STATEMENT OF

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ON

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

BEFORE THE

U. S. HOUSE WAYS AND MEANS COMMITTEE
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As Prepared for Delivery

Chairman Roskam, Ranking Member Levin, it's great to be here today. As many of you here know, Secretary Azar has outlined four priorities for the department: reforming the individual market for health insurance, lowering the price of prescription drugs, taking on the opioid crisis, and putting in place a healthcare system that emphasizes value and outcomes over procedures and spending. The aim of all of the priorities is to provide quality care for the American people.

Regulations, especially ones like the Physician-Self Referral Law (commonly referred to as the Stark Law), can serve as a hindrance to newer and better ways to help Americans live healthier lives. These regulations affect at least one-sixth of the economy and, just as important, often directly affect our family doctors and nurses, who consult with us and provide for us in some of life's most challenging moments. HHS is determined to give healthcare providers space not just to provide quality care and to really listen to their patients, but to innovate, as well.

Our country's thicket of healthcare regulations has gotten in the way of each of these goals in complicated ways, and HHS has committed itself to solving this problem. Building on our success, and to affirm how vital coordinated care is to HHS, I recently launched what we've dubbed the Regulatory Sprint to Coordinated Care. The goal of the sprint is to remove regulatory barriers to coordinated care while ensuring patient safety. We want to genuinely engage stakeholders in this effort, and solicit feedback at each stage—but this is a sprint, not a jog. These words were chosen specifically because we want to fix, as quickly as possible, the regulatory processes that have increased provider burden.

When enacted in 1989, the Stark Law rightfully addressed the concern that inappropriate motives could distort decision-making in healthcare. It recognized a worry that some physicians might order services based on their financial interest in service providers, rather than the good of the patient. And in a largely fee-for-service context, you could see why that would make sense. Congress enacted a law that was intended to protect the American people and the Medicare program from these issues.

This law, as noted, was passed with good intentions: The heart of the law is to ensure that a patient has options for quality care without regard to whether a provider has a financial interest. We don't want people referred to services they don't need or steered to less convenient, lower quality, or more expensive healthcare providers because of their healthcare provider's financial interest. Congress wanted the law to separate a physician's decision-making from certain types of potential financial benefit.

The law did it in two specific ways. First, it banned doctors from referring patients for certain designated health services payable by Medicare to an entity in which the physician, or any immediate family member, holds a financial relationship. Second, it prohibited the entity from filing claims with Medicare, or billing another individual, entity, or third-party payer for those referred services. The restrictions are absolute, with certain enumerated exceptions, and the law grants HHS the authority to carve out exceptions for financial relationships that do not pose a risk of program or patient abuse.

But, what made sense for the healthcare system in the 1980s does not necessarily translate to the modern healthcare system. The President's budget called for a modernization of the Stark Law. That's why, last month, with regard to the Stark Law portion of our Regulatory Sprint, I asked the Centers for Medicare & Medicaid Services to take the lead on the task of reexamining the Stark Law by issuing a Request for Information to obtain public input on ways to address any undue impacts and burdens of the Stark Law.

The Stark Law, which as I noted, is designed for a fee-for-service model, is not one that always works in a system transitioning and moving to value-based payments for healthcare. The Stark Law may unduly limit ways that physicians and healthcare providers can coordinate patient care by restricting ways physicians can organize and work together and with others. In considering changes to the Stark Law, we must be cognizant of the need to preserve competition in the healthcare marketplace where such competition achieves the goal of patient-centered quality care while controlling costs.

Like the rest of HHS, CMS Administrator Seema Verma has made it her priority to find federal regulations that impose a burden to delivering better value for American patients. Over the past year, upon President Trump's direction to reform our regulatory system, CMS has engaged with its portion of the provider community in a discussion about regulatory burdens. Through these discussions and engagements, one of the top four issues raised by stakeholders was, not surprisingly, the burdens imposed by Stark Law compliance. Stakeholders said the Stark Law may sometimes prevent doctors from participating in or considering integrated delivery models, alternative payment models, and arrangements to incentivize improvements in outcomes and reductions in cost.

From the point of view of our activities on the Regulatory Sprint, we have asked CMS to consider input from stakeholders and focus on how the Stark Law may impede care coordination, a key aspect of systems that deliver value. Through a Request for Information published on June 25, under the auspices of the Regulatory Sprint, CMS requested additional feedback from stakeholders and the public on the structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements as well as the need for revisions or additions to exceptions to the Stark Law. HHS is also looking at the Anti-Kickback Statute and its intersection with the Stark Law to see if either law or the interactions between the two is stifling innovative arrangements that could result in better outcomes for patients. Throughout this process, we will be consulting with our enforcement partners in the Office of Inspector General and the Department of Justice.

As shown by the President's budget request and the range of information sought from the healthcare community in the Stark Law Request for Information last month, the Department is open-minded about the types of changes that may be needed to make the Stark Law more compatible with the push toward integrated care and alternative payment models. HHS looks forward to working with this subcommittee to find the best path forward, and I am looking forward to discussing the Stark Law today and working with this subcommittee to find a balanced way that leads to coordinated care and better outcomes for American patients. Thank you again for having me here today.

I look forward to discussing this issue and taking questions.