HEARING BEFORE THE HOUSE WAYS AND MEANS HEALTH SUBCOMMITTEE ON MODERNIZING STARK LAW TO ENSURE THE SUCCESSFUL TRANSITION FROM VOLUME TO VALUE IN THE MEDICARE PROGRAM

July 17, 2018

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Chairman Roskam, Ranking Member Levin and Members of the Subcommittee, thank you for the opportunity to appear before you today to address the critical role that the Stark Law plays in ensuring the integrity of decision-making in federal healthcare programs in order to protect patients and the taxpaying public.

I am a partner in the law firm of Phillips and Cohen LLP, which specializes in representing whistleblowers under the federal and state False Claims Acts. I offer this testimony on behalf of Taxpayers Against Fraud Education Fund, ("TAFEF") a nonprofit organization that provides education about the False Claims Act, which is the Government's primary tool for identifying and pursuing fraud against the Government. TAFEF and its members have a strong interest in supporting laws, such as Stark, that protect the integrity of decisions involving taxpayer funds in the healthcare industry and elsewhere.

The topic of today's hearing is the proposed need for modernizing Stark, the physician self-referral law, and possible changes in the law to increase the ability of the Medicare program to successfully move to a system that rewards higher value, coordinated health care. We submit that Stark is not an impediment to the ability of the Medicare program to successfully move to a system that rewards higher value, coordinated care. The move to value-based and coordinated care does not eliminate the fundamental concern at the core of Stark – limiting the role that profit plays in healthcare decisions affecting individual

patients and subsidized in large part by the taxpayers. The proposals to amend Stark to prevent it from interfering with value-based care and integration involve few specifics and seem to be a solution in search of a problem. Before proposals to amend the law advance, we recommend that the Subcommittee carefully examine the claimed barriers to modernization and whether mechanisms do not already exist to address them. In addition, the Subcommittee should carefully examine whether the proposed "fixes," which involve exempting various providers and unspecified arrangements from a critical anti-fraud law, would allow conflicts of interest to infect medical decision-making. Years of deliberate evaluation have produced substantial gains in reducing the role of provider financial self-interest in delivering patient care funded by the Government. A careful and deliberative approach to legislation should be taken to ensure that progress continues and is not undermined.

As you know, the Stark Law was first introduced by then-Chair of this Subcommittee, Representative Pete Stark, and was enacted by Congress in 1989. The law, which has subsequently been amended to include additional areas of concern as well as to identify exceptions, seeks to prevent physician financial self-interest from interfering with medical decision-making in taxpayer-funded healthcare programs. It has long been clear that financial conflicts of interests present risks of overutilization and decision-making that is not focused foremost on the appropriate care to be provided to individual patients.

The Stark model for constraining conflicts of interest is a familiar one. As in many areas of the law that address conflicts of interest in order to ensure integrity in decision-making, Stark contains a broad prohibition on certain kinds of conduct without regard to whether any particular decision results in the harm to be addressed. In order to prevent

conflicts of interest, the law tends to sweep broadly and tolerate some amount of overbreadth because the underlying goal of integrity is so important. Individual decision-makers may feel that they can be trusted to make choices without regard to their personal financial interest, but the law removes that calculus by creating a strict prohibition on conduct that presents a substantial risk.

As is also typical in conflict of interest laws, Stark contains a number of exceptions to the broad rule and provides safe harbors for persons who can demonstrate that their conduct does not run afoul of the prohibition. In recognition of circumstances in which financial relationships might be unrelated to the financial interest in referrals, Congress crafted specific exceptions to Stark's broad prohibition. Congress also authorized the Department of Health and Human Services to develop these exceptions through regulations, which the agency has done over the years in close consultation with the medical community. In addition, members of the regulated community who have questions about whether their conduct fits within one of the exceptions may seek an advisory opinion from HHS. The agency also issues additional guidance on the application of Stark to specific situations.

Stark has been an important part of the Government's efforts to protect patients and the federal fisc. In the last several years, the Government has recovered substantial sums in cases brought against hospitals and other providers for violating Stark:

- In 2014 the Government settled a Stark case with Halifax Hospital System in Florida for $85 million to resolve allegations that the hospital had entered agreements with oncologists that compensated them based on value of prescription drugs and tests they ordered and the Hospital billed to Medicare.

- In 2015 the government settled a Stark case with Tuomey Hospital in South Carolina. The Government had obtained a $237 million judgment against hospital for paying above fair market compensation

to physicians who referred patients to its hospital, despite warnings from the hospital's own lawyers.

- In 2015, the Government entered into a settlement with Adventist Health Systems for $115 million to resolve allegations that hospitals owned by Adventist were compensating physicians based on a formula that took into account the value of referrals to the hospitals.

As the Department of Justice has stated, these cases illustrate the importance that the Government places on ensuring that healthcare decisions are based upon patient interest and not the financial interests of providers. These were not cases involving allegations of technical violations or mistakes. Each of these cases could no doubt be described as a situation in which the entity sought to provide value and improve coordinated care and that Stark impeded the ability to deliver it. But they are also situations in which the hospitals were paying large amounts of money to providers who referred Medicare or Medicaid business, creating the risk that financial self-interest took precedence over the interests of individual patients.

Notably, each of these cases was brought to the Government's attention by whistleblowers under the federal False Claims Act. Whistleblowers inside healthcare organizations have been able to bring the Government information it would not have otherwise learned about schemes that have been created to circumvent or ignore Stark. The deterrent effect of these cases is even greater than the amount of money recovered for the Government, as the strong message these cases send ensures greater awareness of Stark and more attention paid to compliance.

The damages and penalties for violation of Stark are potentially high, but they are high for a reason. The Government makes clear the importance of the integrity of healthcare decision-making funded with public money by declining to pay for any services that were

provided in violation of Stark. As one court put it, the Government offers a subsidy based on complying with this condition, and if the condition is not met, no subsidy is due. The purpose of the strict liability approach and the significant financial consequences that follow from a violation is to ensure that individuals do not engage in the prohibited behavior. The cost of ensuring compliance with the law has sometimes been presented as a cost to the healthcare system overall, with the implicit suggestion that healthcare costs would be lower if less money were spent on compliance. We submit that the costs to the healthcare system of allowing the prospect of financial gain to drive decisions affecting the expenditure of public healthcare dollars would be far greater.

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In summary, we may all agree that value-based coordinated care is a desirable goal if it results in better patient care and better use of federal healthcare dollars. We may all believe that the vast majority of hospitals and other healthcare providers care primarily about patients and do not intend to place their own economic interests ahead of patient care and fiscal responsibility. We may all want to foster innovation. But we should not lose sight of the fact that healthcare is a business and is motivated by profit. History has shown that doctors, hospitals, and other healthcare providers are not immune to self-dealing. The temptation of financial reward can distort or corrupt decision-making and that is particularly a problem when the money being spent is taxpayer money and patient health is at stake. Paying for value or coordinating care does not eliminate the risk that the profit motive will cause health care providers to overlook or ignore the interests of patients. While there may be specific issues that have arisen under the Stark Law that are worthy of examination, the Subcommittee should carefully evaluate specific, concrete problems and hear from all

stakeholders before proposing changes that could undermine one of the Government's most valuable tools for protecting taxpayer dollars and the integrity of healthcare decision-making.