

I was struck, Doctor, by your testimony starting on the bottom of page 5 going onto 6, about the geneticists and that conversation they would like to have with expectant mothers who have just learned that the child they are carrying will die shortly after birth, and the desire to have that conversation in both a comfortable and familiar setting, and that they would not charge—not charge—the patient or the physician's practice.

So that is about as good an example as you can get for the problem here. I guess I want to know exactly what you hope we would do. Is it your testimony that we need to substantially modify the law, or would you hope we just repeal Stark?

Dr. PAULUS. From my lens, I believe that Stark should be repealed, perhaps retaining the ownership limitation.

Senator CASEY. Right.

Dr. PAULUS. It is the compensation arrangements that are problematic. If you think about any business wanting to align compensation with the outcomes that are desired, we cannot align compensation with the outcomes that are desired unless the physician is employed.

And as a physician myself, why do we want to mandate that all physicians need to be employed? It is fine for them to remain in private practice. They would still need to have those interdigitated relationships with the organizations that they are taking care of patients with.

And Stark is just an extraordinary barrier, not intended. It was well-intended, understandably. But I would completely repeal the compensation-related components of Stark.

Senator CASEY. I guess if you are kind of living in the real world you have to live in, you have a physician practice hoping to take advantage of these new alternative payment models that have been enacted in the law. How does that practice reward or penalize their physician for using the new tools or techniques that are deemed to result in cost savings? How do they do that and then also improve patient outcomes without running afoul of the Stark Law violations which, in many ways, run counter to this value-over-volume determination that we made?

Mr. Mancino, do you have anything to add on this part of it?

Mr. MANCINO. Well, I agree with everything you said. And I think that, again, I believe that Stark as it is currently structured

right now does not work in today's environment. It does not allow the incentives that you want to have under MACRA. So it needs to change.

I believe that the suggestion about eliminating the compensation section of Stark is the best way to go at this time if we are not going to repeal it altogether. I think the ownership requirements under Stark would be more easily applied. So I think that is the way to go, but I defer to the committee.

Senator CASEY. Mr. Barsky, anything before we conclude?

Mr. BARSKY. The only thing I would add is, whether you are in an alternative payment model or not, the question about volume and value of referrals that you have mentioned is one that I think challenges every health system that is trying to comply with Stark in today's health-care economy.

Right now, the standard is subjective in nature. If you think about referrals at all, you may be subject to Stark Law liability, whereas the regulations indicate that instead, it is an objective standard. It does not matter what you think; it matters what you do. Do you pay based on the volume and value of referrals?

Just as an added recommendation, regardless of what we do with regard to MACRA and reform, there definitely needs to be clarity that the agencies do not seem to be capable of providing.

Senator CASEY. Thanks very much.

The CHAIRMAN. Well, thank you, Senator.

Senator Coats?

Senator COATS. Thank you, Mr. Chairman.

Mr. Chairman, I am pleased that both you and the vice chair and many of us here understand that there is a way to address this issue. It can be done in a bipartisan fashion. There has been some good testimony which I have looked through. I apologize for having to step out for another matter.

But I cannot go anywhere in Indiana and talk to hospital administrators or others without this issue coming up, saying, you make a little technical mistake in the back room and so forth, and there is this complex process of trying to work your way through this, and you become subject to massive fines and so forth.

Clearly, the intent of the bill is not being exercised here, and so I really want to thank you that I can have the opportunity to go back to our hospital administrators and others and simply say, yes, we are working on doing this, achieving the right goals. Practices are changing.

I thought your opening statement hit the nail right on the head in terms of how we can go forward. So I really hope the committee can go forward on that basis and finally deal with this issue that has just run amok relative to how it is implemented, not necessarily the motive behind it, but how it has been implemented and over-regulated to the point where it is just driving everybody crazy.

I apologize for not being here earlier. I do not want to be duplicative from the time standpoint of what you might have already addressed, but tell me, just the three of you—you have outlined a path forward, made suggestions as to how we can go forward.

Is there anything that any of you disagree with that the others have said that might be a contentious issue that is more difficult to resolve than what has already been talked about?

And I will start here and go right down the line.

Mr. BARSKY. So I think one issue that has not been raised but I raised in my opening testimony is the issue of in-office ancillary services and that exception which allows for physicians to make referrals in their own offices. There is a specific exception within the law itself that allows for in-office referrals.

So now physicians are allowed to bring in very expensive equipment into their offices, refer to themselves, and increase utilization. GAO has found numerous times over the past few years that this has indeed increased overutilization.

I will admit that that is a contentious issue. I do not know whether it is contentious amongst the panelists here, but I do recognize that there are differing opinions within the health industry as to how to tackle that problem.

But I will say that, from an overutilization standpoint—which is everything we have talked about today that we are trying to combat—that is one issue that I would recommend that the committee should also consider, even though it is probably a tougher issue than maybe some of the other issues that we have discussed.

Senator COATS. Dr. Paulus?

Dr. PAULUS. I actually agree with that, and I would add that there is a specific exception, as we are getting technical, for radiation oncologists, the theory being that they do not refer patients to themselves, which makes perfect sense, but some groups have begun to employ other physicians through those radiation oncologists, like neurologists and others, who then refer and are in this safe harbor exception but for this sort of structure that is a workaround.

But I would agree with Troy and also just say that those issues are more contentious. If we could just get the basic, simple stuff done, that would be terrific. And there is always another day.

Senator COATS. And, Mr. Barsky, is there anything you want to add to that?

Mr. BARSKY. I agree with everything that was said, and I think that Dr. Paulus is exactly right. We need to hit the core issues. There are definitely peripheral issues, like the in-office ancillary exception.

But I think that we seem to have agreement here about what we need to do on the core issues.

Senator COATS. Very good.

Mr. Chairman, thank you.

The CHAIRMAN. Well, thank you, Senator.

We are happy to have all three of you here.

Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman, and I thank the panelists. You probably will not find a bigger supporter of changing to a value-based way of paying for health care than myself, and I think that is because I represent a State that has definitely pursued that model, for a variety of reasons, and has delivered better outcomes because of it.

And so we would love the rest of the country to pursue that, and that is why we authored some of the language that was in the Affordable Care Act and worked on the doc fix and some of that lan-

guage. I would have been much more aggressive at moving the market than what was in that bill.

But I am also a big believer in bright lines, and to me, this discussion this morning is a little bit—I mean, there are a couple of things here that I keep thinking about. We are really talking about reward versus abuse. We are really talking about paying physicians and rewarding them for good outcomes versus somebody who is doing something perverse in the system and not necessarily producing good outcomes, but just paying them for whatever they are doing.

When I think about this from the energy market perspective, we went from a more regulated market to a deregulated energy market, but that did not mean that we still did not have laws to police the energy markets. I mean, we wrote a new anti-manipulation law that FERC just used today to fine BP for manipulating markets.

So to me, this is not an issue of trading one in for the other, and so I do not know what you think that bright line is that we are really trying to articulate here today.

But we need to move forward, and we need physicians to be rewarded for good behavior, but we have to have something that tells us when they have been abusive of that behavior.

And so what do you think that bright line is?

Mr. BARSKY. So, as we have been discussing today the Stark Law, the bright line that the Stark Law creates is in a system of fee-for-service. So if you are paying based on volume, the Stark Law is necessary to protect payments based on incentives based on volume.

But as we move to this new value-based payment system, I think the bright line changes. What you are worried about is not overutilization but potentially underutilization and harm to patients, that you might do better if you provide less care.

At least, when you are thinking about fraud in the program——

Senator CANTWELL. No, I think of it more in the context of somebody doing something like the same kind of practices or abuse you would be concerned about under Stark now, but accentuated, and then saying, oh well, the reason why we did not get the outcomes or the reason why we did not do this is because it was a scam.

Mr. BARSKY. Sure.

Senator CANTWELL. So I think what we are all dancing around here on the back and forth is that, even if we want to move to value-based payment systems because that is a better way to deliver health care—it is proven—then what do we need to do to make sure there are penalties for people who are abusive of that system for other reasons?

So I do not think any of you are saying, no, no, no, like, just in the energy markets. So we went from a regulated market to a less-regulated market. We did not say that there are no rules.

For markets to function—even Alan Greenspan had to admit, oh, he was wrong. They are not always self-adjusting. Sometimes people do bad things. So what are you going to do to catch the bad activity here? And that is, I think, what people on our side of the aisle are going to want to understand about this before they are going to say, oh, just throw out this rule. What are we going to do to catch the abusive behavior?

Mr. BARSKY. I think the existing waivers that HHS has issued are a good model for that. What they have said specifically is that the laws, Stark, Anti-Kickback, False Claims Act, are not waived completely. Instead, if you are engaged in the right activities, if you are working towards quality, the Stark Law is waived.

If you are engaged in an activity, as you have mentioned, which is a sham, it is really to try to enrich physicians without helping patients, the waiver does not apply to you, and the Stark Law will continue to apply.

So what I am saying is that there is a safety valve within these waivers—not a complete blanket waiver, but a safety valve—that if there are defrauding actors, the protections will not exist and the government will still have the ability to prosecute.

Mr. MANCINO. I would just add that nobody here is recommending that we eliminate the Anti-Kickback Statute or the False Claims Act. Those remain in place, and those, in and of themselves, I think prevent fraud.

And I think that it is important to remember that Stark, while it is intended to be a bright-line test, is actually not. I mean, it is really rather dark. Nobody knows what it really means. And regarding commercial reasonableness and fair market value, you can talk to a million experts and get a million different theories about what they actually mean. So that is the problem with Stark. But I think you are protected by the Anti-Kickback Statute and the False Claims Act.

Senator CANTWELL. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman. I welcome all of our witnesses. I am sorry I was not at the hearing earlier. I am ranking member on the Senate Foreign Relations Committee and had to be there.

As I listen to people talk about the Stark rules, I am just reminded of my service in the House of Representatives with Chairman Stark and being lectured—being educated—by him as to the importance of these rules. [Laughter.]

We are now in a different era. And first, I want to welcome Mr. Mancino to our committee. We are very proud of the work that he does at Johns Hopkins and the work that Johns Hopkins does, not just in Maryland and our Nation but globally, on health-care issues. So it is nice to have all of you here, but it is nice to have the person from Maryland.

I want to go a little parochial for one moment, if I might, and say that Maryland has an all-payer rate structure for hospital reimbursement that requires us to have an integrated way to deal with hospital care in our State, where you have to have arrangements between the hospitals and other providers in order to reduce overall costs in our State on hospital care. It is a requirement. Otherwise, we lose our all-payer rate waiver.

Our all-payer waiver is important so that we do not have charity hospitals. At our Maryland hospitals, you get basically the same reimbursement regardless of the payer, whether it is Medicare or

whether it is a private insurance company, for the services that are performed at the hospital.

But the trade-off on that is that we have to show that we are saving the government money, and we have done that historically on a per-unit cost. We have always been lower. But where Maryland was not doing as well as it needed to do was in its overall per capita cost of hospital care.

So 2 years ago we entered into a new arrangement with CMS where our hospital community has agreed that it will work with an overall global budget on hospital costs, which means they have to work with non-hospital providers in order to reduce readmissions, et cetera.

So it seems to me that the Stark rules could present challenges to our community in achieving those targets. Could you just give me your view as to what modifications may be necessary in a State like Maryland that is trying to look at overall cost issues and results when there is responsibility on one provider to do more than just that particular service?

Mr. MANCINO. In Maryland, more than any other State really, because of that system that you are talking about, it is really important for us to be able to team with physicians and nursing homes, et cetera, to keep patients out of the hospital and out of high-cost settings.

And so Stark is an even bigger problem for us. We cannot, for example, provide a physician assistant to a practice to be able to keep a chronically ill patient out of the hospital, and we cannot provide a PA to help in discharge to keep the patient all right. The problem is that Stark prevents us from doing these things, in many cases, because it is considered remuneration.

And so the suggestion that has been floated here, which is to eliminate the compensation requirements of Stark and just have it as an ownership conflict-of-interest statute, I think would be an excellent solution in Maryland.

Senator CARDIN. Of course, one of the things that we recognize is that budgets are going to be tight in health care. We know that. That is a given. So we are all looking for ways that we can do more integrative, collaborative care models in which we look at provider groups working together in order to reduce overall costs. It seems to me that, as has been pointed out, some of the Stark provisions make that very difficult to achieve.

Dr. PAULUS. If I could add to your excellent comments on the situation in Maryland—even beyond Maryland, although Maryland is sort of the poster child. We think about how CMS has penalties now for hospital readmissions if you go above a certain amount, and the question is, what are the mechanisms to reduce those readmissions? They involve care coordination and a bunch of out-of-hospital things that keep people from needing to come back. Most of those things are not paid for.

So if we were to try to set up a system where, let us say, we wanted to embed a care management nurse in a physician practice or we wanted to pay based upon our lower readmission rate, we cannot do those things because of the quote-unquote "volume of referrals."

We are actually specifically trying to reduce the volume of readmissions because it adds something of, quote, "economic value" to the practice.

Senator CARDIN. Thank you.

Thank you, Mr. Chairman. I appreciate it.

The CHAIRMAN. Well, thank you, Senator.

I want to thank the three of you for being here. You have been excellent. Each one of you has added a great deal to our understanding of this, and we are going to try to do something about this before the end of the year.

This is a very active committee. We move a lot of things out of here and, hopefully, we can do this for the medical profession as well. But to the extent that we can, it is going to be largely because of the testimony of the three of you. So we just really appreciate you being here with us. And I appreciate the questions of my fellow colleagues.

So with that, we will recess until further notice.

[Whereupon, at 11:27 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF TROY A. BARSKY, PARTNER, CROWELL AND MORING, LLP

Mr. Chairman, Ranking Member Wyden, and members of this distinguished committee, it is an honor for me to participate in this hearing and to provide my thoughts and insights regarding the Stark Law. I am a partner at the law firm of Crowell and Moring, where I provide advice and counsel to health care entities engaged in new health care delivery models. Prior to joining Crowell and Moring, I spent 11 years working at the U.S. Department of Health and Human Services ("HHS"). I served as the Director of the Division of Technical Payment Policy at CMS for my last 4 years at HHS where I was responsible for Stark Law policy and other Medicare payment issues, including those related to the implementation and creation of new value-based payment models created by the Patient Protection and Affordable Care Act of 2010 ("ACA").[1] I am here today in my own capacity and not on behalf of my firm. My views do not represent those of any client or other organization.

I. STARK LAW REFORM IS OVERDUE AND NECESSARY

The fundamental question at issue here is whether the Stark Law as it is currently drafted is precisely tailored to minimize unwarranted utilization resulting from certain financial relationships and is a net positive to patients/taxpayers. And if not, what reform is necessary to remove extraneous aspects that unnecessarily drive up health care industry, and ultimately, patient costs. As I will discuss in greater detail below, the Stark Law has evolved from the simple objective of removing certain financial incentives from medical decision-making into a tortured web of confusing standards, ambiguous and conflicting definitions, and volumes of regulations that require countless lawyers and valuation experts to ensure compliance.

Compliance then is not only excessively costly, but unachievable as a practical matter. And because Stark is a strict liability statute, there is no need to intend to violate the law. If you fail to meet any of its technical requirements even inadvertently, a health care entity is subject to millions or tens of millions of dollars in payments and penalties, program exclusion, and False Claims Act ("FCA")[2] liability. And yet compliance with many of the elements of the Stark Law—such as requiring a signature on every written arrangement—have nothing to do with fraud, high quality service for patients, or protection of the Medicare program.

With the passage of the ACA[3] and the Medicare Access and CHIP Reauthorization Act of 2015[4] ("MACRA"), the Stark Law is now also an obstacle to the imple-

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[1] My full biography may be found at *https://www.crowell.com/Professionals/troy-barsky.*

[2] 31 U.S.C. §§ 3729–3733; *see, e.g., United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.,* No. 13–2219 (4th Cir. July 2, 2015); U.S. Department of Justice Settlement Announcement (October 16, 2015): *https://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital; United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center,* et al., No. 09–cv–1002 (M.D. FL.); U.S. Department of Justice Settlement Announcement (March 11, 2014): *https://www.justice.gov/opa/pr/florida-hospital-system-agrees-pay-government-85-million-settle-allegations-improper.*

[3] The Patient Protection and Affordable Care Act (Pub. L. No. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111–152) are collectively known as the "Affordable Care Act."

[4] Pub. L. No. 114–10.

mentation of health care delivery and reimbursement reform. The goals of new payment models emanating from the ACA and MACRA are diametrically opposed to the requirements of the Stark Law. New health care payment models are designed to integrate providers clinically and financially and compensate physicians on value and quality care, while the Stark Law is intended to keep parties financially separated. Further, this shift from volume-based (fee-for-service) to value-based payment systems reduces the underlying financial incentives believed to negatively impact medical decision-making for which the Stark Law was initially enacted to combat. As we move away from the fee-for-service world, the need and utility of the Stark Law continues to diminish. Therefore, Congress should consider repealing, in whole or in part, and replacing the law. For example, a balance of harms analysis would support keeping the ownership prohibition, but removing the compensation prohibition.

Absent repeal, there are common-sense reforms that should be implemented to minimize the Stark Law's unjustified, onerous burden. First, the overwhelming vast majority of providers want to comply with the law, but struggle because of ambiguous critical terms. Making bright line rules that providers can follow and expanding CMS's authority to provide guidance through advisory opinions will greatly assist providers in complying. Second, limit the consequences of purely technical violations of the Stark Law. Either remove the technical requirements completely, or ascribe only a monetary penalty for technical violations rather than conditioning Medicare payment and exposing providers to FCA liability based on mere technicalities. Third, lower CMS's heightened standard of "no program or patient abuse" for promulgating new regulatory exceptions to the general prohibition.

Stark Law reform is also necessary to remove barriers to implementing health care reform. The ACA allowed for broad Stark exceptions under the law. Give greater authority to the Secretary to expand this waiver authority in a unified manner to allow for more innovative payment models as opposed to the piecemeal, constrained approach that is now developing. Additionally, Congress should amend the statute to limit loophole exceptions that are contrary to health care reform efforts. For example, the in-office ancillary services exception continues to allow for in-office referrals and overutilization making it less likely these practices will move to an integrated care model. I recommend closing this exception to incent providers to move to value-based payment models. The Stark Law will continue to be a barrier if we do not modernize the law to reasonably protect against patient and program abuse while allowing for innovation.

II. THE BASIC CONSTRUCTION AND HISTORY OF THE STARK LAW

A. Broad Prohibition on Referrals

The Physician Self-Referral Law, or the Stark Law, found in section 1877 of the Social Security Act,[5] consists of a 30-year series of statutory and regulatory enactments reflecting the complexity of the area for which it applies. Unless an exception applies, the Stark Law provides that if (1) a physician (or an immediate family member of a physician) has a direct or indirect financial relationship with an entity, the physician may not make a referral to the entity for the furnishing of designated health services ("DHS") for which payment may be made under Medicare, and (2) the entity may not present (or cause to be presented) a claim to the Federal health care program or bill to any individual or entity for DHS furnished pursuant to a prohibited referral.[6]

The Stark Law is applicable when each of the following are involved: a physician (or a family member of a physician), a "financial relationship," and a "referral." Determining the existence of a "financial relationship" or a "referral" are complex inquiries. A financial relationship is defined as any direct or indirect (a) ownership or investment interest or (b) compensation arrangement by or between a physician (or an immediate family member of the physician) in the entity providing the DHS.[7] Indirect ownership, for example, brings entire chains of ownership into the province of Stark.

B Exceptions to the Broad Prohibition

There are numerous statutory and regulatory exceptions to this general prohibition, which can be grouped into the following general categories:

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[5] Section 1877 of the Social Security Act.
[6] *See* section 1877(a)(1) of the Social Security Act; 42 CFR § 411.353(a).
[7] Section 1877(a)(2) of the Social Security Act.

- General Exceptions to the Ownership and Compensation Arrangements Prohibitions; [8]
- Permitted Ownership and Investment Interests; [9]
- Permitted Compensation Arrangements; [10]
- The Innocent Entity Exceptions and Related State-of-Mind Issues; and [11]
- Waivers for Accountable Care Organizations ("ACOs") in connection with Shared Savings Program [12] and other Center for Medicare and Medicaid Innovation ("CMMI") Models.[13]

C. The Stark Law Was Enacted to Address Possible Overutilization Due to Financial Interests

At its core, the Stark Law was intended to address the concern that physicians paid on a fee-for-service basis will perform or refer more or unnecessary services to earn more income.[14] The impetus behind the Stark Law was a documented positive correlation between physicians' financial ties and increased utilization of services.[15] As such, Congress sought to prohibit referrals to entities with which physicians or physicians' family members had a financial relationship in order to minimize or remove the possible impact of a financial incentive.

As the issue of physician self-referral was gaining attention in the 1980s, the HHS Office of Inspector General ("OIG") and the Government Accountability Office ("GAO") engaged in separate studies examining the relationship between physician ownership and referrals. Both the OIG and GAO studies examined the occurrence of self-referral involving various types of medical services, and both agencies determined that physician self-referral most significantly increased utilization of clinical laboratory services.[16] Congress concluded that such overutilization was undesired, though neither agency's study examined the medical necessity, or lack thereof, of the specific tests ordered.[17]

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[8] Several exceptions apply to both ownership or investment arrangements and compensation arrangements, *e.g.,* physicians' services provided by a physician in the same group practice as the referring physician are exempted by section 1877(b)(1) of the Social Security Act.

[9] For example, ownership of investment securities purchased on terms available to the general public and listed on certain recognized exchanges that exceed a specific level of average shareholder equity over 3 fiscal years are exempted under section 1877(b)(2) of the Social Security Act.

[10] For example, rental of equipment under certain circumstances is exempted by section 1877(e)(1)(B) of the Social Security Act.

[11] For example, an exception applies when the entity did not have actual knowledge or act in reckless disregard of deliberate ignorance of the identity of the referring physician, and the claim complies with all other Federal and State laws under 42 CFR § 411.353(e).

[12] For example, waivers under the Patient Protection and Affordable Care Act apply to arrangements within "accountable care organizations." *See* 80 Fed. Reg. 66726.

[13] All available fraud and abuse waivers for CMS models and programs, including those administered by CMMI, are listed here: *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.* To date, the HHS Secretary has established waivers for the following programs:

- Pioneer Accountable Care Organization ("ACO") Model;
- Bundled Payment for Care Improvement ("BPCI") Model;
- Health Care Innovation Awards ("HCIA") Round Two;
- Comprehensive ESRD Care Model;
- Comprehensive Care for Joint Replacement ("CJR") Model;
- Next Generation ACO Model;
- Oncology Care Model; and
- Medicare Shared Savings Program ("MSSP").

[14] 66 Fed. Reg. 856, 859 (January 4, 2001) (describing the correlation found between financial ties and increased utilization as the basis for the Stark Law).

[15] *See* 66 Fed. Reg. 856, 859 (January 4, 2001).

[16] The OIG surveyed utilization patterns of physician owners of independent clinical laboratories, independent physiological laboratories, and durable medical equipment suppliers. The OIG found that physician self-referral related to laboratory tests was associated with a 45% increase in utilization, though the increased utilization with the other entity types was less significant. OIG—Office of Analysis and Inspections, *Report to Congress, Financial Arrangements Between Physicians and Health Care Businesses* 3 (1989). The GAO found that physician owners tended to order more, and more costly, laboratory services while ordering fewer, but more costly, imaging services. *Medicare, Referring Physicians' Ownership of Laboratories and Imaging Centers, Hearings on H.R. 939 Before the Subcommittee on Health of the House Committee on Ways and Means,* 101st Cong. 9 (1989).

[17] OIG—Office of Analysis and Inspections, *Report to Congress, Financial Arrangements Between Physicians and Health Care Businesses* 3 (1989); *Medicare, Referring Physicians' Owner-*

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1. Stark I Only Addressed Financial Relationships With Clinical Laboratory Services' Entities

In response, Stark I was created by the Omnibus Budget Reconciliation Act of 1989,[18] which became effective January 1, 1992. Stark I prohibited a physician (or an immediate family member) who had a financial relationship with a clinical laboratory services entity from referring Medicare beneficiaries to the entity, unless an exception applied. In addition, it prohibited the lab from billing for any services furnished pursuant to such referrals.

Congress actively decided[19] against applying the ban of physician self-referral beyond clinical laboratory services to a broad array of medical services for which there was no evidence of overutilization resulting from self-referral.[20] Since the agency reports indicated overutilization of only clinical laboratory services, this first legislative enactment targeted financial relationships with only those entities.

2. Stark II's Statutory Amendments Broadened the Self-Referral Ban to a Wide Array of Health Services

Only a few years later, in the second legislative enactment[21] Congress expanded the clinical laboratory prohibition to a number of "designated health services" (DHS). This expansion was based on the latest studies which associated overutilization of several additional services with self-referral[22] as well as former Representative Pete Stark's ongoing efforts to prevent "turning a physician's decision to refer a patient into a marketable commodity."[23]

Stark II, as part of the Omnibus Budget Reconciliation Act of 1993,[24] expanded the physician self-referral ban to the following DHS:[25]

- Clinical laboratory services (Stark I);
- Physical therapy services;
- Occupational therapy services;
- Radiology or other diagnostic services, including MRI, CAT scans, and ultrasound services;
- Radiation therapy services;
- Durable medical equipment;
- Parenteral and enteral nutrients, equipment, and supplies;
- Prosthetics, orthotics, and prosthetic devices;
- Home health services;
- Outpatient prescription drugs; and
- Inpatient and outpatient hospital services.

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ship of Laboratories and Imaging Centers, Hearings on H.R. 939 Before the Subcommittee on Health of the House Committee on Ways and Means, 101st Cong. 9 (1989).

[18] Pub. L. No. 101–239, 103 Stat. 2106 (1989) (Stark I was enacted in the Ethics in Patient Referrals Act).

[19] The original Federal bill prohibiting self-referrals would have applied to a broad array of health-related goods and services. H.R. 5198, § 2(a) 100th Cong., 2d Sess. (1988). The bill was introduced by Representative Fortney (Pete) Stark (D–CA). *Id.*

[20] *Physician Ownership/Renewal Arrangements, Hearing Before the Subcommittee on Health and the Subcommittee on Oversight, House Committee on Ways and Means,* 102nd Cong. 6 (1991) (statement of Representative Pete Stark, Chairman, Subcommittee on Health, House Committee on Ways and Means).

[21] Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103–66, 107 Stat. 312 (1993).

[22] *See, e.g.,* Jean M. Mitchell and Elton Scott, *Physician Ownership of Physical Therapy Services,* 268 Journal of the Am. Med. Ass'n 2055 (1992); Jean M. Mitchell and Jonathan Sunshine, *Consequences of Physicians' Ownership of Health Care Facilities—Joint Ventures in Radiation Therapy,* 327 The New England Journal of Med. (1992).

[23] *See Physician Ownership and Referral Arrangements and H.R. 345, "The Comprehensive Physician Ownership and Referral Act of 1993," Hearings Before the Subcommittee on Health, House Committee on Ways and Means,* 103rd Cong. (1993); *Physician Ownership/Renewal Arrangements, Hearing Before the Subcommittee on Health and the Subcommittee on Oversight, House Committee on Ways and Means,* 102nd Cong. 6 (1991).

[24] Pub. L. No. 103–66, 107 Stat. 312 (1993).

[25] Section 1877(h)(6) of the Social Security Act.

3. CMS Has Created a Complex and Ever-Growing Body of Regulations to Implement the Stark Law

The Centers for Medicare and Medicaid Services (CMS) is responsible for interpreting the Stark Law and issuing regulations and other guidance. The regulatory definition and exception framework and interpretation thereof is ever-changing. The final rules are codified at 42 CFR §§ 411.350–411.389.[26] Below, we provide a list of the most substantive regulatory promulgations, but there are many others. All of these regulatory and other preamble guidance must be read, studied, and understood in order to comply with the Stark Law.

- *Stark I regulations, August 14, 1995.*[27] The first round of regulations was promulgated in connection with Stark I. However, since Stark II maintained the same general prohibitions and some of the exceptions of Stark I, the regulations implementing Stark I were applied by CMS to the other DHS subject to Stark II.
- *Stark II Phase I regulations, January 9, 1998 (proposed rule).*[28] These proposed regulations focused on applying many of the existing provisions of the 1995 rule to additional DHS as well as updating others in accordance with the changes to the Stark Law enacted in the Omnibus Budget Reconciliation Act of 1993 and the Social Security Act amendments from 1994. It also provided additional explanation of CMS's views on the appropriate application of the various exceptions and the scope of the referral prohibition.
- *Stark II Phase I regulations, January 4, 2001 (interim final rule).*[29] These regulations specifically interpreted and implemented Stark II and offered guidance concerning its interpretation and application to a wide range of arrangements and relationships. Because the 1998 proposed rules introduced restrictive interpretations, the 1998 proposed rules were received critically and received extensive comments that CMS interpretation was too conservative. These regulations provided guidance regarding the service-based exceptions that apply to both the ownership or investment interests and compensation arrangements, like the in-office ancillary services exception.
- *Stark II Phase II regulations, March 26, 2004 (interim final rule).*[30] This regulation addressed remaining portions of the statute not covered under Phase I, including reporting requirements and sanctions. CMS attempted to clarify the exceptions to compensation arrangements and added additional exceptions for financial relationships that posed no risk of fraud and abuse. In particular, CMS added a "fair market value" exception.
- *Stark II Phase III regulations, September 5, 2007.*[31] Phase III regulations interpreted provisions relating to direct and indirect compensation arrangements. CMS indicated that all three phases of Stark II regulations "are intended to be read together as a unified whole."
- *Stark II, Inpatient Prospective Payment System ("IPPS") regulations, August 19, 2008.*[32] These regulations expanded the definition of the term "entity" to include those actors that "perform" services billed as DHS. Further, the regulations limited the ability of entities to utilize percentage and per-click compensation formulas for equipment and space lease arrangements.
- *Stark II, IPPS regulations, October 30, 2015.*[33] These regulations clarified the definition of "remuneration" and the writing requirements of compensation exceptions. Furthermore, CMS created an exception for timeshare leases.

Despite the amount of time and money that goes into development, interpretation, implementation, and verifying compliance with the exceptions, sometimes it remains unclear whether the intended purpose of an exception was achieved, *e.g.,* the "whole hospital" exception. The "whole hospital" exception, since Stark I's passage, exempted arrangements where physicians have an interest in an entire hospital—whether

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[26] *See* Significant Regulatory History, Physician Self-Referral, Centers for Medicare and Medicaid Services, *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Significant-Regulatory-History.html.*
[27] 60 Fed. Reg. 41914, 41916 (August. 14, 1995).
[28] 63 Fed. Reg. 1659 (January 1, 1998).
[29] 66 Fed. Reg. 856 (January 4, 2001).
[30] 69 Fed. Reg. 16054 (March 26, 2004).
[31] 72 Fed. Reg. 51012 (September 5, 2007).
[32] 73 Fed. Reg. 48434 (August 19, 2008).
[33] 80 Fed. Reg. 70885 (October 30, 2015).

a general acute care or specialty hospital.[34] Since DHS includes inpatient and outpatient hospital services, absent an exception, referrals by a physician retaining an interest in a hospital would be prohibited. Over many years, some constituents sought to restrict this particularly broad exception, especially given a perception that specialty hospitals appropriate high-margin surgeries from general acute care hospitals. As a result of such efforts, in 2003, Congress imposed an 18-month moratorium prohibiting physicians from referring a Medicare patient to any specialty hospital in which the physician had an ownership interest. Later, the ACA limited the whole hospital exception's application to only those hospitals that are "grandfathered" in, *i.e.,* hospitals with physician ownership and an effective Medicare provider number before December 31, 2010.[35] Further, to avoid circumvention by increasing physician-ownership of exempted hospitals, the law and the regulations strictly limit the expansion of space or service of any grandfathered hospitals.[36] And still, constituents on both sides of this issue continue to debate whether this exception and the imposed limitations on the exception effectively achieve their intended goals.

D. Strict Liability for Stark Law Violations Creates Staggering Consequences

Any proposed arrangement that involves a financial relationship with a physician who refers DHS that are payable by Medicare must be evaluated for compliance with every aspect of an exception to ensure the referral complies with Stark. Most exceptions have very detailed and technical requirements, including signatures on agreements and written contracts. Failure to comply with any of these requirements means an automatic violation of the Stark Law. Given the difficult and lengthy processes necessary to make a Stark Law compliance determination compared with the practical demands and structure of the health care industry, non-compliance is inevitable even for the best intentioned providers. This is troublesome for a number of reasons, such as the steep consequences for non-compliance.

The Stark Law is a condition of Medicare payment: failure to comply with the Stark Law means a denial of Medicare payment for any claims submitted pursuant to the prohibited referral. In addition, sanctions, including civil monetary penalties and potential program exclusion, may be imposed against any person that submits or causes such claims to be submitted or fails to make a timely refund of any amounts collected. It is now well-established that a violation of the Stark Law can lead to FCA liability. This liability for submitting a false claim or causing a person or entity to submit a false claim is the most significant risk that health care providers face under the Stark Law. A violation of the FCA results in potential treble damages and civil penalties for every "tainted" claim.

The penalties under the Stark Law can be much higher than the penalties for other billing issues resulting in a Medicare overpayment. To illustrate, if a hospital has a non-compliant financial arrangement with a physician, all Medicare payments for all inpatient or outpatient services referred by that physician are overpayments and must be returned, regardless of the nature and the amount of the tainted transaction.[37] This impact is further compounded because the Stark Law is also a strict liability statute. So if a physician and hospital violate the Stark Law, the entity must refund the payment amount, is subject to civil monetary penalties, and potential FCA liability even if there was no intent to unlawfully incent the referral and the referral was, in fact, warranted and medically necessary.

III. STARK LAW DEFICIENCIES AND RECOMMENDED RESOLUTIONS

A. The Stark Law Creates Unnecessary Impediments to Healthcare Reform

1. Overview of Reforms Creating Value-Based Payment Models and Incentives

The ACA encourages a fundamental shift away from traditional Fee-for-Service ("FFS") payment models that reward providers based on the quantity of services administered to patients—to value-based and population-based payment models that

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[34] Section 1877(d)(3)(A) of the Social Security Act; 42 CFR § 411.356(c). The exception requires (1) the ownership or investment interest must be in the hospital itself and not merely in a "subdivision" of the hospital; (2) the referring physician must be "authorized" to perform services at the hospital.

[35] ACA § 6001(a)(3) added section 1877(i)(1) of the Social Security Act which sets out conditions that a facility must meet to continue to use the whole hospital exception.

[36] 42 CFR § 411.362 (b)(2).

[37] Senate Committee on Finance, "Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models," p. 5 n. 10 (June 30, 2016) (using this example to illustrate the higher penalties for a Stark violation.)

reward providers based on the quality and efficiency of care delivered. Value-based payment models significantly and, in many cases, entirely eliminate the risk of health care resource overutilization, which is the risk the Stark Law was designed to address. When health care providers earn their margin not by the volume of services they provide, but by the efficiency of their services and the excellence of the treatment outcomes, their economic self-interest aligns with the interest of law enforcement seeking to protect patients from unnecessary services. This is especially critical in an environment where health systems are earning an ever-increasing proportion of their income (Medicare and otherwise) outside FFS.

The ACA chiefly promotes the use of value-based payment models through the creation of integrated care delivery models. Under the ACA's authority, the Center for Medicare and Medicaid Innovation ("CMMI") has created and continues to oversee a number of demonstration projects under section 1115A of the Social Security Act that are changing health care payment and delivery by offering value-based and population-based payments to providers.[38] Similarly, the Centers for Medicare and Medicaid Services ("CMS") administers the Medicare Shared Savings Program ("MSSP"),[39] which is the permanent ACO program for CMS. Of note, the MSSP offers financial incentives under which ACOs—groups of doctors, hospitals, and other health care providers who come together voluntarily to provide coordinated care to their Medicare patients—can share a percentage of their achieved savings with Medicare, if the ACOs meet quality and savings requirements.[40]

Building upon innovative payment models promoted under the ACA, Congress created a new framework to incent physicians to continue to engage in collaborative relationships to provide coordinated care to patients by enacting MACRA. MACRA ended the Sustainable Growth Rate ("SGR") formula that previously dictated payment amounts for physicians enrolled as Medicare providers. In its stead, MACRA establishes the new Merit-Based Incentive Payment System ("MIPS") that uses a combination of existing health care quality reporting programs to provide positive or negative payment adjustments based on value-based metrics. In addition, MACRA gave CMS the authority to provide incentive payments to clinicians who engaged in certain Alternative Payment Models ("APMs").

APMs are defined under MACRA as: (1) section 1115A models being tested by CMMI (except health care innovation awards); (2) the MSSP; (3) a demonstration under section 1866C of the Social Security Act (establishing the Health Care Quality Demonstration Program); and (4) other demonstrations "required by Federal law."[41] According to the law and CMS's proposed rule implementing MACRA, beginning in 2019, if an "eligible clinician" participates in what CMS has deemed an "Advanced APM"[42] and receives a certain percentage of payments set in advance by CMS from delivering care to certain classes of Medicare beneficiaries through the Advanced APM, these clinicians may become "Qualifying APM Participants" ("QPs")

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[38] CMMI, *https://innovation.cms.gov/*. Three of these models include the BPCI, the CJR, the Pioneer ACO Model, and the Next Generation ACO Model.

[39] Section 1899 of the Social Security Act.

[40] As of January 2016, when accounting for participating providers in the MSSP, the Next Generation ACO Model, Pioneer ACO Model, and the Comprehensive ESRD Care Model administered by CMS and CMMI, nearly 8.9 million Medicare beneficiaries are served through a total of 477 ACOs, 64 of which utilize two-sided risk-bearing models. CMS Press Release, "New Hospitals and Health Care Providers Join Successful, Cutting-Edge Federal Initiative that Cuts Costs and Puts Patients at the Center of Their Care" (January 11, 2016), *available at http://www.hhs.gov/about/news/2016/01/11/new-hospitals-and-health-care-providers-join-successful-cutting-edge-federal-initiative.html; see also* CMS, "Accountable Care Innovation Models," *available at https://innovation.cms.gov/initiatives/index.html#views=models&key=accountable care* (last visited July 11, 2016).

[41] *Id.* 81 Fed. Reg. 28161. According to the MACRA proposed rule, CMS would impose three criteria for the fourth category, including that: (1) the demonstration must be compulsory under the statute, not just a provision of statute that gives the agency authority, but one that requires the agency to undertake a demonstration; (2) there must be some "demonstration" thesis that is being evaluated; and (3) the demonstration must require that there are entities participating in the demonstration under an agreement with CMS or under a statute or regulation.

[42] As further explained in the MACRA proposed rule from CMS, an APM must meet all three of the following criteria defined under section 1833(z)(3)(D) of the Social Security Act to be deemed an "Advanced APM:"

1. Require participants to use certified electronic health records technology ("CEHRT");
2. Provide for payment for covered professional services based on quality measures comparable to those in the quality performance category under MIPS; and
3. Either require that participating APM Entities bear risk for monetary losses of a more than nominal amount under the APM, or be a Medical Home Model expanded under section 1115A(c) of the Act. 81 Fed. Reg. 28297.

and be eligible for incentive payments from CMS equal to 5 percent of their prior year's payments from Medicare Part B as well as higher payment updates under the annually issued Physician Fee Schedule ("PFS"). Starting in 2021, eligible clinicians may also become QPs by participating in a combination of Advanced APMs and APMs with other payers, including commercial payers (defined as "Other Payer Advanced APMs").[43] By 2024, the incentive payments will phase out, and the same will occur with the enhanced PFS updates. Overall, the incentives for participation in Advanced APMs and Other Payer Advanced APMs are intended to accelerate the transition from Medicare fee-for-service payments to value-based models.

2. The Incomplete Protection of Existing Waivers for Innovative Payment Models

Both the ACA and MACRA premise health care reform on the coordination of multiple health care providers to provide better care at lower cost. In other words, one of the main goals of the ACA and MACRA is to drive health care entities together, both clinically and financially. Yet, the goals of the Stark Law are diametrically opposed to this goal, having been designed to keep health care entities financially apart.

a. The Fraud and Abuse Waivers Under the ACA

In enacting the ACA, Congress recognized Federal "fraud and abuse" laws are increasingly incompatible with these innovative payment and integrated care models. Thus, the ACA authorized the Department of Health and Human Services ("HHS") Secretary to issue regulatory waivers for innovative payment and service delivery models under MSSP, CMMI's authority, and the Health Care Quality Demonstration Program.[44] Using that authority, the Secretary issued waivers from the requirements of the Stark Law as well as other fraud and abuse laws for participants in the MSSP,[45] and has exercised that authority as well for participants in the BPCI, the CJR and other demonstration programs at CMMI. Because of these waivers, providers can meaningfully participate in innovative payment models without being subject to the Stark Law. However, the waivers under the MSSP and under the CMMI programs operate very differently and provide incomplete protection, as described below.

(i) The MSSP Waivers Are Broad, But May Be Out of Reach for Commercial Entities

Under the MSSP, CMS and OIG collaborated to create five waivers that would provide collective protection from enforcement under the Stark Law as well as from other selected anti-fraud and abuse statutes.[46] The broadest waivers available under the MSSP protect arrangements protect "start-up" and continuing the operations of an ACO as well as distributions and uses of shared savings payments earned under the MSSP.[47]

All of the waivers provide simple requirements regarding the parties eligible for the waivers, the arrangements to which the waivers could apply, the terms during which the arrangements would receive protection under the waiver, and requirements for parties' governing bodies to fulfill in order to memorialize the adoption of the waivers at their respective organizations. Most importantly, however, these waivers are generally available to participants in the MSSP as well as entities that arrange to provide items or services that support the MSSP participants, so long as the governing boards have determined that the arrangements are "reasonably related" to the MSSP. The MSSP waivers have allowed health care systems to engage in innovative care coordination and payment arrangements and ACOs find them relatively easy to adopt and apply to their operations. But despite these benefits, the MSSP waivers are not broad enough to protect arrangements that may involve commercial arrangements that still trigger the Stark Law, as I describe in section III.A.3 below.

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[43] Section 1833(z)(2)(B)(ii) of the Social Security Act.

[44] Section 1899 of the Social Security Act (42 U.S.C. 1395jjj); section 1115A of the Social Security Act (42 U.S.C. 1315a); and section 1866C of the Social Security Act (42 U.S.C. 1395cc–3).

[45] CMS and OIG, "Final Waivers in Connection With the Shared Savings Program," 80 Fed. Reg. 66726 (October 29, 2015).

[46] *Id.*

[47] *Id.* (specifically, the ACO Pre-Participation Waiver, the ACO Participation Waiver, and the ACO Shared Savings Distribution Waiver).

(ii) The CMMI Waivers Are Too Narrow and Time-Limited for Long-Term Results

In contrast, the waivers applicable to CMMI initiatives are extremely program-specific. As CMMI implements more models, the waiver requirements have gotten more prescriptive and extremely narrow. These waivers are too program-specific and too numerous to keep track of to facilitate continued progress toward health reform, especially when a health care entity or system is participating in multiple programs simultaneously. More importantly, however, the waivers related to CMMI's programs offer only temporary protection for participants because they are only available during the time they are being tested by CMMI. Thus, once the program related to the specific waiver is over, there is little incentive to continue the arrangement it previously protected because the parties to the arrangement would have to make it comply with applicable exceptions and safe harbors under the fraud and abuse laws. More likely than not, this means that an arrangement that could have immense cost-efficiencies for the health care system would have to end with the termination of the CMMI program. And given the short-term nature of the CMMI programs (they generally last for 3 to 5 years), many health systems will not want to invest in infrastructure redesign only to have to unwind such arrangements to comply with existing Stark Law restrictions.

b. New APMs Under MACRA

Similarly, MACRA is a landmark shift toward value-based payment systems in the U.S. health care system, but falls short in addressing the still-existing barriers presented by the fraud and abuse laws, including the Stark Law, that were not remedied in the ACA. Although Congress established the HHS Secretary's authority to waive certain requirements including the payment-related requirements imposed by the Stark Law within specific provisions of the ACA, no such authority exists in MACRA. Thus, providers must rely on the authorities granted in the ACA to find relief from the fraud and abuse laws, even though MACRA opened the door to the creation of additional government-based and non-government based programs to support the transition to value-based payment for services to Medicare beneficiaries.[48] But having to "bootstrap" the waivers available under the ACA to new programs under MACRA still provides incomplete protection from the fraud and abuse laws in the following situations:

- In CMMI programs where the HHS Secretary elects to *not* create waivers from the fraud and abuse laws;
- In APMs from the "demonstration programs required by federal law" category where Congress did not provide the HHS Secretary authority to establish waivers; or
- In APMs that are not specified in MACRA, such as Other Payer APMs and Other Payer Advanced APMs.

3. Examples of the Incomplete Nature of Fraud and Abuse Waivers

Currently, in order to use the waivers from fraud and abuse laws, particularly the Stark Law, health care providers or payers must undergo the following steps: (1) choose to participate in a program where a potential waiver exists, (2) examine the requirements of the waiver established by the HHS Secretary to determine the requirements, and (3) fulfill the requirements of the waiver, sometimes without certainty that the waiver provides complete protection against potential enforcement under the Stark Law. As a result, the health care system requires providers and payers to engage in a piecemeal, patchwork approach to conforming to the requirements of the fraud and abuse laws, and prevents a centralized approach to fraud and abuse compliance. Where waivers from the fraud and abuse laws are available only in certain programs, in the absence of a mechanism to allow for application of similar waivers to multiple programs, health care providers are deterred because they do not have the time, money, or staff resources to structure arrangements to address the requirements of each and every program's waivers.

Finally, while the Stark Law is an impediment to the full success of MACRA, it is also a significant barrier to those providers who engage in innovative payment

[48] Of note, however, Congress has requested a report "with options for amending existing fraud and abuse laws in, and regulations . . . through exceptions, safe harbors, or other narrowly targeted provisions, to permit . . . arrangements between physicians and hospitals [] that improve care while reducing waste and increasing efficiency." MACRA § 512(b). I welcome the opportunity to respond and provide comment to this report whenever it is available to the public.

models outside of the MSSP ACOs, CMMI models, and APMs. These arrangements, often found in the commercial market, create the same financial relationships found in Medicare innovative payment models and therefore trigger the Stark Law's application. While some of these relationships will fit within existing Stark Law exceptions, many others do not. It is not clear how broadly HHS has exercised its waiver authority to protect these commercial arrangements, and it has failed to provide definitive guidance on the application of their waivers to these new relationships. This issue is vitally important to the success of MACRA and other CMS innovative payment models, because many of these new non-Medicare models are an "on-ramp" towards more sophisticated payment arrangements. In other words, as physicians and health care providers move towards new payment arrangements, some are not ready to move immediately into a Medicare model. Instead, they are moving at a slower pace, with the intention of moving towards these new models within the next few years. Without specific protection from the Stark Law's application to these intermediate models, these health care providers will never be able to move to more sophisticated models that are being offered by CMS. Removing the Stark Law as a barrier to these partially integrated entities will allow them to leave behind the fee-for-service payment model and begin accepting value based payment without the risk of Stark Law enforcement.

4. Recommendations for Removing Barriers to Reform

For the reasons set forth above, unfortunately, the following quote from Timothy Jost and Ezekiel Emanuel's article 2008 still applies: "[t]he current legal environment has created major barriers to delivery system innovation. Innovation will not occur if each novel way to organize and pay for care needs to be adjudicated case-by-case or is threatened with legal proceedings."[49] Thus, without Congressional intervention, the fraud and abuse laws will still prevent providers from pursuing collaborative, non-abusive relationships that would support value-based payment.

CMS's most recent attempt at such a comprehensive approach occurred 8 years ago, when it proposed a new "Exception for Incentive Payment and Shared Savings Programs" to the Stark Law in the proposed 2009 PFS Rule.[50] It was intended to permit incentive payments between physicians and entities furnishing DHS, conditioned on the fulfillment of 16 conditions. Similar to the issue raised in the prior section, this exception would protect all incentive-based payment arrangements regardless of whether they exclusively focused on Medicare patients. CMS never finalized the exception, but the enactment of ACA and MACRA has accelerated the growth of these models to a point where it is necessary to explore the possibility of a global exception once again. Rather than take the prescriptive, element-by-element approach that CMS attempted in the proposed Stark Law exception, however, I would recommend that Congress provide broad waiver authority for the HHS Secretary to use the same approach employed to establish waivers for the MSSP.

As described above in section III.A.2.a(i), CMS and OIG's joint waivers provide collective protection from enforcement under the Stark Law as well as from other selected anti-fraud and abuse statutes.[51] These waivers are generally available so long as the arrangements at issue are "reasonably related" to the MSSP. Congress should legislatively provide the framework for CMS to employ a similarly flexible approach for any arrangement that is "reasonably related" to APMs under MACRA, and make it clear that CMS can permit health care entities that operate in the commercial marketplace to enjoy waiver protection as well, as long as they are engaged in integrated delivery models paid through a value-based payment methodology. As noted above, while it is clear that CMS needs broader waiver authority for MACRA to succeed, equally as important is waiver authority or a broader statutory exception that allows for innovative payment models that operate outside of the ACA and MACRA, but still violate the Stark Law.

I recommend that in addition to modeling any new exception after the MSSP waivers, that the committee also review and use portions of the managed care safe

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[49] Timothy S. Jost and Ezekiel J. Emanuel, *Legal Reforms Necessary to Promote Delivery System Reform Innovation,* 299 JAMA 2561, 2561 (2008).

[50] CMS, "Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule," 73 Fed. Reg. 38502, 38548–38558 (July 7, 2008).

[51] CMS and OIG, "Final Waivers in Connection With the Shared Savings Program," 80 Fed. Reg. 66726 (October 29, 2015).

harbors under the Anti-Kickback Statute ("AKS") that provide fraud and abuse protection.[52]

B. Penalties for Technical Non-Compliance Far Exceed Possible Harm

The Stark Law has a strict liability penalty scheme, in which even inadvertent violations can trigger enormous repayment obligations. Compensation arrangements between a referring physician and a DHS entity are typically considered to be "substantive" Stark Law violations if the compensation (1) is not Fair Market Value ("FMV"); (2) takes into account the value or volume of referrals or other business generated; or (3) is commercially unreasonable.

In addition to these substantive rules, the Stark Law requires compliance with a number of technical, non-substantive requirements. For example, to qualify under the commonly used "fair market value compensation" exception, compensation resulting from an arrangement between an entity and a physician for the provision of items or services is excepted under the law, if the arrangement meets certain substantive requirements and is "in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing."[53] The writing must specify the timeframe of the arrangement and the compensation to be provided.[54] Under Stark Law's strict liability scheme, any missing element—such as a signature by one of the parties to the agreement—pulls the entire arrangement out of compliance. The compensation could be set at fair market value, not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician, and be commercially reasonable—yet still violate Stark Law due to a technical error.

Under the Stark Law, all Medicare payments for DHS furnished pursuant to a prohibited referral are disallowed.[55] In the above example, failure to include a required signature could result in the disallowance of Medicare payments for DHS, requiring a hospital to repay tens of millions of dollars, depending on the size of the hospital and the length of the unsigned agreement—an enormously disproportionate penalty given the triviality of the violation and lack of resulting harm to patients or to the Medicare program.

There is a general consensus in the industry and among regulators that the unintentional failures to satisfy such documentation requirements are "technical" and do not impact the proclivity of providers to make referrals. Compliance with the law's technical requirements does not reduce the overutilization of medical items and services. Likewise, failure to comply with the technical requirements does not increase the overutilization of medical items and services.

The technical requirements were designed as a means for parties to evidence adherence to the substantive requirements of the Stark Law. For example, signatures provide proof that two parties mutually entered an agreement—a premise necessary to establish that an arrangement is commercially reasonable, set at fair market value, and does not take into account the volume or value of referrals. However, a signature is only *one* means to evidence mutual assent. The rendering of services, invoices, and a payment trail are other means by which by both mutual assent and compliance with the substantive requirements can be shown.

Recognizing some of the challenges posed by the technical requirements, CMS recently clarified aspects of the technical elements (*e.g.,* allowable duration of noncompliance with the "signature requirement").[56] While the clarification provided by CMS relaxes the technical requirements to a degree, it does not provide reprieve from the severe penalties for technical noncompliance. Further, because these technical requirements are based in statute, CMS does not have the authority to revise or remove these requirements. Congress must do so. The technical requirements under Stark Law are unnecessary and result in both high compliance costs and excessive penalties for hospitals and providers. Congress could eliminate these technical requirements with no harm to patients or to Medicare.

If Congress chooses not to eliminate the technical requirements under Stark Law, I recommend removing compliance with technical requirements as a condition of

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[52] *See* section 1128B(b) of the Social Security Act and 42 CFR § 1001.952(t) and (u).
[53] 42 CFR 411.357(l)(1).
[54] *Id.*
[55] 42 CFR 411.353(c).
[56] CMS, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016," 80 Fed. Reg. 70885, 71300–71341 (November 16, 2015).

Medicare payment and granting authority to CMS to impose a simple monetary penalty per arrangement. Currently, CMS has the authority to reduce the amount due and owing under the Stark Law through its Medicare self-referral disclosure protocol ("SRDP"), a process by which health care entities can voluntarily disclose actual or potential violations of the Stark Law. Yet, CMS does not have clear congressional authority to settle such cases on a per-penalty basis. As part of the disclosure, entities must provide copious amounts of referral data to CMS—which is often extremely time and resource intensive for both the health care entity in its data collection efforts and for CMS in its review and assessment of the data to determine the overpayment amount. Providing specific legislative direction to settle these technical non-compliance matters on a per-penalty basis would remove any doubt as to the limited importance of technical violations and would provide for greater efficiency in administration of the Stark Law.

C. The Stark Law's Complexity and Lack of Clarity Raises Costs and Yields Inconsistent Application in the Health Care Industry

The Stark Law was intended to provide a bright line test limiting physician self-referral. As applied, the Law's structure, breadth, and complexity have yielded few bright lines, in part, due to unclear and ambiguous critical terms: "fair market value," "taking into account the volume or value of referrals," and "commercial reasonableness." For example, despite the general lack of case law interpreting the Stark Law, the determination of fair market value has reached judicial review several times.[57] As a result, the health care industry incurs significant costs for legal interpretation from counsel, which, in turn, yields a myriad of differing and sometimes conflicting opinions. Thus, depending on the interpretation adhered to by an entity, an arrangement deemed non-compliant by one institution may be deemed compliant by another.

To achieve greater clarity and certainty, I recommend the following changes to the statute: (1) modify the definitions of the terms identified pursuant to the criteria below, and (2) expand CMS's authority to issue advisory opinions and regulatory exceptions.

1. Define Critical Terms in an Objectively Verifiable Manner

Fair Market Value.[58] Determining what constitutes fair market value is not clear under existing CMS guidance. Further, recent case law has conflated and combined the definition of fair market value and the volume or value standard. To remedy this confusion, I recommend that Congress set forth a clear statutory standard. At the very least, I recommend the establishment of a "safe harbor" for compensation to a physician from a DHS entity that is at or anywhere below the 75th percentile for national compensation for physicians in the same specialty in any national survey designated by the Secretary. The 75th percentile is considered fair market value according to the valuation expert relied on by the government in several recently litigated cases. This "safe harbor" approach builds on a proposal by CMS raised in the Stark II rulemaking that was not adopted. This safe harbor approach should be revisited. While it would not address all physician arrangements, it would provide certainty on the FMV standard in the vast majority of them.

Taking Into Account Volume or Value of Referrals.[59] Under current law, there is confusion over whether the "takes into account the volume or value of referrals" is an objective standard (*i.e.,* did the compensation actually vary based on referrals) or a subjective standard (*i.e.,* did the entity think about potential referrals even if it did not set the compensation using them). I recommend a "safe harbor" for all compensation arrangements that are initially established at a fair market value rate and do not change or vary during the term of the arrangement based on the

[57] *See United States ex rel. Kosenske v. Carlisle HMA Inc.,* 554 F.3d 88 (3d Cir. 2009); *United States ex rel. Goodstein v. McLaren Reg'l Med. Ctr.,* 202 F. Supp. 2d 671 (E.D. MI. 2002); *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.,* 752 F. Supp. 2d 602 (W.D. PA., 2010).

[58] 42 CFR § 411.351.

[59] This phrase is used in fair market value definition cited above, as well as the definitions of "remuneration" and the special rules on compensation relationships defined at 42 CFR § 411.354(d), and the regulatory exceptions at 42 CFR § 411.355(e) (academic medical centers), 42 CFR § 411.357(a) (rental of office space), (b) (rental of equipment), (c) (bona fide employment), (d) (personal service arrangements), (e) (physician recruitment), (f) (isolated transactions), (g) (certain arrangements with hospitals), (h) (group practice arrangements), (j) (charitable donations by a physician), (l) (fair market value compensation), (m) (medical staff incidental benefits), (p) (indirect compensation arrangements), (r) (obstetrical malpractice arrangements), (s) (professional courtesy), (t) (retention payments in underserved areas), (v) (electronic prescribing items and services), (w) (electronic health records items and services), (x) (assistance to compensate a nonphysician practitioner), and (y) (timeshare arrangements).

value or volume of referrals (or other business generated where applicable). This is similar to the approach taken by CMS with respect to only certain per unit of service payments. Because the Stark Law is a strict liability statute, examining a party's intent or frame of mind should be irrelevant. Instead, only an objective, verifiable standard should be applied.

Commercial Reasonableness.[60] While a number of important exceptions have a requirement that the arrangement be commercially reasonable without taking into account Medicare referrals, the term "commercial reasonableness" is not clearly defined anywhere. Under current law, there is confusion over whether a hospital's subsidy of a physician's practice is commercially reasonable even where the physician's compensation is in the range of FMV. I recommend either that this standard be removed completely or that the statute be amended to add a definition of commercial reasonableness *e.g.,* that the items or services are of the kind and type of items or services purchased or contracted for by similarly situated entities and are used in the purchaser's business, regardless of whether the purchased items or services are profitable on a standalone basis.

2. Expand CMS's Advisory Opinion Authority

While the Stark Law authorizes CMS to issue advisory opinions to the industry,[61] CMS's advisory opinion regulations are unduly restrictive.[62] CMS modeled its advisory opinion regulations on the OIG's advisory opinion regulations for the Federal health care programs' AKS.[63] For example, CMS regulations prohibit CMS from issuing advisory opinions to a party if the same or similar arrangement is under investigation by another government agency, and prohibit advisory opinions on hypothetical arrangements. While these restrictions may be appropriate for advisory opinions addressing a criminal statute, they are inappropriate where the regulated community needs to know how to comply as a condition of payment. The Stark Law is a strict liability statute where the regulations are complex, technical, and ambiguous in crucial areas. The regulated community is entitled to clear, timely guidance on how to structure such arrangements in order to qualify for Medicare reimbursement.

I recommend that CMS advisory opinion authority be modified to expressly (a) permit CMS to advise on existing, proposed, or hypothetical compensation or ownership arrangements; and (b) prohibit the agency from declining to issue an opinion on the grounds that a similar arrangement between other parties is under investigation or the subject of a proceeding involving another government agency.

3. Relax the Standard for CMS to Promulgate New Regulatory Exceptions

The Secretary may only create additional exceptions where she determines an arrangement "does not pose a risk of program or patient abuse."[64] CMS has interpreted this language to constrain its ability to create exceptions if there is any theoretical risk, however small. This stance is significantly more restrictive than the Secretary's ability to create safe harbors to the AKS.[65]

The constraint prevents CMS from creating exceptions for arrangements that pose small or minimal risks. For example, it significantly affected efforts by CMS to create a value-based or innovative payment exception. It also requires CMS to impose more safeguards than necessary, which limits the usefulness of the exceptions it does create. For example, each of the Stark Law's regulatory exceptions included a requirement that the arrangement not violate the AKS. Since compliance with the AKS depends on intent and requires a case-by-case investigation, compliance with the Stark exception will also require an investigation into intent and the specific facts. Such limitations are unworkable and unnecessary for a payment regulation.

I recommend that the statute be modified, at a minimum, to allow CMS to create new exceptions to the self-referral prohibition so long as the Secretary determines the exception does not pose a significant risk of program or patient abuse.

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[60] This term is used in the exceptions at 42 CFR § 411.357(a) (rental of office space), (b) (rental of equipment), (c) (bona fide employment), (e) (physician recruitment), (f) (isolated transactions), (l) (fair market value compensation), (n) (risk-sharing arrangements), and (y) (timeshare arrangements).

[61] Section 1877(g)(6) of the Social Security Act.

[62] 42 CFR §§ 411.370–411.389.

[63] 42 CFR part 1008; *see also* OIG, "Advisory Opinions," *https://oig.hhs.gov/compliance/advisory-opinions/index.asp* (last visited July 10, 2016).

[64] Section 1877(b)(4) of the Social Security Act.

[65] Section 1128D(a)(2) of the Social Security Act.

D. Abuse of the In-Office Ancillary Exception is Contrary to the Stark Law's Intent

Since its enactment in 1989, the Stark Law has provided a statutory exception for "in-office ancillary services" ("IOAS"),[66] supplemented by requirements in subsequent regulations.[67] Despite its early adoption and incorporation into the law's regulatory framework, many stakeholders have singled out the IOAS exception as one of the most abused in the law, because it ultimately promotes the very conduct that the Stark Law was intended to prevent—overutilization of services and unnecessary self-referrals of health care services.

1. Background of the IOAS

The IOAS exception was adopted under the guise of promoting patient convenience by allowing physicians to self-refer patients for services that could be provided by other practitioners in the same group practice. The original intent was to allow for limited diagnostic testing such as lab services and x-rays to assist in determining the proper course of treatment.

But over the years, it has become clear that the IOAS exception is being used and abused well beyond its original intent. For example, as evidenced by GAO reports, the use of the IOAS exception has increased dramatically with specific service lines, including radiation therapy, advanced imaging, anatomic pathology services, and physical and occupational therapy. Specifically, "[p]hysician self-referral of ancillary services leads to higher volume when combined with fee-for-service payment systems, which reward higher volume, and the mispricing of individual services, which makes some services more profitable than others."[68] A GAO report determined that "[s]elf-referring providers in 2010 generally referred more anatomic pathology services on average than those providers who did not self-refer these services, even after accounting for differences in specialty, number of Medicare FFS beneficiaries seen, patient characteristics, or geography."[69] In addition, a 2013 GAO report focusing on a high-cost prostate cancer radiation therapy found that "[s]elf-referring providers referred approximately 52 percent of their patients who were newly diagnosed with prostate cancer in 2009" for that therapy, in contrast with the 34 percent of patients referred for the same procedure by non self-referring providers.[70] The self-referring providers were also less likely to refer patients for other, potentially less costly treatments.[71]

2. Remedying the Incompatibility of IOAS With Health Reform

As stated by the Medicare Payment Advisory Commission, "under an alternative payment structure in which providers are rewarded for constraining volume growth while improving the quality of care, the volume-increasing effects of self-referral would be mitigated."[72] Yet, until we move to a fully integrated payment system, the incentives to abuse the IOAS exception remains. Further, because of the significant financial incentives that the IOAS exception affords, providers engaged in in-office referrals have less incentive to shift to innovative payment models. While some providers have argued that the IOAS exception is a type of integrated delivery, referring from one service line to a second service line is not integrated care as the concept is defined under the ACA and MACRA.

Because of the statutory structure of the exception, CMS cannot reform the IOAS exception by regulation to solve this problem. Instead, Congress must provide additional authority. Thus, in order to promote and support the goals of health care reform, I recommend limiting certain service lines from the IOAS exception's protection that have a history of abuse. Yet, in order to further the goals of health reform, I also recommend allowing the IOAS to continue to apply to those group practices that are participating in APMs under MACRA and other value-based payment systems. By doing so, Congress would stop the increasing rate of unnecessary utilization due to IOAS and promote value-focused arrangements among providers that further the goals of higher quality health care at lower cost and better patient outcomes.

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[66] Section 1877(b)(2) of the Social Security Act.

[67] 42 CFR § 411.355(b).

[68] Medicare Payment Advisory Commission ("MedPAC"), "Report to the Congress: Medicare and the Health Care Delivery System," 27 (June 2011) (hereafter, "MedPAC Report").

[69] GAO, GAO–13–445 "Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer" (June 24, 2013).

[70] GAO, GAO–13–525 "Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny" (July 19, 2013).

[71] *Id.*

[72] MedPAC Report at 27.

IV. CONCLUSION

The Stark Law issues I have outlined above are not exhaustive but are issues for which I believe there is the most pressing need to address. Once these concerns are addressed, Medicare patients and the Medicare program will be better off than under the current system.

Thank you again for this opportunity to testify on the Stark Law and recommended reforms. I am happy to answer any questions that the committee has.

PREPARED STATEMENT OF HON. ORRIN G. HATCH,
A U.S. SENATOR FROM UTAH

WASHINGTON—Senate Finance Committee Chairman Orrin Hatch (R–Utah) today delivered the following opening statement at a hearing to examine ways to improve and reform the Stark Law:

As members of the Senate Finance Committee, we have a wide range of duties.

In addition to drafting laws and overseeing their enforcement and implementation, we are also called to assess the impact of existing laws to determine their effectiveness at achieving their intended goals.

When it comes to that last part, there is a quote from a well-known American business leader that applies: "Good intentions often get muddled with very complex execution."

Today we are here to talk about the Stark Law, an important yet extremely complicated, health care fraud law that prohibits physician referrals under certain circumstances. This law is the embodiment of good intentions muddled with complex execution.

At its most basic level, the Stark Law prohibits doctors from referring Medicare patients to hospitals, labs and other physicians for healthcare services if the referring doctor has any direct or indirect financial relationship with that entity. The sweeping nature of that prohibition makes vast swaths of medicine performed in the current healthcare system potentially illegal.

Anyone caught violating the law must give back all the Medicare reimbursements paid to the doctor, hospital, or lab under the tainted arrangement, even if the violations were unintentional, because the Stark Law is a strict liability statute that is indifferent to motive, knowledge, or state of mind.

When the Stark Law passed in 1989, lawmakers believed that, given a bright line rule, providers would self-police their arrangements with physicians. Despite this original intent, the Stark Law has become increasingly complex and created more and more challenges for legitimate health care arrangements.

Today, the healthcare world is populated by scores of legal experts who strive to keep up with the sprawling compendium of statutes, regulations, and legal advisories known collectively as the Stark Law.

The Federal Register contains hundreds, if not thousands, of pages of regulatory text drafted by the Department of Health and Human Services to improve compliance with and implementation of the Stark Law.

Through these regulations, HHS has come up with more than 30 exceptions to the law, each of which carries its own detailed requirements.

Even the original sponsor and namesake of the legislation, Representative Fortney "Pete" Stark, recently lamented the Byzantine turn that the statute has taken, stating: "It gave every shyster and promoter a loophole. . . . We now have to keep rewriting the laws like the tax code."

Because it regulates physicians' financial relationships, the Stark Law has a significant impact on the structure and operation of the healthcare delivery system. Therefore, as we've collectively worked to transition our Federal health programs toward more value-based payment systems and away from fee-for-service models, one question keeps coming up: In its current form, is the Stark Law still necessary?

Last December, in an effort to answer this question and address long-standing concerns about the Stark Law, the Finance and Ways and Means Committees convened a roundtable discussion with stakeholders and legal experts to discuss these issues. All three of the witnesses here today were part of that discussion.

We received feedback on a number of issues related to the Stark Law, including: the barriers it places on the implementation of health reform laws; stakeholders frustrations with the difficulty and expense associated with compliance; and the problems created by the Center for Medicare and Medicaid Services' limited authority to create exceptions and to issue advisory opinions.

Following the roundtable, we issued a broader call for comments industry leaders and received almost 50 responses suggesting a variety of changes, including: additional or expanded waivers or exceptions; enhanced authority for CMS to address specific needs on an ongoing basis; and repeal of the compensation arrangement prohibition. In addition, some suggested that we repeal the law in its entirety.

Commenters across the board expressed concern about the ambiguous way certain terms are defined under the Stark Law. Terms like "fair market value," "volume and value of referrals," and "commercial reasonableness" all have a decisive impact on the application of the law, yet they are not clearly defined. And, finally, virtually everyone we heard from believed that technical violations (of form rather than substance) of the law should be subject to separate sanctions and limited liability.

If the aim of the Stark Law is to prevent physicians from inappropriately referring patients for medically unnecessary treatments, it does so in a rather roundabout way, at least under the current structure.

If we really want to prevent inappropriate self-referrals and address the culture of overutilization, we have to do more than target specific relationships and practices prone to abuse. We must also realign the financial incentives created by our current payment mechanisms.

If, as some have claimed, the Stark Law is impeding the implementation of recently passed health reforms like the Medicare Access and CHIP Reauthorization Act and preventing better integration in the delivery of medical treatment, we should address that as well.

As a committee, we have a responsibility to explore potential changes to make the law more workable in terms of enforcement and compliance in both fee-for-service and value-based payment models, as both are likely to be around for years to come

We're here today to examine these issues and, hopefully, hear some potential answers to the questions that have come up. I look forward to hearing the testimony of our witnesses and getting their input on all of these important issues.

PREPARED STATEMENT OF PETER B. MANCINO, DEPUTY GENERAL COUNSEL, THE JOHNS HOPKINS HEALTH SYSTEM CORPORATION

Chairman Hatch and members of the Senate Committee on Finance, thank you for the opportunity to submit testimony on the timely and important subject of the "Stark Law."[1]

The Johns Hopkins Health System Corporation is a non-profit organization affiliated with The Johns Hopkins University School of Medicine. We serve as the parent to three academic medical centers, three community hospitals, and several physician groups. On the payor side, our health system includes a Medicaid managed care plan, a Medicare managed care plan, and other related businesses.

Since we are active on both the payor and provider sides and on both the academic medical center and community hospital sides, our health system has a unique perspective on the Stark Law. We view the Stark Law as the top compliance risk of our health system, because it is very easy to inadvertently violate Stark and the penalties are substantial. As a result, we have a keen interest in promoting common-sense revisions that will make Stark more understandable and less burdensome to providers.

We estimate that our health system currently spends over $600,000 per year just on Stark compliance. Our compliance program includes regular Stark audits, training programs, and various contract and other tracking programs. Our compliance office includes a full-time Stark attorney, and we routinely seek outside counsel and consultant assistance with difficult Stark issues and fair market value reviews. We believe that an updated Stark Law could foster the Triple Aim while reducing the costs of compliance.

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[1] Section 1877 of the Social Security Act, 42 U.S.C. § 1395nn.

To be clear, we have no interest in facilitating overutilization of health care services or promoting health care fraud. Our health plan experience has demonstrated to us the importance of supporting the Triple Aim and high quality, cost-effective health care. However, our provider experience also has shown us how difficult and unfair the Stark Law can be.

This testimony will focus on three dimensions in particular that would greatly improve the Stark Law and allow health care providers to partner with physicians to improve quality and reduce costs.

1. ELIMINATE THE AMBIGUITY OF KEY STARK TERMS

When the Stark Law was originally enacted by Congress,[2] the goal was to create a bright line test to address the overutilization of health care services resulting from inappropriate physician referrals. The problem is that this bright line test has been transformed over time into a complex and highly technical rule that includes over three dozen statutory and regulatory exceptions. Each exception contains a number of technical requirements, many of which are ambiguous and counterintuitive. In some cases, the exceptions have been redefined and reinterpreted on multiple occasions by the Centers for Medicare and Medicaid Services ("CMS"), and the advisory opinion process and recent judicial decisions have not provided needed clarity. Further, recent CMS Stark regulations, while helpful, have not addressed the core issues. As a result, considerable confusion remains in the provider community about Stark requirements.

Most notably, the terms "commercial reasonableness," "fair market value," and "varies with or takes into account " the "volume or value" of referrals each lack the clear definition necessary for providers to be certain of compliance despite their best efforts. As a health law attorney for 20 years, I have been confronted with numerous physician recruitments and other transactions that raise questions about the meaning of these terms, and no matter how much time, money or effort is expended in analyzing the issues, I have often had the unpleasant duty of informing a client that there are no clear or 100% safe answers. Given that Stark was intended to be an easy bright line test, we believe that the Stark Law should be amended to clarify key terms. Further, there should be a workable process for hospitals and other health care providers to obtain clear and timely compliance guidance.

2. MAKE STARK PENALTIES MORE REASONABLE

The Stark Law's complexity and ambiguity has made it extremely difficult for even diligent health care providers with robust compliance programs to comply with Stark. Failure to satisfy even one of its technical requirements can result in a violation, and despite the best compliance efforts, unintentional mistakes occur.

Liability under the Stark Law can be staggering even for minor violations. For example, a provider may be required to refund any Medicare reimbursement received from impermissible physician referrals even when the violation concerns a low value contract, and additional penalties or treble damages may be assessed. The potential liability associated with an alleged Stark violation creates an enormous barrier to a provider's ability to defend against a claim, even when a provider has valid defenses. When faced with potential Stark liability, providers are often forced to settle. A Federal appellate court judge recently highlighted this troubling result in a concurring opinion to a decision upholding a $237 million dollar judgment against Tuomey Healthcare System, stating, "even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act."[3]

Most health care providers want to be compliant and are willing to be accountable for mistakes. However, accountability should not entail ruinous penalties. Recent judicial decisions like the Tuomey case have had a chilling effect on the health care industry causing clients to be reluctant to try creative arrangements (*e.g.,* gainsharing, physician alignment strategies for population health, etc.) at a time when

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[2] Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989)—Pub. L. 101–239, December 19, 1989—adding section 1877 to the Social Security Act prohibiting physician referrals for clinical laboratory services. This provision, known as Stark I, became effective January 1992. Section 13562 of Omnibus Budget Reconciliation Act of 1993—Pub. L. 103–66, August 10, 1993—expanded the prohibition to ten designated health services (DHS) in addition to clinical laboratory services. This provision, known as Stark II, became effective January 1995.

[3] *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.,* No. 13–2219, 2015 U.S. App. LEXIS 11460 at *56, *69 (4th Cir. July 2, 2015) (Wynn, J., concurring).

innovation is most needed. Accordingly, the Stark Law should be amended to make the potential penalties associated with Stark violations more reasonable.

3. REFORM THE STARK LAW TO PERMIT INNOVATIVE PAYMENT METHODOLOGIES

The Stark Law imposes substantial limits on a hospital's ability to participate in innovative payment arrangements with physicians. For example, gainsharing and value-based payment arrangements are often problematic under Stark, because they are not susceptible to fair market value assessment and may take into account the volume or value of physician services. However, these types of arrangements promote care coordination, enhance quality, improve patient care experience and control costs. Given the changing face of medicine, including the recent enactment of MACRA,[4] innovative payment arrangements are needed.

Therefore, we support reforming Stark to allow hospitals to make incentive payments to physicians based on the physicians' achievement of quality metrics and cost-reduction targets. This change would be consistent with MACRA and the Triple Aim and would give hospitals an important tool in their efforts to enhance quality and reduce health care costs. We also support providing the health care community the ability to create other value-based payment arrangements that meet the same goals.

CONCLUSION

Now is the time for Congress to modernize the Stark Law to promote fairness and further the goals of MACRA and the Triple Aim. MACRA requires providers to innovate, but we need the tools and the freedom to do so. We urge Congress to act quickly to address our concerns so that the health care industry can transform itself to meet today's challenges.

Thank you for your consideration of this important topic.

PREPARED STATEMENT OF RONALD A. PAULUS, M.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, MISSION HEALTH SYSTEM

Mr. Chairman, Ranking Member Wyden, and members of the committee, thank you very much for the opportunity to testify about essential reforms to the Physician Self-Referral Law ("Stark Law" or "Stark"). I am the Chief Executive Officer of Mission Health System ("Mission Health"), the largest health care system in western North Carolina and the region's only safety net health system. We care for nearly 900,000 people across our State's 18 most western counties. Our patients are older, poorer, sicker and less likely to be insured than State and national averages. More than 75% of our care is provided to Medicare or Medicaid beneficiaries or to the uninsured; 10% of our babies are born addicted to narcotics.

Even in the face of these significant demographic challenges, Mission Health has received numerous national awards, had the Nation's lowest Medicare readmission rate for any general acute care hospital and has been named a *Top 15 Health System* for 4 consecutive years,[1] the only health system in the Nation to ever achieve this recognition.

As a senior executive at Geisinger Health System, I saw first-hand the impact that a value-based system can have on its patients and region before coming to Mission in 2010. Upon my arrival, I began to lead a transformation to create a value-based health system including: establishing a culture of physician and clinician leadership, creating a Medicare Shared Savings Program Accountable Care Organization ("MSSP ACO")—now the largest in North Carolina and one of the largest in the Nation—and joining the joint replacement bundled payment program. More broadly, Mission Health is proactively funding quality performance incentives for our ACO and employed physicians and we are implementing nearly 100 care process models that rely upon evidence-based care, consumer engagement and activation and which incorporate numerous virtual care technologies. Presently, we are evaluating which of the alternative payment models ("APMs") in the Medicare and CHIP Re-Authorization Act ("MACRA") we will adopt as a system.

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[4] Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. No. 114–10 (2015).

[1] Thomson Reuters in 2012; successor firm Truven Health Analytics (*http://truvenhealth.com/*) in 2013–2015.

We are actively trying to push our market to a value-based payment framework because it offers great promise for patient care and our local employers while also providing needed financial stability for Mission Health and the U.S. health care system. However, our crucial responsibility as the region's only safety net health system demands that we avoid unnecessary risks. Some of the most significant risks we face originate from the unclear legal boundaries in our fraud and abuse laws. In the current environment, health systems cannot responsibly make the long term human and capital commitments necessary to truly align incentives for the system and physicians to truly transform care.

As a physician executive and someone who has both contributed to and extensively read the literature on healthcare performance and innovation, I am convinced that it is simply not possible to transform healthcare without a strong, aligned, shared partnership between health systems and physicians. Physician decisions drive the overwhelming majority of all healthcare spending and of course, patient outcomes. The Stark Law creates a choking fog of uncertainty and not uncommonly creates truly absurd outcomes that directly cause patient harm. It also fails to add any important protections for the Medicare and Medicaid programs beyond those already in place under the Anti-Kickback Statute (perhaps with the exception of ownership restrictions, which are admittedly important).

Mission Health submitted comments on Stark Law reform to this committee in January 2016. Our comments focused on the need for new exceptions to: (1) remove obstacles to APMs; and (2) facilitate "gainsharing" between physicians and hospitals. The recently released Senate Finance Committee Majority Staff Report[2] ("Report") is an excellent summary of the submitted comments and it includes these ideas and many more. The weight of those comments makes it clear that Stark has largely outlived its usefulness and has multiple problems that make it unlikely to be "fixed" with simple tinkering around the edges. Rather than rehash our earlier comments or focus on the tremendous cost burden that technical compliance induces, I will use my time today to build upon the Report's indictment of Stark and explain how a total Stark repeal would not only help health systems do what we need to do, but precisely what you've asked us to do: *focus on what's best for patients and transform our outdated fee-for-service system to a value-based care system.*

To explain how the repeal of Stark is critical to enable payment reform, I will describe a typical issue for Mission Health as we implement our pay for performance programs. Stark regulations prohibit linking payments to the "volume or value of referrals"[3] while the Anti-Kickback Statute does not contain this requirement.[4] Under Stark, any incentive program must be structured to distribute payments to *all* participating physicians regardless of a particular physician's level of effort. The result is that underperforming physicians have no financial incentive to change their practices.[5] If the government relied only on the Anti-Kickback Statute, with its focus on illegal intent to induce referrals, we could target incentives to the physicians who actually achieve congressional, CMS and patients' quality goals, thus improving the impact and cost-effectiveness of those incentives. Let me ask you this: if you wanted to achieve a particular goal, would you reward everyone equally no matter what their performance, or would you reward those who actually achieved the desired goal?

Let me make this point real and tangible. Our system and many others use the Centers for Medicare and Medicaid Services ("CMS") data on various patient care issues to develop quality measures. One of CMS's quality indicators and a focus for Mission Health is to decrease (and ultimately eliminate) hospital-acquired infections. Under the current Stark regime, Mission's ACO could include that measure in a quality incentive program since Stark does not apply to the ACO and there are Anti-Kickback Statute waivers available.

However, in our many other contractual relationships with physicians outside of the ACO, the Stark Law significantly and deleteriously constrains what we can do. We can only offer incentives to employed physicians but not to the independent physicians who comprise the majority of practice at our hospitals. Furthermore, we

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[2] Senate Finance Committee Majority Staff Report, "Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models" (July 7, 2016).

[3] *See,* for example, the exception for rental of office space at fair market value found at 42 U.S.C. section 1395nn(e)(1)(A)(ii)(2006).

[4] While the statute itself does not contain this provision, some safe harbors do. *See* 42 CFR §§ 1001.952(b)–(d).

[5] U.S. Government Accountability Office, GAO 12–355, "Medicare: Implementation of Financial Incentive Programs Under Federal Fraud and Abuse Laws," at 21 (2012).

have to reward all physicians equally if we achieve our infection-reduction goal rather than rewarding those physicians who specifically achieved their goal. In fact, we would have to reward a physician who had a dramatic increase in his or her infection rate exactly the same as a physician who eliminated all infections. That literally makes no sense and in any other industry, would be laughable. In most industries, shareholders and watchdogs are demanding outcome-based pay for performance linkages; in healthcare, Stark specifically prohibits us from using them.

These limitations result from Stark requirements that any payments to physicians be at "fair market value" and unrelated to the volume or value of referrals made by the physician to the hospital.[6] These terms are not clearly defined in the regulations and are "fact specific," meaning that we can never be sure in advance that any quality incentive program will pass muster if scrutinized. The risk of our guessing wrong is that *all* hospital reimbursement attributable to referrals from those non-employed physicians is subject to repayment, a catastrophic penalty.

Aside from the many ways the Stark Law affects Mission Health's ability to fully implement pay for performance programs, the law also impacts our day to day patient care in very significant and let me emphasize, negative ways. A real example will illustrate one way that Stark prevents us from providing the kind of care our patients deserve. For a number of years, a geneticist with Mission Health has met with expectant mothers who have just learned that the child they are carrying will die shortly after birth. The geneticist helps the mothers and fathers understand their child's fatal condition and what to expect during the delivery. The geneticists strongly desire to have this conversation with the parents at the obstetrician's office so they could share this devastating information in a comfortable, familiar environment that is calm and supportive. They would not charge the patient or the physician's practice. However, when this compassionate suggestion was brought to the attention of Mission Health's attorneys, they immediately became concerned that the service could be seen as providing "something of financial value" to the obstetrician's practice. Since there is no Stark exception to cover this circumstance, they rejected the suggestion of having the conversation in the obstetrician's office at no charge, despite the fact that the geneticists' motivation was solely to help these women—often indigent—at an extraordinarily difficult time in their lives. If we had only been subject to the Anti-Kickback Statute, this service could be provided as the intent behind the program is clearly not abusive. Unfortunately, since Stark is a strict liability statute, we could not take that risk. In a very similar situation, a Mission employed neonatologist focused on palliative care desired to offer similar, free services to support babies born with very significant life challenges. Again, we had to decline. These are just two examples of incredibly harmful impacts on patient care, dignity and support. I assure you Mission and other health systems could provide hundreds of similar patient-centered initiatives that are deemed problematic under Stark.

Although I desperately hope for the contrary, I do recognize that Congress may not be ready to take the step of repealing the Stark Law, so I will spend a few moments explaining how some of the less comprehensive reforms described in the report could help health care providers move to value based care. If you are unwilling to eliminate Stark entirely, I urge you to consider the many possible revisions to Stark described in the Majority Staff Report. In particular, I believe that a waiver program similar to the MSSP ACO waiver program or an exception for APMs would be valuable. ACOs are able to avoid many of the problems I described because they can apply for certain fraud and abuse waivers. Allowing entities other than ACOs to invoke waivers if they are using APMs would provide at least some relief from the unnecessary burden of Stark.

The rationale for the current ACO waivers is that the many statutory requirements to become an ACO and the public scrutiny involved in posting the waivers on an ACO's website assure that the ACO is focused on meeting Medicare's patient care and financial goals. A similar waiver program for Stark would give a health care system that wanted to create a quality incentive important flexibility. Any system would have to fully describe its program to CMS and on the organization's website, thus protecting the Medicare and Medicaid programs from abuse, while allowing it to reward physicians who actually meet the measures. One of the comments described in the Report offers an interesting twist on applying a waiver regime to APMs; it suggests creating an exception that would use the kinds of conditions present in the ACO waivers.[7] Either a waiver approach or an exception using

[6] 42 U.S.C. section 1395nn(e)(2)(B)(ii) (2006).
[7] Report at 10.

similar requirements would give health care providers a much clearer path toward APMs than exists today.

Some have argued that CMS can make any necessary Stark reforms without action by Congress. Indeed, in the most recent round of Stark regulations released October 30, 2015, CMS made a number of changes to address the issue of unintentional lapses in contracts.[8] These new regulations have helped to prevent many self-disclosures of harmless failures to comply with the absurdly strict language of Stark. As a side note, we had several very small facilities that we acquired self-disclose such minor findings after our acquisition due diligence. They spent nearly 2 years pending review and paid significant (though markedly reduced) penalties for relationships where both the payment for services and physician work performed continued. No harm, no foul, just a technical error and a large penalty payment.

But CMS simply does not have the legislative authority to go much further in addressing problems. In 2012, the Government Accountability Office ("GAO") issued a report on the changes needed in fraud and abuse laws to facilitate health care reform.[9] While the report is now 4 years old, sadly, its major points have yet to be addressed. That report stated that:

> CMS has acknowledged that existing Stark Law exceptions may not be sufficiently flexible to encourage a wider array of non-abusive and beneficial incentive programs that both promote quality and achieve cost savings. CMS can create additional exceptions as long as the exception does not pose a risk of program or patient abuse. According to CMS officials, this "no risk" requirement is high and limits their ability to create new regulatory exceptions to the Stark Law. In 2008 CMS attempted to use its authority to propose a new exception covering financial incentive programs. However, the "no risk" requirement necessitated a narrow exception with many structural safeguards in light of the risk that financial incentive programs could be used to disguise payments for referrals or adversely affect patient care. In its proposed rule, CMS noted that the design of the proposed exception created a challenge in providing broad flexibility for innovative, effective programs while at the same time protecting the Medicare program and patients from abuses. The agency solicited comments, and many of the comments it received criticized the number and complexity of safeguards needed to achieve the "no risk" standard. To date, the agency has taken no further action to finalize this regulatory exception, and CMS officials told us the agency has no plans to do so in the near future.[10]

CMS cannot solve the fundamental problems in the Stark Law: it is very complex and requires no intent whatsoever to violate the law. It sets up barriers to the necessary alignment between hospitals and physicians that is absolutely essential to transform our delivery system. Because of the extraordinary penalties involved, it often "freezes" health systems in place and absolutely impairs patient care, performance improvement and the shift to value-based payment. The stakes are simply too high and the need for healthcare reform too great—for our patients, our businesses and our Nation. Only Congress can remove those barriers. Thank you for being willing to take on this very important issue. It's been an honor and privilege to share these thoughts with you, and I truly appreciate your interest in this very important topic. With you leadership, we can make the changes necessary to remedy these problems and succeed in our transition to a high quality, efficient and effect value based health care system. If I can answer any questions or provide any additional information on this topic, I would be delighted to be of help.

PREPARED STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON

The U.S., over the last few years, has seen the beginning of a major transformation in the way medical care is paid for. This country is moving away from an old system—fee for service—which opened the till for every visit, every test, and every procedure in a doctor's office or hospital. Today the focus is on paying for the quality of care rather than the quantity—and getting more bang for the buck. Even though this sea change is in its early stages, already 30 percent of Medicare pay-

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[8] Stark II Phase V, IPPS regulations, October 30, 2015.

[9] GAO 12–355 at 22–23.

[10] *Id.* (citing 42 U.S.C. § 1395nn(b)(4) and "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B," 73 Fed. Reg. 38502, 38604 (proposed July 7, 2008)).

ments are going through the new system focused on value and efficiency. That number is only going to rise in the years ahead.

In my view, when you make this kind of transformational change in our health care system—which makes up one out of every $6 in the American economy—you're going to run into challenges. One of those potential challenges is the subject of today's hearing.

There's a question, in my judgement, as to how you balance two important priorities. On one hand, there's a drive toward bringing doctors and specialists together, promoting coordination, and making health care more efficient whenever possible. On the other hand, there's a longstanding protection that comes from what's known as the Stark Law. It says that financial relationships between providers must not influence a patient's medical care.

Some providers are concerned that parts of the Stark Law that date back years or even decades might be an impediment to treatment. For example, when fee-for-service was king, a jump in referrals from a doctor to a physical therapist would have raised red flags if they had financial ties. Today it's common for doctors and physical therapists to work in the same medical practice or hospital system. And the science has demonstrated that physical therapy is often the right choice to keep a lifelong golfer with a bad shoulder or an older woman with a knee replacement healthy and out of the emergency room. That means that in this day and age, an uptick in referrals for physical therapy in one medical practice shouldn't automatically be branded a violation of the Stark Law. When it comes down to it, every case is different.

In my judgement, those two important priorities—promoting coordination, and upholding the Stark Law—do not have to come into conflict. As long as there are clear guidelines around what's fair game when it comes to patient referrals and the relationships between doctors, it will be possible to guarantee that patients are getting the care that's right for them—not for somebody else's pocketbook. In certain ways, it could be as simple as revisiting the rules that are already on the books.

I'm hopeful that the committee is able to have a productive, bipartisan discussion of these issues today. I want to thank our witnesses for being here, and I look forward to hearing your testimony.

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The Advanced Medical Technology Association (AdvaMed) Supports the Transition of Health Care Delivery to Value-Based Payments and a Legal Framework That Protects Patients From Fraud and Abuse.

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide a statement for the record for the Senate Finance Committee's July 12, 2016 hearing entitled, "Examining the Stark Law: Current Issues and Opportunities." We applaud the Senate Finance Committee for addressing concerns with the federal fraud and abuse legal framework that are impeding a broader, more integrated transition to value-based health care delivery.

AdvaMed is a trade association that represents nearly 300 members, consisting of the world's leading innovators and manufacturers of medical devices, diagnostic products, and health information systems. Together, our members manufacture much of the life-enhancing health care technology purchased annually in the United States and globally. Our members are committed to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. The devices AdvaMed members make help patients stay healthier longer and recover more quickly after treatment, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

AdvaMed supports the transformation of health care to value-based delivery and payments. Medtech manufacturers are key collaborators with providers and payers to improve outcomes, enhance the patient experience, and reduce costs. Medtech companies develop and heavily invest in technologies and services that are vital to realizing quality, clinical outcomes, patient satisfaction, and cost savings goals.

We stress that AdvaMed supports a legal framework that protects patients and the federal health care reimbursement programs from fraud and abuse. Our member companies further recognize the importance of ensuring ethical interactions between medtech companies and providers so that medical decisions are centered on the best interests of the patient. That is why AdvaMed developed a Code of Ethics[1] (also known as the "AdvaMed Code") to distinguish beneficial interactions from those that may inappropriately influence medical decision-making.

The Current Fraud and Abuse Laws Contemplate a Volume-Based Payment System (Fee-for-Service) and Are Ill-Suited for Innovative Value-Based Payment Arrangements.

The existing fraud and abuse laws seek to prevent inappropriate medical decision-making and overutilization by ensuring that the financial interests of parties involved in the provision of care are not structured in a manner that creates inappropriate incentives to provide unnecessary services, leading to increased costs. Value-based payment arrangements generally lack overutilization concerns since payments are not directly tied to the volume of services provided. Instead frameworks such as risk-sharing, shared savings, and/or capitated payments are inherently designed to limit overall costs to the system with strong measurable quality goals to safeguard against underutilizing or withholding medically necessary services and lim-

[1] *Available at: http://www.advamed.org/CodeOfEthics.*

iting patient choice. Value-based arrangements align the financial interests of providers, industry, and payers to achieve clinical quality goals and manage costs. However, this alignment creates tension under the current fraud and abuse legal framework.

The federal Anti-Kickback Statute proscribes the "knowing and willful offer, payment, solicitation, or receipt of any remuneration (directly or indirectly, overtly or covertly, in cash or in kind) in return for or to induce a referral of services or goods payable by Medicare or Medicaid."[2] Congress enacted the Anti-Kickback Statute in 1972, in the context of Medicare's then-retrospective reimbursement system. In a fee-for-service environment, the Anti-Kickback Statute was intended to discourage overutilization of Medicare-reimbursed items and services by prescribers motivated by their own financial interest.[3] Congress was further concerned with: (1) possible harm to beneficiaries; (2) increased Medicare and Medicaid costs; and (3) the potential of kickbacks to freeze competing suppliers from the system, mask the possibility of government price reductions, and misdirect program funds.[4] The Anti-Kickback Statute originally prohibited only "bribes and kickbacks,"[5] but Congress extended its reach in 1977 by substituting "any remuneration" for the "bribes and kickbacks" language[6] and increasing the severity of the penalties from a misdemeanor to a felony.[7]

Congress recognized that the expansive reach of the Anti-Kickback Statute created uncertainty as to which routine commercial arrangements are permitted,[8] and it excluded certain types of payments from consideration by the statute, including discounts.[9] However, when the Office of Inspector General (OIG) promulgated final implementing regulations, the "safe harbor" for discounts/rebates was very narrowly drawn. For example, the regulation directs that supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service is not permitted unless the goods and services are reimbursed by the same federal health care program using the same methodology.[10] This has the potential to significantly restrict a value-based bundled offering of services and product if the reimbursement methodology for all discounted items or services is not the same.[11] Further, there is ambiguity around protection for discounts linked to and/or premised on the performance of personal services since the safe harbor regulation excludes from the definition of a protected discount "services provided in accordance with a personal or management services contract."[12]

The OIG adopted similarly narrow safe harbors in other areas, also intended to protect Medicare from overutilization of reimbursable items/services.[13] In promulgating the warranty safe harbor, the OIG explained:

> "It is in the public interest to have companies offer warranties as an inducement to the consumer to purchase a product." The OIG declined to protect broader warranties, including those relating to competitive warranties on other products, stating "We believe that safe harbor protection is proper

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[2] 42 U.S.C. § 1320a–7b(b); AdvaMed's commentary on the federal Anti-Kickback Statute serves to inform the discussion regarding its interplay with the Stark Law as reforms to the fraud and abuse laws are considered to advance value-based health care delivery.

[3] 59 Washington and Lee Law Review, March 1, 2002 (The Medicare Anti-Kickback Statute: In Need of Reconstructive Surgery for the Digital Age), citing Jost and Davies, "The Law of Medicare and Medicaid Fraud and Abuse" 100 (2001–02 ed. 2000) (listing concerns that "patients will suffer, program funds will be unnecessarily depleted, and taxpayer dollars will be wasted" if kickbacks are permitted).

[4] *See* 56 Fed. Reg., 35952 (July 29, 1991) (original safe harbors, citing *United States v. Ruttenberg*, 625 F.2d 173, 177, n.9 (7th Cir. 1980)).

[5] Social Security Amendments of 1972, Pub. L. No. 92–603, § 242(b), 86 Stat. 1329, 1419 (1972) (codified as amended at 42 U.S.C. § 1320a–7b (1994)).

[6] Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95–142, 91 Stat. 1175 (1977).

[7] *See* Pub. L. 95–142, 91 Stat. 1175 (1977).

[8] *See* S. Rep. 100–109, 27, 1987 U.S.C.C.A.N. 682, 707–08 ("It is the understanding of the Committee that the breadth of this statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed. The Committee bill therefore directs the Secretary, **708 in consultation with the Attorney General, to promulgate regulations specifying payment practices that will not be subject to criminal prosecution under the new section 1128B(b) and that will not provide a basis for exclusion from participation in Medicare or the State health care programs under the new section 1128(b)(7).")

[9] 42 U.S.C. § 1320a–7b(b)(3).

[10] 64 Fed. Reg. 63518, 63554 (November 19, 1999).

[11] *Id.*

[12] 42 CFR § 1001.952(h)(5)(vi).

[13] Note 3, *supra.*

> where a replacement program honors the original manufacturer's warranty and the agreement provides remuneration on the same terms as the original manufacturer's warranty without providing additional incentives or shifting additional costs to the Medicare and Medicaid programs." [14]

Under value-based payment arrangements, this restriction on competitive warranties to "terms equal to the agreement that it replaces" [15] limits collaboration options that would add value. Another constraining element of the Warranties Safe Harbor is that to qualify for safe harbor protection a "manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself." [16] This deters the formation of value-based arrangements that would include services and items among different manufacturers, as warranty remuneration between manufacturers is not protected.

The Personal Services and Management Contracts Safe Harbor includes the requirements that: (1) the agreement specifies exactly the schedule of service intervals, their precise length, and the exact charge for such intervals; [17] (2) the term of the agreement be at least one year; [18] and (3) the aggregate compensation paid over the term of the agreement be set in advance.[19] These requirements do not account for risk-sharing, cost-savings, and performance-based payment models.

AdvaMed's Priority Concerns in Advancing Value-Based Care are:

(1) The limitations in the Anti-Kickback Statute safe harbors for discounts, warranties, and personal services to provide protection for bona fide value-based arrangements among collaborating providers, payers, and medtech manufacturers;

(2) The current off-label promotion enforcement framework, which may aggressively construe the sharing of scientific and health care economic information to develop and operationalize value-based arrangements as implied off-label claims; and

(3) Ensuring that the emphasis on value-based care does not create perverse incentives for hospitals and providers that compromise patient access to necessary care.

Medtech manufacturers want to comply with the fraud and abuse laws. However, there is no direct guidance from the government regarding the application of the fraud and abuse laws to value-based collaborations between manufacturers and providers and/or payors. Currently, value-based arrangements between medtech manufacturers and providers and/or payers are structured by cobbling together constructs within the discounts, warranties, and personal services safe harbors. However, this analysis necessitates the commission of immense resources, both in terms of time and legal costs. Because of the current regulatory limitations, these costs may be expended by all stakeholders without ultimately moving forward with a value-based collaboration given the uncertainty and concern for enforcement applying historic fee for service reimbursement principles as a framework. In short, regulatory uncertainty concerning the application of the criminal Anti-Kickback Statute chills value-based/outcomes-based collaborations.

Medtech company contributions to value-based health care arrangements can range from integrating data analytics infrastructure and services (to optimize care to achieve quality goals) to services that streamline the supply chain to reduce costs. These collaborations might involve bundling services, data collection and analytics, and medtech products to deliver high quality care, improved patient satisfaction, and cost reductions. Safe harbor protection is arguably afforded only to those arrangements that meet all of the conditions set forth in the safe harbor regulations. Unfortunately, as stated above, the Safe Harbor constructs are narrowly fashioned around fee-for-service payment models and no longer match the reality of value-based health care delivery and payment models. This serves to inhibit value-based

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[14] *Id.*

[15] 42 CFR § 1001.952(g) ("the term warranty means either an agreement made in accordance with the provisions of 15 U.S.C. 2301(6), or a manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item (which is covered by an agreement made in accordance with this statutory provision), on terms equal to the agreement that it replaces.)

[16] 42 CFR § 1001.952(g)(4).

[17] 42 CFR § 1001.952(d)(3).

[18] 42 CFR § 1001.952(d)(4).

[19] 42 CFR § 1001.952(d)(5).

frameworks designed around quality care, which have the potential for greater impact. For example, the Discount Safe Harbor includes the limitation that the bundled good or service be reimbursed by the federal health care program using the same methodology and the additional limitation that for cost-reporting entities, the discount must be earned based on purchases of that same good or service within a single fiscal year.[20] The "same methodology" limitation can materially restrict the range of possible devices and services that may be integrated to deliver the best value. Uncertainty exists around what items or services would be considered to fall under the "same methodology." Finally, the single fiscal year limitation may prevent bundling items and/or services that are critical to supporting health care delivery frameworks which measure clinical outcomes and economic value over periods of time extending beyond the same fiscal year or that measure outcomes over multi-year periods that capture the long-term value of a value-based health care program, device or service. This is a major limitation of potential value-based care arrangements.

Integral to developing and executing value-based arrangements is the need for manufacturers to be able to communicate with providers, payors and other stakeholders on establishing clinical goals, efficiency measures, and economic performance terms. Starting points for these goals, measures, and terms may originate from economic and clinical data (with varying levels of support) that may not be specified in the approved or cleared label of the device. This scientific and health care economic information will be needed to both establish and optimize the clinical and economic goals of the value-based collaboration.

Medtech manufacturers support delivery reform models and their goals to achieve lower cost and higher quality health care. At the same time, we are concerned that the financial incentives inherent in the various delivery reform/alternative payment models can have the inadvertent effect of discouraging providers from (1) considering the full array of treatment options, due to concerns regarding exceeding "benchmark" threshold costs, or (2) using innovative treatments, technologies, and diagnostics that may bring value to the health care system over the longer term, but are more costly in the short run. The potential negative impact of the financial incentives of these models is magnified by the short payment windows used in the programs to compare actual spending against benchmarks in order to determine the level of savings that may be shared among providers. This is particularly concerning because many medical devices and technologies provide benefits over a long period of time spanning multiple years.

Additionally, gainsharing and other similar arrangements have created a major shift in incentives that have significant and potentially negative ramifications for patient care. AdvaMed continues to believe that "gainsharing" arrangements pose a risk of patient abuse and may violate the civil monetary penalty law prohibiting hospitals from offering remuneration to physicians for limiting medical care to their patients, § 1128A(b) of the Social Security Act (the "Act"). The federal anti-kickback statute and the "Stark" physician self-referral law also prohibit certain financial relationships such as those created in gainsharing arrangements. As such, we recommend that alternative payment arrangements be implemented in a way that makes their operation transparent and that these arrangements be evaluated and assessed to determine their impact on patient access to necessary care.

Recommendations to Advance Value-Based Care

In light of the challenges noted above, AdvaMed offers the following recommendations for consideration:

- Create a new *Risk-Sharing Safe Harbor* for value-based arrangements between manufacturers and providers and/or payers that incentivize and reward improvements in clinical outcomes and/or reductions in cost.
    - This safe harbor should allow for:
        - Sharing value-based rewards (*e.g.,* ACOs sharing some of the benefits received from meeting benchmarks with a medtech manufacturer if its products contributed to meeting that goal);
        - Shifting of risk over the course of an engagement so long as such risks are set in advance (*e.g.,* the initial phases of a bundled device and services program are paid for by a manufacturer, but as benchmarks are

[20] 42 CFR § 1001.952(h).

reached, efficacy is shown and savings recognized, the hospital would share a portion of the savings generated with the manufacturer);

- Multiple entities to engage in a complex study where costs may shift from one company to another and then potentially to the hospital, as efficacy is proven.

- Prior to proving that a system is efficient, the manufacturer would be in a better position to invest in the R&D of the engagement. However, once savings and efficiencies are proven, the manufacturer would also be able to share in the net benefit.
- While there may be ways to construct these engagements currently, they do not offer the fluidity that is possible with a single agreement with benchmarks and shifting fees. The freedom and efficiencies afforded by a Risk-Sharing Safe Harbor would permit greater investments into value-based solutions.
- The applicability of the Medicare Secondary Payer Statute to performance-based payments under this safe harbor should be clarified as well.

- Create a new *Safe Harbor for Bundling Services, Data Collection and Analytics, and Medtech Products in Value-Based Arrangements* (*e.g.,* to determine whether clinical outcomes and cost savings metrics have been met, medical technologies are bundled with services to collect and monitor data, analytics, monitoring equipment, and IT infrastructure);
- Create a new *Safe Harbor for Outcome Warranties* that specifically addresses warranting an outcome instead of a product failure and protects payments for bundled products and services provided when an outcome is not met.
  - For example, this would provide a targeted approach to addressing scenarios where a medical device company agrees to reimburse a hospital not only its aggregate purchase price for the implant device acquisition costs, but also unreimbursed wound care products and services if a patient is re-admitted to the hospital within 90 days following the surgical procedure because the surgical site is infected or a revision surgery is needed. Currently, when this occurs, there is arguably protection under the safe harbor warranty for only the device cost when the device fails. This may lead to litigation over whether there was a product failure. Litigation adds substantial costs, may not resolve in a timely manner, and may be upsetting to the patient. Permitting manufacturers to warrant the outcome, instead of against product failure, through the protection of a safe harbor would allow for more coordinated and timely management of post-operative complications.
- Issuing guidance that expressly delinks the provision of scientific and health care economic information supporting the value-based health care goals to providers and payors from any regulated product promotional or labeling restrictions. This guidance should include:
  - Clarification that communications on efficiency (*e.g.,* performance/throughput claims), population outcomes/cost, and economics that are not specifically part of the product labeling are necessary and permissible to develop and operationalize value-based arrangements and that varying levels of supportive data are acceptable (*e.g.,* case study, big-data analytics).
  - Clear guidelines for industry to rely on in providing appropriate medical information to Health Care Professionals regarding medical technologies with only general claims in the product labeling; and
  - Clarification on the scope of what may be discussed with payors and sophisticated providers about medical technologies and drugs undergoing review (*e.g.,* 510(k) review) to facilitate planning.
- Consider directing the creation of a *Fast Track Guidance Process* (that is less formal than the advisory opinion process) that would apply across all safe harbors for value-based considerations.
- If there was a preference to work within the existing Anti-Kickback Statute Safe Harbors, we offer the following for consideration to advance value-based payment models:

- *Discount Safe Harbor*—We recommend that OIG issue guidance on the Medicare secondary payer statute's applicability to performance-based payments.
- *Warranties Safe Harbor*—With regard to the Warranties Safe Harbor, we recommend:
  - Expanding warranty coverage in value-based arrangements to permissibly include other direct costs, associated products, associated services, service as a product, and replacement outsourcing costs, which are all means of making the provider whole;
  - Expanding competitive warranties to permit exceeding competitor's terms; and
  - Permitting warranty remuneration between manufacturers to allow for bundled items among different manufacturers to provide care.
- *Personal Services Safe Harbor*—With regard to the Personal Services Safe Harbor, we recommend:
  - Allowing the parties to set the compensation formula in advance (*e.g.,* percentage of savings or capitation), instead of being required to set the aggregate compensation paid over the term in advance;
  - Removing the limitation that the term is for not less than one year (*e.g.* percentage of savings or capitation);
  - Removing the interval schedule, length, and charge specificity requirement for services (*e.g.* percentage of savings or capitation);
  - Expanding and revising the definition of fair market value to account for services/arrangements tied to new value based payment models that incentivize improved quality of care and cost effectiveness; and
  - Issuing guidance that permits utilizing publicly available health care professional salary surveys as an acceptable methodology to determine fair market value.

Conclusion

In closing, we would like to reiterate our appreciation to Chairman Hatch, Senator Wyden, and the Senate Finance Committee for their work on this issue, and to also emphasize AdvaMed's support for a legal framework that protects patients and the federal programs from fraud and abuse. We believe that targeted reforms to our fraud and abuse laws for value-based arrangements will maintain the protections for patients and the federal health care programs while allowing for greater involvement and investment in value-based payment models. AdvaMed welcomes opportunities to collaborate on advancing value-based care, especially where medtech may offer unique contributions to the value equation.

ALLIANCE FOR INTEGRITY IN MEDICARE [1] (AIM)
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The Alliance for Integrity in Medicare (AIM) is pleased to submit a Statement for the Record for the Committee on Finance Hearing entitled "Examining the Stark Law: Current Issues and Opportunities," held on July 12, 2016. We commend Chairman Hatch, Ranking Member Wyden, and all other members of the Committee on Finance for holding this bipartisan hearing to examine the urgent need to reform the physician self-referral law in greater detail. AIM, a broad coalition of medical specialties committed to ending the practice of inappropriate physician self-referral in Medicare, is pleased to share our recommendations with the Committee for vitally-needed reforms so that beneficiaries and program integrity may be better protected than under current law.

Even though implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) continues alongside that of other novel physician payment models, such as accountable care organizations (ACOs), AIM strongly believes there remains a moral imperative to narrow the in-office ancillary services (IOAS) exception to the

[1] Alliance for Integrity in Medicare, c/o Francesca Fierro O'Reilly, Vice President, Government Relations, ACLA, 1100 New York Avenue, NW, Suite 725W, Washington, DC 20005.

Stark Law. Despite all the progress made and still forthcoming in the area of alternative physician payment models, fee-for-service (FFS) has not been eliminated from the Medicare program. Thus, FFS will continue to exist for the foreseeable future, in addition to the financial incentive for clinicians to take advantage of the IOAS exception. AIM strongly recommends that anatomic pathology, physical therapy, radiation oncology, and advanced diagnostic imaging should be removed from the list of designated health services protected under the IOAS exception, for which physicians can self-refer and bill Medicare. However, in situations where a practice truly is clinically integrated or participating in a federally approved alternative payment model, which improves quality and value, the IOAS exception should continue to apply. Restricting use of the IOAS exception in this manner will drive greater participation in alternative payment models, consistent with the goals of MACRA.

Note that the intent of the IOAS exception was to allow for the provision of certain non-complex services, such as x-rays or simple blood tests, deemed necessary by the clinician to help inform the diagnosis and treatment of a beneficiary during an initial office visit, primarily for beneficiary convenience. But in most instances, advanced diagnostic imaging, anatomic pathology, physical therapy, and radiation therapy services cannot be provided to beneficiaries during an initial or single office visit. Allowing these more complicated services to be protected under the IOAS exception does not facilitate greater patient convenience. Rather, the IOAS exception only bolsters the continuation of questionable utilization patterns of these services under FFS. Narrowing the IOAS exception will realign provider incentives to help ensure appropriate utilization. The ability of all providers to render the highest quality, safest, and most clinically appropriate care to all patients will be maintained, while eliminating the lure of personal financial gain.

The Government Accountability Office, the Office of the Inspector General of the U.S. Department of Health and Human Services, the *New England Journal of Medicine,* and *Health Affairs,* among others, also have called attention to the fact that the IOAS exception has substantially diluted the self-referral law and its policy objectives. Current law allows Medicare providers to avoid the Stark Law's prohibitions by structuring arrangements for advanced diagnostic imaging, anatomic pathology, physical therapy, and radiation therapy services that meet the IOAS exception's technical requirements but otherwise violate the true intent of the exception.

The Administration has advocated specifically for this policy change in the last four Department of Health and Human Services Budgets in Brief, Fiscal Years 2014–2017. Most recently, the Centers for Medicare and Medicaid Services (CMS) lamented the ongoing conflicts of interest for physicians referring beneficiaries to entities with which they had financialties in the Calendar Year 2017 Physician Fee Schedule Proposed Rule (CMS–1654–P). "[R]ecent studies by GAO indicate that financial self-interest continues to affect physicians' medical decision making:" [2] Later in the Proposed Rule, CMS went on to state: "when physicians have a financial incentive to refer a patient to a particular entity, this incentive can affect utilization, patient choice, and competition. Physicians can overutilize Medicare resources by ordering items and services for patients that, absent a profit motive, they would not have ordered. A patient's choice is diminished when physicians steer patients to less convenient, lower quality, or more expensive providers of health care, just because the physicians are sharing profits with, or receiving remuneration from, the providers. And lastly, where referrals are controlled by those sharing profits or receiving remuneration, the medical marketplace suffers if new competitors cannot win business with superior quality, service, or price." [3]

CMS has long said that it does not have the statutory authority to address abuse of the IOAS exception. Reforming the IOAS exception through remedial legislation is long overdue, and we urge Congress to act. AIM's recommended changes to the IOAS exception will prevent unnecessary utilization of resources by providers, protect Medicare patients from unnecessary care, promote effective gainsharing arrangements, and further the goals of higher quality health care at lower cost, resulting in improved clinical outcomes for beneficiaries. Furthermore, the realignment of financial incentives for Medicare providers would save the program at least $3.3 billion over 10 years, as scored by the Congressional Budget Office.

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[2] Page 761, accessed here: *https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-16097.pdf.*

[3] Page 762–3, accessed here: *https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-16097.pdf.*

In conclusion, the AIM coalition strongly encourages the Senate Finance Committee to include in any Stark Law reform legislation language to narrow the IOAS exception by removing anatomic pathology, advanced diagnostic imaging, physical therapy, and radiation therapy from the list of permitted designated health services under the exception. Accountable Care Organizations and other alternative payment models will not be successful if overutilization continues to be incentivized in any element of the Medicare program. Closing the loophole supports the original intent of the Stark Law and the cornerstone goals of the ACA and MACRA to improve patient care and reduce overutilization. Protecting both Medicare beneficiaries and program integrity from misaligned financial incentives is in the best interests of taxpayers, patients, and the American health care system overall.

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS ET AL.

July 22, 2016

Senator Orrin Hatch
Chairman
U.S. Senate
Committee on Finance
104 Hart
Washington, DC 20510

Senator Ron Wyden
Ranking Member
U.S. Senate
Committee on Finance
221 Dirksen
Washington, DC 20510

Re: Senate Finance Committee Hearing: "Examining the Stark Law: Current Issues and Opportunities"

Dear Chairman Hatch and Ranking Member Wyden:

The American Academy of Orthopaedic Surgeons (AAOS), the American Association of Orthopaedic Executives (AAOE), and the OrthoForum would like to thank you for the opportunity to submit comments regarding the recent Senate Finance Committee hearing, "Why Stark, Why Now? Suggestions to Improve the Stark Law and Encourage Innovative Payment Models." We appreciate the need to improve and modify the Physician Self-Referral Law ("Stark Law") in light of the shift from Medicare fee-for-service to alternative payment models. The structure of the Stark Law has not been updated statutorily for more than two decades and is now an anachronistic hindrance to the 21st century delivery of health care and limits the full potential envisioned by Congress when it enacted MACRA. Additionally, the overly complex regulatory restrictions have negatively impacted the efficiency of patient care while serving to drive many private practice physicians into hospital employment.

Two issues we would like to emphasize are the importance of protecting the In-Office Ancillary Services Exception (IOASE), which allows for an integrated continuum of care, and the need to lift the physician-owned hospital (POH) ban on expansion and new construction, which increases access to quality care. These issues will be addressed further.

What changes need to be made to the Stark Law to implement the Medicare Access and CHIP Reauthorization Act (MACRA, 2015) and Accountable Care Organizations (ACOs)/Medicare Shared Savings Program (MSSP)?

Issue of continued relevance: The wide-range of regulations governing physician financial incentives are an impediment to the transition to value-based Medicare reimbursement. The U.S. Department of Health and Human Services (HHS) set a goal to tie at least 30 percent of the fee-for-service Medicare payments to quality/value through Alternative Payment Models (APMs) by 2016 and to 50 percent of payments by the end of 2018. CMS announced in March 2016 that the agency was ahead of schedule in the realization of its 30 percent goal. However, a significant portion of that goal was accomplished through demonstration initiatives such as the Bundled Payments for Care Improvement (BPCI) initiative in which multiple waivers were required to allow physician groups and hospitals to work in concert to lower costs and improve quality. BPCI along with the more recently implemented Comprehensive Care for Joint Replacement (CJR) model reveal weaknesses in current Stark Law which is structured to have some control over volume of referred services. Rewarding providers for the value of care and not the volume of services, such as in these current initiatives, renders a driving intent of the Stark Law obsolete.

Costs for compliance: As MACRA is implemented, regulations should make it less burdensome for physicians to participate in APMs and earn incentives through the

Merit-based Incentive Payment System (MIPS). The costs of compliance and disclosures required per the Stark Law can be prohibitive for small and medium-sized physician practices. We are concerned that this cost will lead to a drop of specialty providers in the Medicare program as the cost of compliance continues to grow.

Recommended waivers: Existing Stark Law requirements are highly technical and the waivers can get very complex. For example, physician referrals in Accountable Care Organizations (ACOs) are theoretically exempt from the Stark Law requirements through fraud and abuse waivers. There should be similar exceptions/protections to physicians participating in APMs. However, we anticipate that as MACRA provisions are implemented, such waivers will become more complex. An alternative to waivers may be a statutory exception modeled on the Medicare pre-paid plan enrollees under Section 1877(b)(3) of the law. On the whole, regulatory agencies such as CMS should have greater flexibility to refine the regulations as the health care policy and delivery environment changes.

Other recommendations

The complexities of the Stark Law regulatory infrastructure make it burdensome for clinicians to comply. The "group practice" definition places strict limits on the ways that a physician practice may compensate its owners. Agreements with physician contractors must satisfy seven distinct regulatory conditions, making them prone to technical infractions. Unlike other laws that regulate healthcare, the Stark Law does not require demonstration of intentional offers of remuneration to induce referrals or any risk to patient care. Current waivers are skewed toward primary care and financial relationships with hospitals. It is critical to incorporate protections for independent specialty groups. Finally, the Stark Law impedes care coordination needed to quality for alternative payment models in MACRA due to the Law's consideration of "other business generated" in its limitations on referrals. There are five fundamental revisions that we would like to see in order to align the law with MACRA:

- Revise the definition of "group practice" by removing the current "volume" or "value" standard so that physicians who are part of a group practice may be paid on the basis of furnishing care without violating the Stark Law.
- Provide the same protections from the Stark Law for physicians operating in an Alternative Payment Model for those provided waivers through Accountable Care Organizations eligible for the Medicare Shared Savings Program.
- Permit physician compensation for providing high-quality and efficient care without violating the Stark Law's "fair market value" standard even if the compensation is related to the volume or value of the referrals.
- Define Stark Law "technical violations" as compensation arrangements that do not otherwise violate the Anti-Kickback statute.
- Empower CMS to create new regulatory exceptions to the Stark Law now and in the future for purposes of promoting non-fee-for-service payment structures.
- Quality- and value-based physician reimbursements may violate the Stark Law fair market value or reasonableness standards. Under the current delivery and payment system, these standards should be repealed by Congress or CMS should be able to issue new and relevant standards.

Stark Law technical violations vs. more serious violations—where is the line?

We would like to point out that the Stark Law is a liability statute unlike other health care legislation. Thus, the physician's actual intent to improperly refer services is not pertinent to the liability. Thus, unintentional and technical errors of physicians and their staff may lead to heavy penalties. Such liability statutes are not encouraging of physicians to participate in new demonstrations and payment models. These requirements are also not helpful toward developing coordinated care models such as the CJR, led by hospitals but coordinated by several stakeholders including physicians.

Lifting the moratorium on new construction for physician-owned hospitals

The Whole Hospital Exception to the Stark Law allows for a physician to have an ownership or investment interest in a hospital to which the physician refers designated health services when the physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself. The Affordable Care Act (ACA) amended the Whole Hospital Exception to impose additional restrictions on physician-owned hospitals (POHs). The ACA restricted a POH from new construction or facility expansion after March 23, 2010.

There are approximately 250 POHs operating in 34 states across the country. These hospitals have a long history of providing the highest quality care for affordable prices. They are often the most efficient, state-of-the-art facilities in the country, which is the result of a doctors' desire to be involved in making detailed decisions. In CMS's Value Based Purchasing Program results, 7 of the top 10 hospitals, and 40 of the top 100 hospitals, receiving quality bonuses in FY 2016 were POHs. A POH has been the top bonus recipient in each of the 4 years of the program. This is impressive, considering that POHs represent less than 5% of the 5,700 hospitals nationwide. Likewise, more than 40% of POHs earned CMS's top 5-star rating for patient satisfaction in October 2015, while less than 4% of non-physician-owned hospitals received that distinction.

POHs treat similar patient populations as other hospitals. A 2015 British Medical Journal study, published by a Harvard University researcher, found that there is no "clinically or statistically significant differences in patient mix between POHs and non-POHs." The study found that "POHs and non-POHs admitted similar proportions of Medicare patients . . . Medicaid patients . . . Black patients . . . and Hispanic patients," as well as patients with "comparable numbers of comorbidities . . . and similar predicted mortality scores."

Despite the strong track-record of superior performance, POHs serving Medicare and Medicaid patients have been restricted from growing and expanding through the ACA's change to the Stark Law Whole Hospital Exception. The restrictions have limited POHs from developing or expanding services in numerous rural and urban communities where additional care is desperately needed. In many instances, local community hospitals are simply not able to handle the caseload and patients do not have access to the care they need.

We strongly believe that the ACA change to the Whole Hospital Exception is detrimental to the U.S. healthcare system, and Medicare and Medicaid beneficiaries. POH's are a model that encourage the move from volume to value and are therefore consistent with the current trends in physician reimbursement.

Maintenance of current exceptions for in-office ancillary services

We would like to conclude by stressing the importance of maintaining current exceptions. For orthopaedic surgeons, current exceptions such as the IOASE, are absolutely essential for providing necessary care. For example, in high shortage and low resource rural areas, having magnetic resonance and other imaging services in the physician's office is often the only way that our surgeons can deliver and their patients can get timely diagnoses and care. The IOASE provision has enabled our practices to provide convenient, integrated and less expensive high-quality care.

Several recent studies have made it clear that utilization of ancillary services in physician practices does not lead to overutilization. In a study published by Health Economics Review found that there was no statistically significant difference between physicians who self-refer for Magnetic Resonance Imaging (MRI) and those who do not. A June 2015 study by Milliman Inc.—commissioned by the American Medical Association and the Digestive Health Physicians Association—showed utilization of ancillary services in physician practices is a small percentage of total spending on ancillary services and is declining or growing more slowly than in hospital settings. Additionally, a study by Braid-Forbes Health Research, LLC found that financial ownership was not related to MRI referral rates for practices that owned MRI equipment during the period of the study. A 2014 Government Accountability Office (GAO) study on physician-owned physical therapy services showed that physicians owning physical therapy services utilize the services less than physical therapy provided in non-physician owned settings. Finally, in a June 2011 report to Congress, the Medicare Payment Advisory Commission (MedPAC) recommended against limiting the Stark Law exception for ancillary services, citing potential "unintended consequences, such as inhibiting the development of organizations that integrate and coordinate care within a physician practice." Any effort to repeal the In-Office Ancillary Services Exception should be rejected.

We sincerely appreciate your endeavor in updating the Stark Law requirements and regulations and should you have any questions, please feel free to get in touch with AAOS's Senior Manager of Government Relations, Ms. Julia Williams, at jwilliams@aaos.org, or AAOE's Government Affairs Manager, Mr. Bradley Coffey, at bcoffey@aaoe.net, or Joel James, OrthoForum Advocacy Committee member at jjames@signaturehealth.net.

Sincerely,

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American Association of Orthopaedic Surgeons

Eric Worthan
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The American College of Cardiology supports the following principles related to the Stark Law and believes they must guide any policy changes in this area:

- Changes must improve access to/quality of care, especially for vulnerable patient populations.
- Revisions must actually simplify the law to reduce the exorbitant legal fees and administrative burdens imposed on clinicians.
- As we transition to paying for quality vs. quantity, changes must allow clinicians to be compensated appropriately for the work they do/quality of care they provide.
- Modifications must allow and encourage collaboration between clinicians themselves, as well as between clinicians and hospitals, across private practices and multiple health systems, to provide coordinated care in an appropriate manner.
- Modifications to the law should reflect an emphasis on quality measurement, the use of outcome-based clinical data registries such as the National Cardiovascular Data Registry, the importance of collaborative, team based care models, and other innovative payment structures that underscore best practices.
- Changes must allow for the evolution of clinical practice and future flexibility in the structure of the Medicare program.
- Revisions must allow clinicians the ability to offer their patients both the best care and easy access to care, particularly in regard to clinical and diagnostic testing in an appropriate setting of their choice.
- Revisions must distinguish between willful and inadvertent violations of the law.

AMERICAN COLLEGE OF SURGEONS

On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we welcome the opportunity to comment and provide information on long overdue and much needed modifications to the Physician Self-Referral Law, commonly referred to as the Stark Law. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) has created great opportunity to improve patient care coordination through development of new alternative payment models (APMs) but has also increased the urgency to modernize the Stark Law to take into account the way that care is delivered today and will hopefully be delivered in the future. Even before passage of MACRA, ACS has been working to develop APM options for our members to help achieve the goal of improving the quality, experience, and value of care to the patient and the health care system. While these efforts are still in the early stages of development, it is clear that coordinating care throughout the five phases of surgical care (pre-operative, peri-operative, intra-operative, post-operative and post-discharge) will be key to their success.

Removal of real or perceived barriers inherent in the Stark Law will help to speed adoption of newly developed APMs. Furthermore, the definition of the fair market value (FMV) of the services provided in APMs and other models that have perhaps not yet been developed will need to be revisited, since the role of the surgeon in such a model may go beyond simply providing high quality surgical interventions to playing a role in coordinating care that helps to avoid or delay the need for surgery.

Technical violations vs. more serious or problematic violations—where is the line?

The Stark Law is a strict liability statute, meaning that a physician's actual intent to improperly refer services is irrelevant to the imposition of liability and damages. Thus, inadvertent errors (including technical errors) of physicians provide grounds for harsh penalties. Consequently, whereas MACRA seeks to encourage physicians to provide quality care and to be innovative and efficient through APMs, the Stark Law with its strict liability and severe financial penalties can dissuade physicians from innovating their care delivery models. It can also deter physicians from adopting best practices that require integration unless the penalties under the Stark Law are eliminated or substantially reduced, especially in the case of technical errors. The lack of an intent requirement also diverges substantially from the related Federal Anti-Kickback Statute, which creates a "knowingly and willingly" standard. Congress should also require that some level of intent on the part of physicians to improperly refer patients to designated health services (DHS) be found in order to establish grounds for a violation of the Stark Law. The Stark Administrative Simplification Act (H.R. 776), introduced by Rep. Charles Boustany, represents one potential step in the right direction of addressing the laws inflexibility. This bill provides for an alternative sanction in the case of technical noncompliance with the Stark Law. In cases where noncompliance is due solely to the arrangement not being set forth in writing, not having been signed by one or more parties, or where a prior arrangement expired, the parties involved could disclose this technical noncompliance, fix the cause of the noncompliance, or terminate the arrangement and pay an alternative sanction in the form of a single civil monetary penalty. Changes such as these would help reduce uncertainty and the fear of liability and potentially large monetary damages, increasing the chances that providers will be comfortable to move into innovative payment arrangements.

What changes need to be made to the Stark Law to implement MACRA (Medicare Access and CHIP Reauthorization Act of 2015) in its current form and ACOs/shared savings programs?

The existing Stark Law exceptions do not provide sufficient protection or guidance for physicians to make fully informed decisions about participating in innovated care delivery models. More clarity is needed as to whether reimbursement models under MACRA would be protected under a current Stark Law exception or whether their payment arrangements, including risk/reward sharing and delivery of services in an integrated care delivery model, violate Stark or other fraud and abuse laws. If no exception applies, we recommend that CMS consider a statutory exception for any models approved as eligible APMs. At a minimum, the current fraud and abuse waivers applicable to the Medicare Shared Savings Program (MSSP), the Centers for Medicare and Medicaid Innovation (CMMI) Accountable Care Organizations (ACOs), and bundled payment programs should be codified in statute and extended to services furnished under a potential MACRA APM, where the same requirements for innovation, quality of care, efficiency, and care coordination are part of the care delivery model.

Other—Fair Market Value Issues

Basing payments to physicians on their performance on clinical quality and cost measures may violate the Stark Law fair market value or commercial reasonableness standards, which are requirements of many of the Stark Law exceptions. These standards were logical at the time the Stark Law was devised. But given that Congress has specifically enacted policies intended to incentivize physicians and other providers of services to deliver quality care, the fair market value requirement as a part of Stark Law exceptions should either be repealed or modified to permit physicians to participate in these types of payment incentive programs without fear of running afoul of the Stark Law.

Other—Preservation of the Current Exception Categories

Improving coordination of care to patients, especially those with complex conditions, is a major goal of our health care system in general and of the recently enacted MACRA law. We believe that in addition to changes in the law, it is important that Congress maintain the current exceptions to provide the flexibility needed to deliver care in the new health care system's delivery environment. In particular, we believe that preservation of the Stark Law In-Office Ancillary Services Exception (IOASE) is crucial to ensuring physicians can provide coordination of care for patients. This provision permits physician practices to provide critical services in an integrated and coordinated fashion within their respective practices. Eliminating this provision

could prevent patients from receiving these services with their preferred provider, in hospital settings, thereby reducing access and increasing costs.

Again, we thank you for taking the initiative to begin the process of modernizing the Physician Self-Referral Law and we look forward to working with you in efforts to remove unnecessary barriers to the provision of high quality, high value, and coordinated care.

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On behalf of more than 93,000 physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to provide this statement to the Senate Finance Committee on "Examining the Stark Law: Current Issues and Opportunities."

APTA's vision is to transform society by optimizing movement to improve the human experience. Physical therapists diagnose and manage individuals across the lifespan who have conditions that limit their ability to move or function in their daily lives. We are committed to protecting and preserving resources within the health care system, and we continue to strive for the highest levels of ethics, professionalism, and evidence-based practices for our members. APTA's own Integrity in Practice campaign is aimed at educating not only current and future physical therapists on methods and reasons to prevent fraud, but also educating the public on questions they should ask to make wise decisions on care. APTA applauds the committee's interest in improving the Stark Laws. As the committee continues to look at ways to reform these laws to make them stronger and less prone to abuse, we strongly urge you to consider reform of the in-office ancillary services (IOAS) exception.

The IOAS exception to the Stark Laws was intended to improve coordination of care and promote patient convenience by allowing physicians to self-refer for designated health services integral to their primary care that are furnished in their group practices. Unfortunately, the current use of this exception goes well beyond its original intent. This is evident in MedPAC's June 2010 report to Congress. MedPAC found that physical therapy services were provided on the same day as the initial appointment only 3% of the time, clearly illustrating that these are not services that are provided for a patient's convenience.

Abuse of the IOAS exception has been examined by the Government Accountability Office, the Office of the Inspector General of the U.S. Department of Health and Human Services (HHS), and the *New England Journal of Medicine (NEJM)*, among others. MedPAC also raised questions about abuse under the IOAS exception in the aforementioned June 2010 report while the Centers for Medicare and Medicaid Services (CMS) asked for feedback from stakeholders in its 2008 notice of proposed rulemaking. Both MedPAC and CMS found that the existing IOAS exception has substantially diluted the self-referral law and its policy objectives, allowing Medicare providers to avoid the law's prohibitions by structuring arrangements meeting the technical requirements for physical therapy services while violating the true intent of the exception. Based on the NEJM study and the government reports, the abuse of the IOAS exception has also led to overutilization of several services. For these reasons, **APTA strongly urges Congress to remove physical therapy as a designated health service (DHS) permissible under the in-office ancillary services exception to the federal physician self-referral laws.**

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) required HHS to submit a report to Congress in April 2016. This report, which has not been made public, should contain ". . . options for amending existing fraud and abuse laws in, and regulations related to, titles XI and XVIII of the Social Security Act (42 U.S.C. 301 et seq.), through exceptions, safe harbors, or other narrowly targeted provisions, to permit gainsharing arrangements that otherwise would be subject to civil money penalties . . . or similar arrangements between physicians and hospitals, and that improve care while reducing waste and increasing efficiency." (Pub. L. 114–10 §512.) We believe that closing the IOAS exception loophole would surely fall under this mandate. Since Medicare fee-for-service is still in place, it should remain a priority to close the loophole by removing physical therapy, advanced diag-

nostic imaging, anatomic pathology, and radiation oncology as designated health services, which will eliminate unnecessary care for patients and stop abuse. Furthermore, we believe the promulgation of laws to end the unintended abuses under the IOAS exception are essential to the success of alternative payment models such as accountable care organizations and bundled payment. Congress should make clear that the flexibilities afforded under the IOAS exception apply only to physician group practices participating in alternative payment models that demonstrate true clinical integration evidenced through participation in quality reporting and improved outcomes initiatives. APTA also advocates for the very narrow use of the IOAS exception in rural and underserved areas, and we urge Congress to direct the secretary of HHS to delineate these limited circumstances in regulatory rulemaking.

APTA asserts that care furnished under the IOAS exception is often degraded, raising serious quality concerns. There is evidence that beneficiaries may actually receive higher-quality care—and therefore better outcomes—when self-referral is not involved. A recent study on low back pain episodes of care, published in the July 2015 issue of the *Forum for Health Economics and Policies* by Jean Mitchell, Ph.D., of Georgetown University, found that non-self-referred episodes of care were far more likely to provide "active," or hands-on, services than self-referral episodes—52% compared with 36%. This, according to the study's authors, suggests the care delivered by physical therapists in non-self-referred episodes is more tailored to promote patient independence and a return to performing routine activities without pain. It is important to note that "passive" treatments, which are more likely found in self-referring episodes, can be performed by a person who is not a licensed physical therapist. The authors of this paper also cite evidence that these passive physical therapy modalities are "ineffective" in treating low back pain.

Of note, the study highlights the difference in overall expenditures for episodes of care provided by self-referring vs. non-self-referring physicians. The study examines the total insurer allowed amounts for low back pain episodes of care and parses out expenditures on physical therapy only. On average, spending for self-referring providers was $144 as opposed to only $73 for non-self-referring providers. This is a significant difference for a very common episode of care. Even more, when the expenditures for the entire episode of care are calculated—not just physical therapy but all care for the episode—self-referral episodes averaged $889 compared with only $602 for non-self-referral episodes. The implication is clear: not only is this a problem for physical therapy, it has spread far beyond.

Another study published in February of this year in *Health Services Research,* also by Jean Mitchell, Ph.D., examined the use of physical therapy following total knee replacement (TKR) surgery. This population consisted of Medicare beneficiaries. Patients that were treated by an orthopedic surgeon who had an ownership interest in the physical therapist that treated the patient after the surgery received 8.3 more physical therapy visits as well as 6.6 fewer PT service units per episode than patients who had surgery from an orthopedic surgeon with no ownership interest in the subsequent physical therapy. Since patients were under Medicare, the study was also able to examine the codes billed for these episodes. It found that episodes directed by a self-referring orthopedic surgeon consisted of billing for 8.2 percent fewer therapeutic exercise codes, but higher billing for group therapy and manual therapy, the latter of which consists mainly of joint massage and mobilization to reduce swelling.

This second study, which mirrors findings of the first, shows patients treated by physicians with a financial self-interest in the follow-up physical therapy receive less active, hands-on, and one-on-one care than those patients who are treated by physicians who have no financial interest in the follow up therapy. The incentive exists to extend care for more visits while billing less intensive therapy codes that do not necessarily expedite patient recovery.

APTA would like to thank Chairman Hatch and Ranking Member Wyden for looking into this important policy issue and allowing APTA to share its recommendation. We look forward to being a partner in rooting out Medicare fraud and abuse and establishing an efficient, patient-centered health care system. APTA strongly encourages the committee to support the original intent of the IOAS exception for same-day services by removing physical therapy, anatomic pathology, advanced diagnostic imaging, and radiation therapy services. This reform is in the best interests of taxpayers, patients, and the American health care system overall.

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July 26, 2016

The Honorable Orrin Hatch
Chairman
U.S. Senate
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
U.S. Senate
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Re: Examining the Stark Law: Current Issues and Opportunities

Dear Chairman Hatch and Ranking Member Wyden:

On behalf of Gundersen Health System, we write to provide testimony in response to the Senate Committee on Finance recent hearing "Examining the Stark Law: Current Issues and Opportunities." Overall, we are very supportive of the committee's focus on reforming the barriers presented by the existing Stark Law.

Gundersen Health System provides integrated care for patients in predominantly rural areas along the Mississippi River in western Wisconsin, northeast Iowa, and southeast Minnesota. As the largest employer in the La Crosse, Wisconsin region with over 7,000 employees, Gundersen provides a range of services including: clinical care, level II trauma care, medical education, and air and ground ambulance services. In addition, Gundersen has maintained a five-star rated Medicare Advantage insurance plan for the past 5 consecutive years. Gundersen has consistently achieved top national rankings in many areas of medical excellence including being named as a Healthgrades Top 50 hospital in overall care, many clinical specialty services, and patient experience.

We believe value-based payment policies can drive better quality, lower cost of care, and reduce overall costs for the Medicare program. Gundersen Health System is a leader in efforts to reduce healthcare costs and improve quality, but certain outdated statutory and regulatory barriers hinder opportunities to further develop and expand new models of care. As a founding member of the Healthcare Quality Coalition (HQC), we strongly support continued implementation of payment systems that reward value

Alleviating Statutory Barriers Through Stark Law Reform

Gundersen Health System supports developing and advancing legislation for reforming the antiquated Stark Law. The Stark Law's oversight of compensation arrangements is anchored in a fee-for-service environment, and enacted during a time where physicians were predominately self-employed, hospitals were separate entities, and both billed for services on a piecemeal basis. The Stark Law is outdated and not suited to the new models and should not be the locus of oversight for these new arrangements. The statute and its complex regulatory framework are designed to keep hospitals and physicians apart—the antithesis of the new models and certainly not an aspect integrated healthcare at Gundersen Health System.

Increasingly, public and private payers are holding hospitals accountable for reducing costs and improving quality, and using financial incentives, which we strongly support. Achieving Congress's goals for value-based care and innovative community delivery models can be accomplished only through teamwork among hospitals, physicians and other health care providers across sites of care. Existing Stark Laws are significant barriers to developing innovative community-based care models to help patients recover faster and stay out of the hospital, ultimately reducing readmissions and healthcare costs.

Policy Solutions

We recommend legislative solutions in the Senate be developed in tandem with the committees of jurisdiction in the House of Representative. Introducing bipartisan, bicameral legislation would establish a strong signal to the healthcare community that policymakers are working diligently across both Congressional Chambers to enact laws to improve quality and population health, increase collaboration, and lower the cost of care.

At minimum, Congress should adopt legislation that provides a single, broad exception for integrated healthcare delivery systems. An integrated healthcare organization exception should cut across the Stark Law, the anti-kickback statute and relevant civil monetary penalties for financial relationships designed to foster collaboration in the delivery of health care and incentivize and reward efficiencies and improvements in care. We recommend the exception be created under the anti-kickback statute and arrangements protected under the exception be deemed compliant with the Stark Law. Addressing this barrier will help with the implementation of the Medicare Access and CHIP Reauthorization Act by developing new alternative payment models, reducing hospital readmissions, increasing coordinated care, and improving population health programming.

Conclusion

In sum, we are strongly supportive of the Senate Committee on Finance's focus on exploring policy solutions to remove legal barriers in the advancement of new, alternative payment models. We are pleased with the bipartisanship that has encompassed these early hearings. The released white paper titled *Why Stark, Why Now?* is an excellent step at identifying potential solutions. We look forward to continue working with you to provide input and help move the issue forward to legislation.

Sincerely,

Michael D. Richards
Executive Director of External Affairs
Gundersen Health System

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July 11, 2016

U.S. Senate
Committee on Finance
Dirksen Senate Office Building
Washington, DC 20510–6200

Re: Examining the Stark Law: Current Issues and Opportunities—July 12, 2016 Hearing

To the Members of the Committee:

This letter is submitted for inclusion in the hearing record in connection with the above hearing. The law firm of Horty, Springer and Mattern, PC. devotes its practice exclusively to hospital and health care law. We work with health care providers throughout the country, consulting with hospital boards, management, medical staff leaders and other attorneys. We are intimately familiar with regulatory implications of the financial relationships between physicians and hospitals, especially those arising out of the Physician Self-Referral Act, 42 U.S.C. § 1395nn, also known as the "Stark Law." We routinely draft hospital-physician arrangements, advise our clients about them, and represent clients in False Claims Act litigation when such arrangements are challenged based on alleged violations of the Stark Law. We also represent clients who have made self-disclosures to CMS and the OIG involving Stark Law and similar violations. In submitting these comments, we are not acting on behalf of any client. We appreciate the opportunity to submit these comments.

Hospitals must enter into a wide variety of compensation arrangements with physicians in order to carry on their day-to-day operations. Nonprofit charitable hospitals have additional needs for physician relationships essential to carry out their charitable mission. The Stark Law, as it has been implemented by CMS in its regulations and regulatory commentary, applied by the Department of Justice and relators in False Claims Act cases, and interpreted by the courts, presents very real barriers to achieving clinical and financial integration of physicians and hospitals required to achieve the "triple aim" of health care reform—reducing cost, improving quality and enhancing access. The Stark Law has also imposed significant expenses on health care organizations in the form of legal and compliance costs.

In our opinion, the Stark Law should be repealed in its entirety, or at least be substantially amended by repealing the prohibitions against compensation arrange-

ments that fall outside the statutory and regulatory exceptions. In lieu of that, we would offer the following comments on specific provisions in the Stark Law.

1. Volume or Value Standard

As CMS has repeatedly stated, the requirement that compensation not vary with or take into account the volume or value of physician referrals, which appears in a number of statutory or regulatory exceptions, should be uniformly interpreted wherever it appears. Such uniform interpretation is essential. However, other agencies and some courts have interpreted the volume or value standard to consider the subjective intent of the parties, rather than applying an objective "bright line" test as Congress intended, making compliance with the statute much more difficult and uncertain. In addition, prior CMS commentary has added to this confusion by applying the volume or value standard to other exception criteria, such as the definition of fair market value, thereby conflating two standards that were intended to stand on their own. The Committee should consider amending the Stark Law to address this confusion.

(a) Objective vs. Subjective Interpretation

A number of recent court cases have stated that if a hospital discusses or analyzes the potential referrals, it "takes referrals into account" thereby tainting an otherwise compliant arrangement, even one that pays a fixed fee. This introduces an element of subjective intent into an ostensibly "bright line" statutory and regulatory scheme.

The volume and value standard says that the compensation cannot "take" into account the volume or value of referrals—not "took." This distinction is crucial. What the parties to an arrangement may have intended to achieve is irrelevant for the purposes of the self-referral law. As CMS pointed out in the Phase 1 regulations: "a compensation arrangement does *not* take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary *over the term of the agreement* in any manner that takes into account referrals." 66 Fed. Reg. 877–878 (January 4, 2001) (emphasis added). This is also supported by the legislative history of the self-referral law. Congress said that compensation simply could not "fluctuate *during the contract period* based on the volume or value of referrals between the parties to the lease or arrangement." H.R. Rep. No. 103–111, at 545 (1993), reprinted in 1993 U.S.C.C.A.N. 378, 779 (emphasis added). What the parties may have wanted to accomplish through the arrangement is not relevant to the legality of the compensation arrangement under the Stark Law. Unlawful intent is to be addressed by the Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a–7b.

Congress should therefore amend the Stark Law to clarify that the intent of the parties to an arrangement is completely irrelevant to the application of the Law or the eligibility to fit within any of the exceptions.

(b) Circular Definitions

The definitions of "fair market value" and "not take into account the volume or value of referrals" (the "volume or value standard") as used in the regulations to the Stark Law are completely circular. The regulations, at 42 CFR § 411.351, define "fair market value" as follows:

> Fair market value means the value in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, *where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals* (emphasis added).

On the other hand, the volume or value standard, while not defined m the body of the regulations, has been described in CMS commentary as follows:

> A compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance *and will result in fair market value compensation,* and the compensation does not vary over the term of the arrangement in any manner that takes into account referrals or other business generated (emphasis added).

66 Fed. Reg. 877–878 (January 4, 2001).

In other words, to comply with the fair market value standard, a compensation arrangement must not take into account the volume or value of referrals, but the compensation arrangement will not take into account the volume or value of referrals only if it results in fair market value compensation. This definition is circular and is not consistent with the statute. The statute defines "fair market value" as "the value in arm's-length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee." 42 U.S.C. § 1395nn(h)(3). There is no mention of the volume or value standard in this definition, nor should there be, since these are two separate and independent concepts. Congress should amend the law to make it clear that the volume or value and fair market value standards are independent of one another, and that compliance with one does not depend on compliance with the other.

(c) Correlation of Professional Services to Technical Fees

CMS has repeatedly stated that a physician's compensation can always be based on personally performed services—69 Fed. Reg. 16054, 16067 (March 26, 2004)—even if the payment is "linked to a facility fee." *Id.* at 16088–89. Unfortunately, at least one court has misinterpreted or ignored this guidance and held that if an employed physician eligible for productivity compensation personally performs a professional service in a hospital and the hospital also bills a technical fee to Medicare, the physician's compensation varies with his or her referrals and thus fails to comply with the volume or value standard. The vast majority of hospitals and health systems in the country pay doctors on a productivity basis linked to their personally performed professional services performed in the hospital. Without further statutory clarification affirming that this would not violate the volume or value standard, hospitals and physicians will be faced with grave uncertainty about whether their compensation arrangements are compliant.

2. Definition of Referring Physician

The statute provides: ". . . the request or establishment of a plan of care by a physician which includes the provision of the designated health services constitutes a 'referral' by a 'referring physician.'" 42 U.S.C. § 1395nn(h)(5)(B). However, the regulations go on for over 250 words in defining the term "referral" which creates confusion. Furthermore, the Government has been allowed to prove referrals by simply offering into evidence summaries of UB–04 claims forms that identify "attending" or "operating" physicians and which were never intended to identify referring physicians. This has also allowed the Government to claim damages equal to the entire payment for inpatient claims when the physician in question is simply listed anywhere on the claim form, even if he or she did not admit the patient. This has resulted in wildly inflated damage awards and settlements. To address this problem, we would suggest limiting the definition of "referring physician" to the physician who actually ordered an outpatient service or inpatient admission, and require proof from the medical record rather than from the claims forms.

3. Physician Compensation

The majority of physicians are now employed by hospitals and health systems. Having those employment arrangements micromanaged by CMS and DOJ through the Stark Law not only stifles innovation, but flies directly in the face of the Prohibition Against Federal Interference set forth in the very first section of the Medicare statute: "Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person." 42 U.S.C. § 1395. Absent repealing the Stark Law or its prohibition against compensation arrangements falling outside its exceptions, or creating an all-encompassing statutory carve-out for

employment arrangements as there is in the Anti-kickback Statute, there are several changes to the Stark Law that should be considered.

(a) Value-Based Purchasing and Alternative Payment Models

Hospitals and health systems need immediate guidance concerning the ability of a hospital to compensate physicians who assist the hospital under Medicare's Value-Based Purchasing Program ("VBP") or who participate in Alternative Payment Models ("APM") under the proposed MACRA regulations. It is difficult, if not impossible, for a hospital to achieve the desired goals under VBP or APM without physician input and cooperation. However, the fair market value of that input and cooperation is difficult to determine and hourly payment rates are often not reflective of the fair market value of the services actually being provided to the hospital by the physicians.

Hospitals need to be assured that utilizing a payment methodology that is based, in whole or in part, on the amount of the payment that the hospital or physician receives under VBP or APM will satisfy an exception to the Stark Law.

In addition, since 2001, the Office of Inspector General for HHS has provided Advisory Opinion Guidance on gainsharing arrangements. (*See,* OIG Supplemental Compliance Program Guidance for Hospitals, Part C "Payments to Reduce or Limit Services: Gainsharing Arrangements," 70 FR 4869–4870 (January 31, 2005).) However, CMS has failed to issue any type of formal guidance on gainsharing. The Stark Law should be amended to state unambiguously that a hospital that complies with the OIG's published guidance on gainsharing will satisfy the personal services exception to the Stark Law.

(b) Personally Performed Services

Hospitals would also benefit from further statutory clarification as to what constitutes "remuneration in the form of a productivity bonus *based on services performed personally by the physician* (or immediate family member)" when a hospital employs a physician directly. 42 CFR § 411.357(c)(4) (emphasis added).

For example, many physician groups use an incentive compensation model that is based on the group achieving certain goals. The bonus earned is then often divided equally between and among the physicians in the group. What is unclear is whether a hospital that employs physicians directly pursuant to 42 CFR § 411.357(c) is permitted to have a similar incentive compensation model that permits the employed physicians to share in the professional revenue generated by all of the physicians in a particular specialty. Such group-based specialties are common in physician organizations and encourage common goals. However, CMS has never provided guidance as to whether such a group-based incentive compensation model would be "based on services performed personally by the physician" for purposes of complying with 42 CFR § 411.357(c)(4).

(c) Non-Physician Practitioner

More and more care is being delivered by non-physicians such as nurse practitioners and physician assistants. However, these providers always must practice in collaboration with or under the supervision of physicians. Present law is unclear as to whether a hospital that directly employs physicians pursuant to § 411.357(c) and bills for the services of non-physician practitioners who are supervised by those employed physicians under the Medicare "Incident to Rules" is permitted to include that revenue in the hospital's compensation of the supervising physician. Such an arrangement is specifically permitted in a physician group that is organized and operated in a manner described in 42 CFR § 411.352. *See* 66 Fed. Reg. 876 (January 4, 2001).

However, despite the increase in the utilization of non-physician practitioners since 2001, when the Phase 1 rules were published, CMS has not updated the statement in the Preamble to the Phase 1 rules that stated that such payments are limited to physicians in a group practice organized and operated pursuant to 42 CFR § 411.352 or to physicians in solo practice (*see* 66 Fed. Reg. 891) and would not constitute "services performed personally by the physician" in the incentive compensation model of a hospital-employed physician for purposes of 42 CFR § 411.357(c)(4).

Therefore, we would recommend that the Stark Law should clarify that employed physician compensation may include credit for time spent for supervision of or collaboration with non-physician practitioners as well as credit for services performed by such practitioners.

(d) Fair Market Value Issues

Finally, hospitals and health systems recruit physicians in a national market. Hospitals often employ physicians in needed specialties, even if the patient population served by that hospital will not financially support that service. Such professional services are often needed to further the charitable purposes of the hospital regardless of the profitability of that service.

Hospitals that employ physicians also have limited ability to control the amount that they are paid by various third-party payors for the professional services provided by the employed physicians. As a result, it is not uncommon for a hospital to pay a physician more in compensation than the hospital will be reimbursed for the professional services that are provided by that physician. In many types of value-based and bundled payment models, it is difficult, if not impossible, to even determine if the hospital is losing money on the professional services being provided by the hospital.

While CMS mentioned "compensation arrangements involving 'mission support payments' and 'similar payments' ('support payments')" in the Preamble to the Phase 4 Rules (73 Fed. Reg. 48691 (August 19, 2008)), the Stark Law should be amended to make it clear that there is no presumption that a hospital or hospital-affiliated entity that compensates a physician an amount in excess of the reimbursement that is paid to the employer for that physician's professional services is compensating the physician in a manner that is based on, or takes into account, the volume or value of the physician's referrals to the hospital.

CMS should also make it clear that while salary surveys are excellent benchmarks, they are intended to be nothing more than a *benchmark.* No salary survey (or any specific percentile within a salary survey) should dictate the fair market value of a physician's services.

4. Conclusion

In his introductory remarks to the Comprehensive Physician Ownership and Referral Act of 1993, Congressman Stark stated that "the only way to protect health care consumers from unnecessary referrals is to impose a 'bright line rule.'" 139 Cong. Rec. E84–01 (January 6, 1993). While Representative Stark's intent was to create a bright line rule, the current state of the law is anything but that.

We believe that the Stark Law has outlived its usefulness and should be repealed, or at least substantially amended to repeal its prohibitions against compensation arrangements. In lieu of that, we would respectfully request that the Committee consider the above suggestions. Our recommended changes are provided in the hope that they will restore the "bright line" rules that were originally intended by the Law's drafters and permit hospitals and physicians to care for patients without federal interference and make the Stark Law less of a "booby trap rigged with strict liability and potentially ruinous exposure."

Sincerely,

Daniel M. Mulholland III
dmulholland@hortyspringer.com

PHYSICIAN HOSPITALS OF AMERICA (PHA)

Dear Chairman Hatch, Ranking Member Wyden, and Members of the Committee,

On behalf of the Physician Hospitals of America (PHA) and the more than 250 physician-owned hospitals (POHs) across the country, thank you for the opportunity to submit a statement for the record regarding reforms to the Stark Law. PHA offers support, advocacy, and educational services to the POH industry, reflecting at all times the best interests of the patients, physicians and other specialty providers who play an inextricable and essential role in the provision of health care services.

Currently, the Stark Law prevents POHs from competing on a level playing field with other hospitals, subjecting them to an onerous moratorium which prohibits their ability to expand to treat the growing population of Medicare and Medicaid patients in their communities. If POHs are able to fairly compete in the health care marketplace, patients will benefit through greater access to quality and affordable care, while the Medicare program will benefit through paying less for better outcomes. POHs are an important component of the health care system—ensuring competition, preserving physician autonomy, and promoting innovation. This anti-

competitive moratorium is bad for our health care system, bad for the Medicare program, and bad for patients.

Multiple independent, peer-reviewed studies and government quality ratings programs have demonstrated that POHs are centers of excellence, leading the way in quality, patient satisfaction, and cost. **The facts so clearly point to the high performance of POHs that the authors of a study in *BMJ,* titled "Access, Quality and Costs of Care at Physician-Owned Hospitals in the United States," concluded that there is "a need to re-examine existing public policies that target all hospitals with physician owners."** [1]

Based on these facts and the need for greater competition, higher quality outcomes, and reduced costs in the health care marketplace, Congress should allow POHs to compete on a level playing field with every other hospital in the country by enacting the reasonable, common-sense provisions included in H.R. 2513. This bipartisan legislation, introduced by Rep. Sam Johnson (R–TX), will improve and sustain the Medicare program by allowing existing POHs to expand to meet their communities' demand for high-quality, low-cost health care services.

Background

Physician ownership of hospitals has a long and distinguished history in this country. Physicians and surgeons often opened the first hospitals in communities and many of these POHs evolved into important medical centers that set new standards of excellence. The contemporary interest in POHs is the result of the physician's desire to return decisions regarding medical care back to healthcare providers and their patients.

In some cases, physicians have found themselves to be the buyers of last resort for hospitals that have been abandoned due to low profit margins, even though the community needed such a facility. Physicians are no longer allowed to save hospitals that are being abandoned by the very opponents of our industry.

Physicians have invested in a wide array of hospitals, including full-service community, rural, multi-specialty, surgical, rehab, orthopedic, cardiac, children's, psychiatric, and long-term acute hospitals. POH business models are equally diverse and include joint ventures with non-profit or for-profit community hospitals, joint ventures with development/management companies or other investors, and hospitals that are 100% physician-owned.

POHs provide high-quality care to millions of patients throughout the United States and bring many benefits to the communities in which they are located. Many POHs operate in Medically Underserved Areas (MUAs), serving as refuges for patients with otherwise limited options for healthcare services.

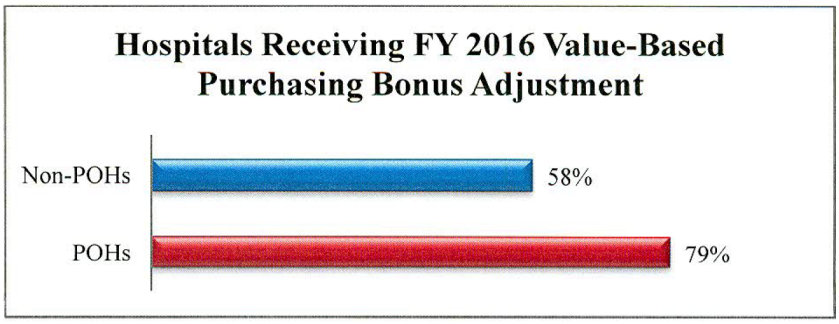
Government Ratings Programs

Hospital Value-Based Purchasing Program

Beginning in FY 2013, CMS established the Hospital Value-Based Purchasing (VBP) program to award and penalize hospitals across the country for quality of care. Medicare payments to the more than 3,500 participating hospitals are increased or reduced based upon performance in measured domains for care quality, including patient experience, outcomes, process of care and efficiency.

POHs consistently outperform their non-POH competition in the VBP program. In FY 2016, 7 of the top 10 hospitals in the program were POHs. Seventy-nine percent of POHs received a bonus payment adjustment, compared to only 58% of non-POHs.[2]

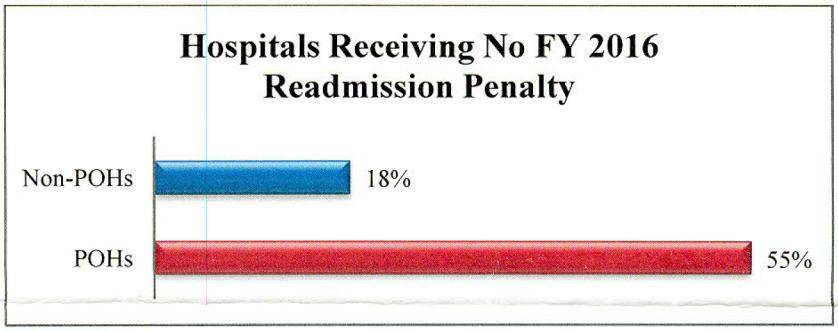
[1] *BMJ* 2015, 351: h4466.
[2] FY 2016 Final Rule, Correction Notices, and Consolidated Appropriations Act of 2016 Tables.



Readmissions Reduction Program

Effective on October 1, 2012, CMS reduces payments to hospitals participating in the Readmissions Reduction (RR) program for excessive readmissions of patients to a hospital within 30 days of a discharge.

As with the VBP program, POHs consistently outperform their non-POH counterparts. In FY 2016, 55% of POHs received no penalty for readmissions, compared to only 18% of non-POHs.[3]

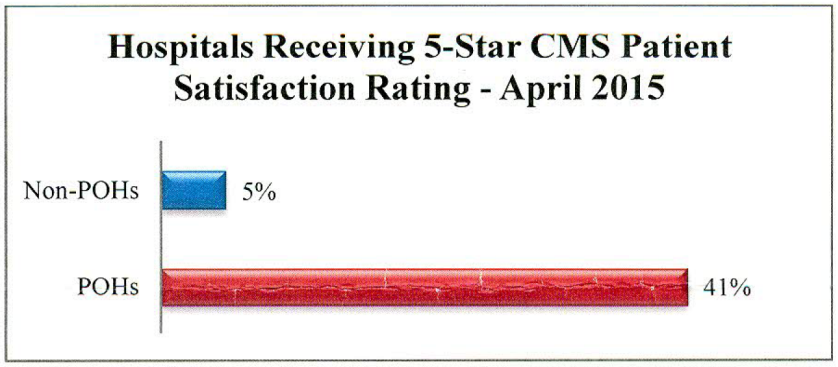


Star Ratings for Patient Satisfaction

In 2015, CMS began issuing summary star ratings for hospitals' patient satisfaction scores. The star ratings allow patients to compare performance between nearly 3,500 Medicare-certified hospitals on a wide array of metrics evaluated in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, including communication with nurses and doctors, pain management, staff responsiveness, care transition, hospital cleanliness and quietness, etc.

These star ratings are issued quarterly, beginning with April 2015. In each of the reported quarters thus far, POHs have displayed unparalleled patient satisfaction through their consistently high star ratings. The charts below demonstrate the superior performance of POHs in the April 2015 reporting period.[4]

[3] 2016 Hospital IPPS Final Rule and Correction Notices Impact Public Use File.
[4] CMS Hospital Compare website.



Academic Studies

"Cherry Picking" Myth

There are many unfounded myths about POHs that have been employed as reasons to restrict patient choice. One of the most commonly cited accusations is that POHs "cherry pick" healthier, more profitable patients. Recent research, however, shows that POHs treat similar patient populations as other hospitals. An independent, peer-reviewed 2015 *British Medical Journal* study found there are no "clinically or statistically significant differences in patient mix between POHs and non-POHs." The study found that "POHs and non-POHs admitted similar proportions of Medicare patients . . . Medicaid patients . . . Black patients . . . and Hispanic patients," as well as patients with "comparable numbers of comorbidities . . . and similar predicted mortality scores."[5]

Low Costs

Beyond debunking the "cherry picking" myth, this study also asserted that POHs perform as well or better than non-POHs in terms of cost. The study states, "Costs and Medicare payments at POHs were similar to, or lower than, those at non-POHs. Taken together, our findings suggest that most POHs are not outliers in terms of patients served, the quality of care provided, or their costs to the healthcare system."[6]

High Quality

Another recent academic study published in the *Journal of Hospital Medicine* further validated that POHs are high-quality facilities. The study, titled "Hospital Characteristics and 30-Day All-Cause Readmission Rates," found that "Physician partial or full ownership was significantly associated with lower readmission rates (P = 0.00); hospitals partially or fully owned by physicians had adjusted readmission rates 0.36 percentage points lower than non-physician-owned hospitals." The study's authors asserted, "Ownership aligns physicians' incentives with hospital performance and is therefore likely to be associated with better readmission rates."[7]

The Stark Law and the ACA

Despite this strong track-record of superior performance, POHs serving Medicare and Medicaid patients have been restricted from growing and expanding through a dramatic overhaul of the Stark Law Whole Hospital Exception, via adoption of the ACA in 2010. PHA strongly believes that the newly-revised Whole Hospital Exception is detrimental to the U.S. healthcare system, and Medicare and Medicaid beneficiaries most seriously. The following troubling aspects of the Whole Hospital Exception were neither necessary nor beneficial nor constitutional:

1. The prohibition in the newly modified Whole Hospital Exception, set forth at 42 CFR § 411.362(b), prohibiting billing and collecting for services referred by physician owners in a POH that did not have both Medicare certification and physician ownership prior to enactment of the ACA on March 23, 2010; and

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[5] *BMJ* 2015, 351: h4466.
[6] *Ibid.*
[7] Al-Amin, M. (2016), Hospital characteristics and 30-day all-cause readmission rates. J. Hosp. Med. doi: 10.1002/jhm.2606.

2. The prohibition on the ability of POHs to expand their critically necessary operating rooms, procedure rooms, and bed capacities except in extremely limited circumstances that are rarely applicable.

The foregoing restrictions have limited POHs from developing or expanding services in numerous rural and urban communities around the country where additional care is so desperately needed. In many instances, local community hospitals are simply not picking up the slack to provide the much needed services such that a great chasm exists in these communities where patients simply do not have access to the care they need. In most instances, if the Whole Hospital Exception did not include these two most troubling aspects, physicians who are so vested in the community would step in to purchase a failing hospital, or expand their existing hospitals, thereby bettering healthcare in the area and allowing the community to experience the acclaimed care that existing POHs provide. For these reasons, PHA strongly urges Congress to adopt legislation removing these troubling provisions of the Whole Hospital Exception.

H.R. 2513

Introduced by Rep. Sam Johnson (R–TX) with bipartisan support, H.R. 2513—the Promoting Access, Competition and Equity (PACE) Act of 2015—is an important, patient-centric piece of legislation that would improve patients' access to some of the highest quality, lowest cost hospitals in the country: POHs.

H.R. 2513 would address the most egregious aspects of the ACA moratorium on POHs by providing a reasonable pathway for higher quality POHs to apply for an exception to expand facility capacity and allow hospitals that missed the arbitrary deadline for Medicare certification as a POH to be grandfathered under the law.

Specifically, H.R. 2513 would:

- **Allow POHs to apply for expansion if they receive at least 3 stars from CMS in the new Summary Star Ratings program for hospitals over 3 consecutive years.** While the policy is common sense and is good public policy—tying expansion to quality outcomes and the overall patient experience—it should apply for *all* hospitals. Why should Congress allow a hospital that treats Medicare patients to expand if they provide poor quality of care? Hospitals that are 1- and 2-star facilities invariably are hurting patients physically as well as financially. They certainly cost Medicare more money. Why does Congress allow them unfettered expansion? Hospitals with physician ownership have offered to be held to a higher standard for quality of care, but all hospitals should submit to this concept as it would increase quality for all. This patient-first idea is indicative of the POH industry and we challenge those that disparage POHs to apply this requirement to themselves.
- **Grandfather two hospitals that were under development as POHs when the ACA was passed but were unable to meet the arbitrary Medicare certification deadline.**

Patients should be able to seek treatment at the hospital of their choice and Medicare should embrace hospitals that provide high quality care and that save the system money. H.R. 2513 will move us towards this goal by holding POHs to a high standard, ensuring the best outcomes for patients and thereby setting an example for the entire system.

Summary

Patients throughout the nation know the benefits of POHs firsthand. They choose to go to POHs because they know they will receive excellent care and have a stellar experience. Patients deserve the choice of a high-quality, low-cost facility, and that is what PHA and the POH industry are fighting to protect.

As POHs treat similar patient populations with higher quality outcomes, better patient experience, and lower costs of care, it is time for Congress to remove the onerous restrictions on POH expansion and give patients more freedom of choice in where they receive care. As the authors of the BMJ study stated, Congress should "re-examine existing public policies that target all hospitals with physician owners" and enact common sense reforms. To not act would be to perpetuate an unsound policy that is bad for patients and bad for Medicare.

Thank you again for the opportunity to submit this statement for the record. PHA looks forward to working with the Committee to allow POH expansion.

Sincerely,

R. Blake Curd, M.D.
CEO, Sioux Falls Specialty Hospital
President, Physician Hospitals of America

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July 25, 2016

U.S. Senate Committee on Finance
Hon. Orrin Hatch, Chairman
Hon. Ron Wyden, Ranking Member
Dirksen Senate Office Bldg.
Washington, DC 20510

RE: Hearing: "Examining the Stark Law: Current Issues and Opportunities"
Date: July 12, 2016

Dear Chairman Hatch, Ranking Member Wyden, and Finance Committee Members:

I am writing to urge the Committee embrace a go-slow approach as regards to the overhaul of Stark Law.

On July 12, several witnesses before your Committee suggested that the rules governing the federal anti-kickback statute (AKS) and the Federal False Claims Act (FCA) were adequate to keep doctors and hospitals walking the straight-and-narrow when it comes to medical procedures and billing.

I wish it were so.

The anti-kickback statute has numerous safe-harbor provisions which, absent the Stark Law, would allow hospitals to incentivize doctors in such a way as to create naked conflicts of interest which would inexorably lead to overutilization of expensive procedures done by specialized surgical centers.

If the Stark Law is gutted, the result will not just be bad economics and bad policy; it will also be bad medicine for patients.

It is worth reminding this Committee that it was its own investigations in the area of medical billing by physician-owned labs and centers that first illuminated the scope and nature of the problems that the Stark Law sought to address when it was passed by Congress in 1989.

Sadly, the rapacious nature of people and companies has not changed.

While the federal anti-kickback statute (AKS) and the Federal False Claims Act (FCA) are strong laws, they alone will not stop the core conduct that the Stark Law is designed to discourage, because they do not explicitly prevent the bundling of unreasonable compensation for services and tie them to incentives for doctor referrals and the number of procedures being performed.

One need only look at recent cases involving Stark Law violations tied to increased utilization of spinal implants and heart stents to see that if the Stark Law is swept away, billions of dollars will be lost in fraud, and scores of thousands of unnecessary and medically dangerous procedures are likely to be performed. How can this be done in the interest of patients and taxpayers? It cannot.

Yes, the world of health care is changing, and the future appears to be in some form of alternative payment system, but now these systems will work in the real world is not yet fully understood. One thing seems clear: so long as fee-for-service Medicare exists, U.S. taxpayers and patients are going to need Stark Law protection.

To be clear, no one is against increased efficiency in the health care arena, and no one is opposed to sweeping away unnecessary or redundant regulation. That said, the Stark Law is *not* one of those unnecessary or redundant regulations

In fact, it is *because* hospitals and doctors are so eager to enter into increasingly complicated remuneration arrangements that the Stark Law is needed now more than ever. As we have learned time and again in the False Claims Act arena, "in

the complexity is the fraud." By mandating a simple bright line standard, the Stark Law prevents a great deal of chicanery, and forces doctors and hospitals to review their contracts, their billing, and their relationships with an eye towards turning square corners.

We believe CMS is capable of reviewing, drafting, and updating rules governing Stark Law implementation with an eye towards ironing out problem areas where major fraud schemes are unlikely to be implicated or become established.

We urge this Committee to *not* throw out the baby with the bath water by moving too quickly or changing too much.

The private profit and corporate market forces that drive and encourage fraud, and which caused the Stark Law to be embraced in the first place, have not abated.

An ounce of caution at this juncture may be worth many billions in fraud prevented down the road—and many unnecessary and dangerous surgeries and procedures as well.

Sincerely,

Patrick Burns
Acting Executive Director

cc: Rep. Sander Levin, Ranking Member, and Rep. Kevin Brady, Chair of the Committee on Ways and Means

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TRINITY HEALTH
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Thank you for the attention the Committee has devoted to examining the effect the Stark Law has on the health care industry, in particular as it relates to the movement to alternative payment models (APMs). In this time of transformative change—in the way in which health care is paid for and delivered—we believe the thoughtful exploration by Congress of the issues is important for achieving the goals of delivering better health and better care at a lower cost, while protecting the health care industry from potentially devastating penalties.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation. It serves people and communities in 22 states from coast to coast with 91 hospitals, and 120 continuing care locations—including home care, hospice, PACE and senior living facilities—that provide nearly 2.5 million visits annually. Trinity Health employs more than 95,000 people, including 5,300 employed physicians. Trinity Health has committed to having 75 percent of its billings in value-based payment models by 2020, and is bringing this commitment to life as a participant in more than a dozen Medicare Shared Savings Program accountable care organizations (ACOs), a Next Generation ACO and deep involvement with the Bundled Payment for Care Improvement (BPCI) program.

The movement away from fee-for-service payments toward models that pay for better health, better care at lower cost naturally results in the need and motivation for hospitals and physicians to become financially connected. These alignments facilitate collaboration on quality improvement and efficient care coordination, the adoption of clinical best practices, and the achievement of better patient outcomes.

Trinity Health agrees that there are significant obstacles to accomplishing these goals within the current fraud and abuse legal structure, and the Stark Law is specifically hindering Trinity Health's progress towards achieving 75 percent of its billings in value-based models by 2020. As the Committee recognizes in its white paper, *Why Stark, Why Now?,* the Stark Law was enacted to combat behavior in a fee-for-service health care world. The Stark Law has become increasingly unnecessary for—and is a significant impediment to—value-based payment models that Congress, the Centers for Medicare and Medicaid Services (CMS), and commercial health insurers have now promoted. We generally agree with many of the suggestions that roundtable panelists offered to address the Stark Law and would like to highlight a few suggestions we think have critical importance.

A. Create an APM Exception

Within the Stark Law's existing structure, Congress could create an exception specifically addressing the new population-based/alternative payment model (APM) sys-

tem. This exception would apply to the financial relationships between any provider or supplier that participates in an APM. Providers and suppliers that willingly participate in an advanced payment model should be entitled to relief from the regulatory burdens imposed by Stark. The exception could require certain criteria such as being a Qualifying APM Participant provider, which is a provider that receives a percent of their payments or patients through an eligible alternative payment entity (a QP). If the provider is a QP, then any financial relationship between two or more QPs would satisfy the exception.

This new exception is needed because, under the current law, any compensation relationship between a Designated Health Services (DHS) entity and a physician needs to meet an exception. When the APM payment bundles both the hospital's facility and the physicians' professional services reimbursement, it is unclear whether any of the current Stark Law exceptions apply to protect the financial arrangements between the hospital and physicians (as well as potentially other providers and suppliers) that are necessary to divide up the APM payment.

Furthermore, under the potentially applicable exceptions, the Stark Law requires that the compensation be fair market value and limited to the physician's personally performed services. The most common method for calculating physician compensation now is using Work-RVU (Relative Value Unit) values for their personally performed services. As payment models change to APMs, however, physicians will likely see a decrease in their Work-RVU performance over time. As APMs become predominate, health systems and hospitals will face uncertainty as to how to continue to pay physicians when those services do not directly translate into a Work-RVU. It is unclear about how to measure the fair market value of services when those services involve meeting quality outcome goals to enable the hospital to qualify for incentive payments. Even more unclear is how to calculate the value of services *not provided* by a specialty physician because a population's health has been better managed through better preventative or primary care.

For example, one way for an integrated delivery system to manage population health and preventive care is greater use of non-physician professionals, such as nurse practitioners and physician assistants. Historically physicians often resist greater use of non-physician professionals because that results in a decrease in the number of services that the physician performs, which in turn impacts physician compensation. Yet, team-based care is becoming more common and more essential from a clinical integration/population health perspective. To ensure high-quality and coordinated care, it is desirable for a primary care physician to work closely with multiple non-physician professionals. Under the Stark Law's existing structure, the professional's productivity could not be a factor in the compensation arrangement with the physician even though the physician is required to oversee the care delivered by the non-physician professional. Yet, encouraging this team approach would greatly expand access and lower the cost of delivering care without diminishing quality.

Conclusion: Creating an APM exception could provide protection for the financial relationships between hospitals, physicians, and other providers and suppliers that are necessary to coordinate care and allocate compensation within the construct of an APM. The exception could apply to payments from an entity concerning cost savings, quality measure achievement, and other population health management goals. Having a clear exception that applies to employed and independent physicians would enable hospitals and integrated delivery systems to have uniform compensation models with their physicians and facilitate a team approach to patient care delivery.

In order for this APM exception to work, it would need to (1) eliminate any fair market value requirement (for the reasons discussed above); and (2) permit payments that reflected or varied with the volume or value of DHS. For example, cost savings per admission would be a reasonable compensation metric to include in an arrangement implementing an APM with a physician, even though the payment amount would naturally vary depending on the physician's admission volume or value. The gainsharing civil monetary penalty law already prohibits payments to reduce medically necessary services and should provide sufficient incentives for the providers and suppliers to structure the relationships in compliance with that law. We believe that the statute should permit flexibility in designing the standards or matrix for achieving the savings. Clinical practice and evidence-based medicine is ever-evolving. The exception could require providers maintain clear documentation of the standards used and their application in calculating payment amounts to ensure

transparency to the government. But, too strictly prescribing what standards can be used could result in an unworkable rule.

B. Remove or Clarify the Meaning of Commercial Reasonableness

In recent cases, the Department of Justice (DOJ) appears to have taken the position that commercial reasonableness relates to the economic terms of an arrangement, such as whether there is a "practice loss" because the physician's professional collections do not cover the physician's compensation. This position has created considerable concern among hospital/health systems regarding their employment of physicians. This position seems inconsistent with the legislative intent.

To illustrate this concern, a system may decide to acquire a physician practice for a variety of reasons, such as to ensure that the system has a physician network which satisfies the network adequacy requirements applicable to Medicare Advantage plans. In other words, if a hospital system desires to have a contract with a Medicare Advantage plan then it often needs to have a network of providers that is attractive to the plan and that meets applicable adequacy requirements. The Medicare Advantage plan then pays the hospital network a capitated payment. In this context, it is difficult to determine whether the hospital system is "subsidizing" the acquired physician practice. As we move further toward capitated payment arrangements and bundled payments in both the commercial and federal context, distinguishing between professional and technical revenue loses relevance in the actual operation of a system, especially when new payment methodologies eliminate these categories.

"Losses" on physician practices are so commonplace that the leading survey company, Medical Group Management Association (MGMA), tracks data on the average practice loss from hospital-owned practices by specialty.[1] Simply put, the position that any "loss" from a physician practice violates the Stark Law is not reasonable or realistic, and could expose many hospitals to enormous penalties.

The better reading of the employment exception's language[2] suggests that the purpose of this requirement relates to the non-economic or non-payment aspects of the arrangement; in other words, that the "arrangement" be commercially reasonable, not the "remuneration." Examining an employment arrangement for commercial reasonableness involves ensuring the employment was bona fide and that the employer needed the services of the employee, separate from whether the employee made referrals to the employer. Whether the compensation amount is appropriate is addressed in the separate fair market value and volume/value requirements.

Conclusion: Congress should remove the commercial reasonableness requirement from the Stark Law, or clarify that commercial reasonableness is connected to analyzing the bona fide nature of the arrangement and not the remuneration. An affirmative statement in the Stark Law that states operating losses in a physician practice owned by a DHS-entity are not commercially unreasonable, would be helpful as well.

C. Expand CMS Authority to Create Waivers and Exceptions

As roundtable participants noted, the current authority of CMS to create waivers and exceptions is limited and should be expanded to provide CMS with greater flexibility to address APMs, regardless of how they are created. In addition, the statutory authority of CMS to create new regulatory exceptions is limited to arrangements that do "not pose a risk of program or patient abuse," 42 U.S.C. § 1395nn(b)(4). Because this standard is so strict, CMS cautiously creates exceptions that are narrowly drafted, and thus not truly useful for the health care industry.

Conclusion: To aid CMS in achieving its goal of shifting a greater percentage of revenue to APMs, Congress should adjust the Stark Law to provide CMS expanded authority to create waivers and exceptions for arrangements that do not pose a significant risk of program or patient abuse.

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[1] MGMA survey data for 2014 reported a median loss of $176,153 per physician for integrated delivery/health system owners of multispecialty practices (primary and specialty care).

[2] The statute's phrasing is slightly different than the regulation, but also consistent with the above interpretation that the requirement speaks to the non-payment aspects of the relationship. Compare "the remuneration is provided *pursuant to an agreement which would be commercially reasonable* even if no referrals were made to the employer" (emphasis added) (42 U.S.C. § 1395(e)(2)) with "the remuneration provided *under an arrangement that would be commercially reasonable* even if no referrals were made to the employer" (emphasis added) (42 CFR § 411.357(c)(3)).

D. Sunset the Stark Law

At its most basic level, the Stark Law is incompatible with APMs. The intended purpose of the Stark Law was to limit Medicare over-utilization caused by financial incentives rather than the medical needs of the patient. These financial incentives were based on a fee-for-service system where physicians and other providers made more money by ordering or providing more DHS. APMs alter that system and those incentives entirely, which may be more effective to controlling the over-utilization risk with which Congress was concerned and the Stark Law was enacted.

Conclusion: We recommend that the Stark Law sunset entirely once a certain percentage of Medicare payments are made through APMs.

We truly appreciate the opportunity to engage in this discussion on this critical topic, and hope that our perspective is helpful in your important work. We encourage the Committee to take action to reform the Stark Law in ways recommended herein, and stand ready to provide additional information if helpful to the Committee's work. Please contact Tonya Wells, Vice President, Federal Public Policy and Advocacy, at (734) 343–0824 or wellstk@trinity-health.org if you have any questions.

STATEMENT FOR THE RECORD BY SCOTT C. WITHROW

July 15, 2016

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Hon. Orrin Hatch, Chairman
Hon. Ron Wyden, Ranking Member

Re: Full Committee Hearing—"Examining the Stark Law: Current Issues and Opportunities"

Dear Chairman Hatch, Ranking Member Wyden, and Members of the Committee:

Thank you for your interest in examining the Stark Law. I respectfully submit this statement on the Stark Law for your consideration and for the hearing record. I am a founding partner of the law firm of Withrow, McQuade and Olsen, LLP and have practiced healthcare law for 32 years. I authored two books entitled *Managing Healthcare Compliance* (1999) and *Managing HIPAA Compliance* (2001), both published by Health Administration Press, a division of the American College of Healthcare Executives. I have nationally recognized expertise in the areas of the federal anti-kickback and physician self-referral laws ("Stark") and I speak frequently on those subjects. My views are my own and not on behalf of my law firm, any client or organization.

Chairman Hatch posed the ultimate question in his opening statement: "Is the Stark Jaw still necessary?" The answer is an emphatic YES!

The Stark Law Remains Necessary to Regulate Risks of Program and Patient Abuse

The Stark Law was first adopted in 1989 to regulate physician ownership of clinical laboratories and was expanded in 1993 to regulate referrals of designated health services. The Stark Law addressed overutilization of services by physicians who stood to profit from referring patients to facilities or entities in which they had a financial interest. The Stark Law was enacted in the wake of several reports suggesting that physicians with a financial interest in referrals tended to provide excess care. For example, in 1989 the Office of the Inspector General for the Department of Health and Human Services ("HHS") issued the results of a study that found that "patients of referring physicians who own or invest in independent clinical laboratories received 45% more clinical laboratory services than . . . Medicare patients in general." [1] Later studies showed significant increases in referrals by physicians with financial interests (either due to ownership or receipt of bonuses) for

[1] Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals,* 27 Law and Psychol. Review 1, 5 (2003).

such things as X-rays (16%), physical therapy and rehabilitation (39–45%), MRI scans (54%) and CT scans (27%).[2]

While federally reimbursed healthcare is undergoing a gradual shift to value-based and other alternative payment mechanisms, roughly 70% of Medicare payments remain fee-for-service.[3] Fee-for-service reimbursement will continue to comprise a major portion of Medicare payments for many years to come. The Stark Law remains needed in fee-for-service reimbursement to regulate the risks of Medicare program abuse whenever physicians have financial interests tied to referrals.

Advances in medical technology and procedures may have actually increased the risks of patient abuse whenever physicians have financial interests tied to referrals. Disturbing evidence of overutilization of invasive procedures such as spinal fusions[4] and cardiac stents[5] is mounting. This Committee has recently examined the dangers of physician-owned distributorships ("PODs") that derive revenue from selling implantable medical devices ordered by their physician owners and are prevalent in the field of spinal surgery.[6] This Committee's Majority Staff Report summarized the dangers of physicians' financial interests:

> Surgeons have a unique and powerful role in influencing both patient and medical practice decisions. When a surgeon recommends surgery, patients are strongly inclined to follow their doctor's recommendation. Within the field of spinal surgery, spinal fusions are among the most serious and costly types of back surgery, and are typically only recommended for patients with the most serious back problems. Spinal implants are generally "physician preference," meaning hospitals typically purchase the devices recommended by their surgeons. Spinal surgeons therefore have significant influence over both the frequency of spinal fusion surgeries and the devices used in those surgeries.
>
> Unchecked, this position of power can give POD spinal surgeons the opportunity to grant themselves a steady stream of income by increasing the use of the products supplied by their POD. PODs present an inherent conflict of interest that can put the physician's medical judgment at odds with the patient's best interests.[7]

The Committee's Majority Staff Report also exposed troubling findings of overutilization of spinal fusion procedures, including:

> 1. POD surgeons saw significantly more patients (24% more) than non-POD surgeons.
>
> 2. In absolute numbers, POD surgeons performed fusion surgery on nearly twice as many patients (91% more) than non-POD surgeons.
>
> 3. As a percentage of patients seen, POD surgeons performed surgery at a much higher rate (44% higher) than non-POD surgeons.
>
> 4. In absolute number, POD surgeons performed nearly twice as many fusion surgeries (94% more) as non-POD surgeons.[8]

Overall, the Committee's Majority Staff Report found that POD surgeons performed nearly 15 percent of spinal fusions billed to Medicare while making up only 8 percent of the total spinal fusion surgeons who billed to Medicare in 2011.[9] The Committee's Majority Staff Report recommended that HHS OIG and law enforcement should investigate potential violations of the Stark Law.[10] Thus, the Stark Law re-

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[2] *Id.* at 6.

[3] *http://www.hhs.gov/about/news/2016/03/03/hhs-reaches-goal-tying-30-percent-medicare-payments-quality-ahead-schedule.html* (last viewed July 13, 2016).

[4] *https://allmedmd.com/landing-pages/Spinal-Fusion-WP.pdf* (last viewed July 14, 2016); *http://www.cbsnews.com/news/tapping-into-controversial-back-surgeries* (last viewed July 14, 2016).

[5] *https://allmedmd.com/collaboration/articles/allmed-articles-1/addressing-overutilization-in-interventional-cardiology-catheterization-stent-placement* (last viewed July 14, 2016); *http://www.usnews.com/news/articles/2015/02/11/are-doctors-exposing-heart-patients-to-unnecessary-cardiac-procedures* (last viewed July 14, 2016); *http://www.nytimes.com/2015/01/30/business/medicare-payments-surge-for-stents-to-unblock-blood-vessels-in-limbs.html* (last viewed July 14, 2016).

[6] Senate Finance Committee Majority Staff Report, *Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern, http://www.finance.senate.gov/imo/media/doc/Combined%20PODs%20report%202.24.16.pdf* (last viewed July 14, 2016).

[7] *Id.,* at 1 (internal footnotes omitted).

[8] *Id.,* at 14–15.

[9] *Id.,* at 15.

[10] *Id.,* at 25.

mains a critical tool for protecting patients from possible abuse when physician decision-making may be compromised by the physician's personal financial interests.

Stark Law Should Continue to Provide Important Regulation of Physician Compensation

The three hearing witnesses quickly retreated from recommending full Stark Law repeal and admitted that Stark Law should continue to regulate physician ownership arrangements. However, the witnesses recommended the elimination of all Stark Law regulation over physician compensation arrangements because regulation provided by the federal anti-kickback statute ("AKS") and the Federal False Claims Act ("FCA") would be adequate. I strongly disagree with this recommendation because Stark Law provides important regulation of physician compensation that is not present under AKS and FCA alone.

AKS, which was first enacted in 1972 well before the Stark Law, is a criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business, whether a physician is involved or not. Congress mandated in 1987 that the regulators adopt safe harbor regulations to give healthcare providers assurance that normal arrangements would not fall within the broad reach of AKS. In particular, regulators adopted a very generous AKS safe harbor for employees which permits "any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer."[11] Under this AKS safe harbor for employees, the hospital can pay an employed neurosurgeon "any amount" including amounts or bonuses that might incentivize the neurosurgeon to overutilize spinal fusions.

Medicare fee-for-service reimbursement provides hospitals with strong motivation to employ high-producing neurosurgeons because Medicare rewards hospitals with lucrative facility fees for inpatient spinal fusions. For example, when a neurosurgeon performs a spinal fusion under CPT® code 22633 ("lumbar spine fusion combined") as the lead surgeon, Medicare Part B would allow a total reimbursement for the facility-based physician service of $1,864.92 (54.79 RVUs × $34.0376—geographically unadjusted) in fiscal year 2012. Medicare Part A would also pay the hospital a facility fee for the inpatient spinal fusion procedure. For example, in fiscal year 2012, Medicare paid Mission Memorial Hospital in Asheville, North Carolina average Medicare payments of $22,805.62 for each of 286 instances of Diagnosis-Related Group ("DRG") 460—Spinal Fusion Except Cervical without Major Complication/Comorbidity for facility fees on a fee-for-service basis.[12] Mission Memorial Hospital received from Medicare a total of $6,522,407.32 in facility fees for spinal fusions under one DRG code, DRG 460, in one fiscal year.

The Stark Law provides regulation focused on physician financial relationships to protect against the risks of program and patient abuse when an inherent conflict of interest is present that can put the physician's medical judgment at odds with the patient's best interests. Like AKS, the Stark Law allows compensation arrangements between hospitals and employed physicians, but with three critical and additional regulatory protections. The amount of the remuneration under the employment must be:

1. Consistent with the fair market value of the services;[13]

2. Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician;[14] and

3. The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.[15]

HHS regulators have previously and rightly determined that these three regulatory protections are necessary to protect against the risks of program and patient abuse when an inherent conflict of interest is present that can put the physician's medical judgment at odds with the patient's best interests. These three regulatory protections do not exist under AKS and FCA alone. The recommendation to limit the Stark Law to ownership arrangements only would expose taxpayers and patients to

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[11] 42 CFR § 1001.952(i) (2016).

[12] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Inpatient2012.html* (last viewed July 14, 2016). In fiscal year 2012, Mission Memorial Hospital billed Medicare for DRG 460 more often than any other hospital in the State of North Carolina and 4th most in the entire United States.

[13] 42 CFR § 411.357(c)(2)(i) (2016).

[14] 42 CFR § 411.357(c)(2)(ii) (2016).

[15] 42 CFR § 411.357(c)(3) (2016).

abuse resulting from inappropriate compensation arrangements. The Stark Law should continue to provide these three important regulatory protections on physician compensation arrangements.

Stark Compliance Costs Are Justified and Affordable

Dr. Ronald A. Paulus, President and Chief Executive Officer of Mission Health System, complained during the hearing about spending "millions" for Stark compliance and review of physician contracts which provide no more protections than kickback law already provides. I question whether Mission Health really spends "millions" on Stark compliance, but even if it did the risk of program and patient abuse justifies the expense. As noted above, Stark Law most definitely provides three important regulatory protections on employed physician compensation that are not provided by AKS and FCA alone.

Healthcare entities such as Mission Health and Johns Hopkins Health System can easily afford Stark compliance costs. Many healthcare entities, including Mission Health and Johns Hopkins Health System, are exempt from federal taxes in the first place. Moreover, these entities have amassed huge treasure chests during the era of fee-for-service reimbursement. For example, Mission Health, which provides 75% of its care to Medicare or Medicaid beneficiaries or to the uninsured, accumulated $940 million in cash and investments as of September 30, 2015.[16] Johns Hopkins Health System had cash and investments totaling $2.792 billion as of March 31, 2016.[17] Healthcare entities can easily afford the Stark Law compliance costs which are necessary to provide taxpayers and patients with reasonable protections against abuses resulting from conflicts of interests inherent in physician financial arrangements.

The Stark Law Exception for In-Office Ancillary Services ("IOAS") Should Be Retained

I oppose the recommendation of Troy A. Barsky to limit the IOAS exception to the Stark Law due to abuse well beyond the original intent of the exception. The IOAS exception itself contains a number of regulatory protections limiting the exception based on who[18] and where[19] the service is performed and how the service is billed.[20]

More importantly, the real value of the IOAS exception in the healthcare industry is in the context of Stark-compliant physician group practices. The Stark Law provides additional regulatory protections limiting abuse of the IOAS exception within the definition of "group practice," including eight regulatory requirements for a Stark-compliant physician group practice.[21] In particular, the definition of a Stark-compliant group practice prohibits a physician from directly or indirectly receiving compensation based on the volume or value of his or her referrals unless the compensation arrangement complies with special rules for profit shares and productivity bonuses.[22] Many Stark-compliant physician group practices appropriately utilize the IOAS exception by designing compensation arrangements in compliance with the special rules for profit shares and productivity bonuses. These physician group practice compensation methods are especially important in states where corporate practice of medicine doctrine prohibits hospital employment of physicians, such as California. I believe the existing IOAS exception combined with the existing definition of a Stark-compliant physician group practice strike the right balance of allowing flexible and even productivity-based compensation arrangements while still providing regulatory protection against program and patient abuse.

Simplify the Existing Stark Exception for Community-Wide Information Systems

While not the subject matter of the Stark Law hearing, I would also like to share with the Committee a recommendation that I made to regulators at the U.S. Department of Commerce for improving the Stark Law and removing a barrier to real-

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[16] Mission Health System, Inc, Annual Continuing Disclosure per Loan Agreement section 5.06, Selected Utilization and Financial Information, *http://emma.msrb.org/EP906235-EP702606-EP1104565.pdf* (last viewed July 14, 2016).

[17] The Johns Hopkins Health System Corporation and Affiliates, Quarter End Report, Three and Nine Months Ended March 31, 2016 and 2015, *http://emma.msrb.org/ER962785-ER752998-ER1154544.pdf* (last viewed July 14, 2016).

[18] 42 CFR § 411.355(b)(1) (2016).

[19] 42 CFR § 411.355(b)(2) (2016).

[20] 42 CFR § 411.355(b)(3)(2016).

[21] 42 CFR § 411.352(a)–(h) (2016).

[22] 42 CFR § 411.352(g) and (i).

izing the benefits in healthcare from the development of the Internet of Things ("IoT").[23]

By 2025, the total global worth of IoT technology could be as much as $6.2 trillion, with roughly 40% of that value from devices in healthcare ($2.5 trillion).[24] IoT value in healthcare will greatly benefit patients, the Government, and the taxpayers by increasing healthcare quality and reducing healthcare costs.

AKS and the Stark Law stand as major barriers to the realization of IoT benefits in healthcare. In 2004, the Centers for Medicare and Medicaid Services ("CMS") created a regulatory exception to the Stark Law for community-wide information systems.[25] However, the Stark exception for community-wide information systems has not been useful to date because there is no corresponding anti-kickback safe harbor for community-wide information systems. In order to foster IoT development and deployment in healthcare, the Government should adopt a new anti-kickback safe harbor for community-wide information systems that corresponds to the existing Stark exception.[26]

The existing Stark exception for community-wide information systems is fairly straightforward, with only three conditions for the exception to apply:

1. The information technology items and services are available as necessary to enable the physician to participate in the community-wide health information system, are principally used by the physician as part of that system, and are not provided in a manner that takes account of referrals or other business generated by the physician;

2. The community-wide health information system is available to all providers, practitioners and residents in the community who desire to participate; and

3. The arrangement does not violate the anti-kickback statute or any billing or claims submission laws or regulations.

IoT includes information technology items and services that enable the physician to participate in information systems. The Stark exception requires that the information system be "community-wide" and "available to all providers, practitioners and residents in the community who desire to participate." These requirements conflict with the common concerns in healthcare over privacy and security of individually identifiable healthcare information. The Stark exception also requires that the information technology items and services "are principally used by the physician," which excludes IoT devices principally used by patients themselves, physician extenders or other non-human things. The third condition about not violating the anti-kickback statute is problematic until a corresponding anti-kickback safe harbor is created. The Stark exception would be even more useful for IoT if it was further simplified to only one condition:

1. The information technology items and services are available as necessary to enable the physician to participate in a health information system, and are not provided in a manner that takes account of referrals or other business generated by the physician.

I recommend simplifying the existing Stark exception for community-wide information systems as suggested above, and then adopting a new corresponding anti-kickback safe harbor. These simple steps would remove major barriers to the realization of trillions of dollars in value from IoT in healthcare.

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[23] *https://www.ntia.doc.gov/federal-register-notice/2016/comments-potential-roles-government-fostering-advancement-internet-of-things* (last viewed July 14, 2016).

[24] *http://www.intel.com/content/www/us/en/internet-of-things/infographics/guide-to-iot.html* (last viewed May 18, 2016).

[25] 42 CFR § 411.357(u) (2016); adopted at 69 Fed. Reg. 16054, 16112–16113 (March 26, 2004).

[26] Section 205 of the Health Insurance Portability and Accountability Act of 1996 requires the Government to annually solicit recommendations for developing new anti-kickback safe harbors, although the comment period for the most recent annual solicitation has closed. 80 Fed. Reg. 79803 (Dec. 23, 2015).

I appreciate your consideration of these comments. Please feel free to contact me if I can provide any additional information (404–814–0037 or swithrow@wmolaw.com).

Sincerely,

Scott C. Withrow

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