

What's Past is Prologue: How Capitol Hill Can Set the Stage for Future Regulations

Last month, the US Department of Health and Human Services (HHS) released proposed changes to regulations promulgated under the Anti-Kickback Statute (AKS)¹ and the physician self-referral law (Stark Law)² to encourage providers to move toward more coordinated, value-based healthcare. The proposed rules, which we [summarized](#), make significant changes and create broad, new safe harbors and exceptions to the AKS and Stark Law that will make it easier for providers to enter into value-based agreements for shared patients.

Interestingly, many of the ideas and themes included in the proposed rules can be traced back to a meeting convened on Capitol Hill in late 2015. The following details the results of that meeting, compares those results to the recently proposed rules and provides insight into what will likely happen next.

Past: Committees on Capitol Hill Setting the Stage

The history and discussion surrounding the proposed regulatory changes to the AKS and Stark Law demonstrate how ongoing engagement with policymakers from both parties, particularly those that serve on the congressional committees with relevant jurisdiction, can affect outcomes both on Capitol Hill and within the administrative agencies.

In December 2015, the Senate Committee on Finance and House Committee on Ways and Means convened a roundtable discussion with experts on the AKS and Stark Law. These committees have a long history of focusing on eliminating healthcare fraud and abuse, and roundtable meetings allow members to receive input from experts and industry stakeholders in a less formal setting than a hearing. The 2015 roundtable was memorialized in a Finance Committee majority report authored by staff of then-Chairman Orrin Hatch (R-UT), titled "[Why Stark, Why Now?](#)" which was then followed by a Finance Committee hearing with a few roundtable attendees as witnesses.

Specifically, the report provided general recommendations that include:

- Aligning the Stark Law with AKS
- Simplifying Stark Law exceptions and clarifying definitions
- Expanding the HHS Secretary's waiver and exception authority

The Proposed Rules Follow These General Recommendations

The HHS Office of Inspector General (OIG) worked closely with the Centers for Medicare and Medicaid Services (CMS) to develop and publish the AKS and Stark Law proposed rules simultaneously. The two agencies worked to align the regulations by attempting to define, clarify and make uniform terminology describing value-based care arrangements.

CMS also proposed to simplify the Stark Law regulations by clearly defining key terms that apply in many of the exceptions, including "commercial reasonableness," "fair market value," "volume or value of referrals" and "other business generated" between the parties.

The majority staff report noted that while the HHS Secretary has authority under the Stark Law to create regulatory exceptions as long as they do "not pose a risk of program or patient abuse," CMS had "taken a cautious approach in issuing Stark exceptions."

In its proposed rule, CMS makes a significant shift in the way it views its authority to establish exceptions under the Stark Law. CMS states that previous exceptions "have generally followed the blueprint established by the Congress for compensation arrangements that exist in a FFS system," and then states, "[v]alue-based healthcare delivery and payment shifts the paradigm of our analysis" under the Stark Law. It then creates broad new exceptions for value-based payment programs, establishes a new exception to address "non-abusive business practices" and revises certain payment exceptions to expand their scope. With this shift, CMS enabled the HHS Secretary to expand current Stark Law exceptions and create new ones without Congress acting to provide additional authority.

It is not surprising that many of the proposed AKS and Stark Law changes were informed by work previously completed on Capitol Hill. When administrations change, incoming administrations often look to congressional staff with specific experience in issues they want to prioritize. HHS is no different – the current administration enlisted many staffers who had previously served on the congressional committees with healthcare jurisdiction. With HHS personnel who had previously focused on Stark Law reform in Congress, the new administration has been able to utilize valuable expertise as it seeks to lessen provider concerns on the road to value-based care.

¹ 42 U.S.C. § 1320a-7b(b).

² 42 U.S.C. § 1395nn.

Prologue: Next Steps for the Proposed Regulations

In January 2019, current Finance Committee Chairman Chuck Grassley (R-IA) said that he would “work to ensure that anti-fraud statutes are enforced . . . and closely evaluate potential changes to [the] Stark Law and the Anti-Kickback Statute.”³ Many expect the Chairman to follow up on that promise by holding a hearing on the rules, but current congressional priorities, including healthcare extenders, drug pricing, surprise billing, appropriations battles and impeachment, will likely delay congressional consideration of the rules until next year.

Stakeholder and Congressional Reaction

The proposed changes to the relatively complicated AKS and Stark Law regulations were met with strong support from industry stakeholders; major physician and hospital groups like the American Medical Association, American Hospital Association and the Federation of American Hospitals published supportive statements shortly after the proposed rules were released. Those groups, and others like the Medicare Group Management Association that were less enthused with the proposed changes, have expressed that they intend to provide official comments within the extended 75-day comment period. Stakeholders that were excluded from participating in value-based and patient engagement arrangements under the proposed rules – pharmaceutical and medical device manufacturers, and laboratories – are expected to push OIG and CMS to be allowed to participate.

Congressional reaction to the proposed rules has been minimal. The Senate Committee on Finance and House Committee on Ways and Means have jurisdiction over the AKS and Stark Law, and none of the chairmen nor ranking members have commented on the proposed rules. Their silence could be due to the complexity of the issues involved, and it is likely that committee staff are still reviewing the agency proposals. However, if either proposed rule included anything particularly offensive to one of the members, they likely would have voiced their concerns when the proposed rules were announced.

The combination of strong industry support and minimal congressional reaction suggests that the proposed rules will likely be finalized by the agencies with few significant changes sometime next year. Providers interested in moving toward more coordinated, value-based healthcare should begin thinking now about how best to utilize these coming changes.

How We Can Help

We are nationally recognized for our sophisticated knowledge of intricate legislative and regulatory issues, strong ties to leading policymakers and a record of accomplishment in the healthcare and life sciences industries. This reputation, paired with our substantive legal, regulatory and policy expertise in this sector, enables us to better guide clients through regulatory reform issues like this one.

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³ Press Release, [Grassley Becomes Finance Committee Chairman, Outlines Agenda for 116th Congress](#), (Jan 10, 2019), (last visited Nov 5, 2019).