Ronald A. Paulus, MD
President and CEO

Testimony
Before the Senate Finance Committee
July 12, 2016

Ronald A. Paulus, MD
President and Chief Executive Officer,
Mission Health System

Reform of the Physician Self-Referral Law
In a Value-based, Pay for Performance Era

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 eighteen 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 four 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

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

509 Biltmore Avenue, Asheville, North Carolina 28801 | 828-213-1111 fax (828) 213-1151 | mission-heath.org

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.

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 US 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

[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).

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

[3] See, for example, the exception for rental of office space at fair market value found at 42 U.S.C. Sec. 1395nn(e)(1)(A)(ii)(2006).
[4] While the statute itself does not contain this provision, some safe harbors do. *See* 42 C.F.R. §§ 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).

majority of practice at our hospitals. Furthermore, we 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

[6] 42 U.S.C. Sec. 1395nn(e)(2)(B)(ii) (2006).

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. ACO's are able to avoid many of the problems I described because they can apply for certain fraud and abuse waivers. Allowing entities other than ACO's to invoke waivers if they are using APM's 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 APM's; 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 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

---

[7] Report at 10.
[8] Stark II Phase V, IPPS regulations, Oct. 30, 2015.

acquired self-disclose such minor findings after our acquisition due diligence. They spent nearly two 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 four 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.

---

[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.* 38,502, 38,604 (proposed July 7, 2008))

509 Biltmore Avenue, Asheville, North Carolina 28801 | 828-213-1111 fax (828) 213-1151 | mission-heath.org

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.