

Secretary Azar Addresses Drug Pricing and Care Coordination in AHLA Keynote

Friday, March 22, 2019

Earlier this week, **Alex Azar, Secretary of the Department of Health and Human Services** (“HHS”), delivered [keynote remarks](#) at AHLA’s 2019 Institute on Medicare and Medicaid Payment Issues.

Framing his remarks around two key initiatives of the Administration, regulatory reform and affordable healthcare, Secretary Azar promised a bold and swift approach to regulatory reform over the coming years.

Secretary Azar discussed HHS’ initiative known as the “Regulatory Sprint to Coordinated Care,” which we’ve previously [discussed on the blog](#). The agency is undergoing a “comprehensive reexamination of rules that may be impeding coordinated care.” As a “sprint,” he noted the goal is to issue rulemaking to alleviate impediments “as soon as possible.”

In his speech, Secretary Azar highlighted the following areas of focus for HHS:

- **The Stark Law** – Secretary Azar identified the Stark Law as a major impediment to value-based compensation arrangements. He noted that the Stark Law is necessary in a for-fee-service environment to prevent incentives to increase the volume of services. However, as the Administration seeks to transition to payment based on outcomes rather than volume, Azar views the Stark Law as an obstacle. The Stark Law was the first issue targeted by the Administration’s Sprint to Coordinated Care with the OIG seeking comments on a potential exception for advanced payment models and other changes in a [Request for Information \(“RFI”\)](#) issued in June.
- **Anti-Kickback Statute (“AKS”)** – Shifting to the Administration’s focus on affordable healthcare, Secretary Azar’s discussion of AKS reforms focused on the recent proposed rule to eliminate discount safe harbor protection for formulary rebates. We previously addressed this proposal on the blog [here](#). As he has done in prior remarks on pharmaceutical rebates, Secretary Azar used strong language in attacking the use of rebates:

“Any approach to drug pricing that does not tackle the issue of rebates—whether through our proposed approach or otherwise—will simply not get list prices down. If you stand for rebates, you stand for ever-higher list prices, and against transparency and lower patient out-of-pocket costs at the pharmacy. It’s that simple.”

- **HIPAA and 42 CFR Part 2 (“Part 2”)** – Secretary Azar discussed HIPAA and Part 2’s mental health and substance abuse privacy rules together, noting that the current environment may be impeding high quality care. The government implemented Part 2 to protect patients disclosing substance abuse disorders to their health care provider and provides additional protections for records related to substance abuse disorders and treatment that go beyond HIPAA’s requirements. The stringent restrictions on the sharing of information can be harmful for patients, especially in light of the opioid epidemic. As we’ve previously mentioned on the [blog](#), Congress tried – but failed – to pass a bill that would align Part 2 with HIPAA as part



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of the opioid package. Amidst the opioid crisis, there are concerns that providers are hesitant to include substance abuse disorders in the medical records out of fear of inadvertent disclosure under Part 2. With the goal of reducing regulation, Secretary Azar stated that HHS wants to ensure that patients have access to their medical records and that providers have all the required information to treat patients who may be prescribed opioids.

Secretary Azar closed his remarks commenting on the success HHS has already had in reducing regulatory burdens. As a key focus of his tenure, he indicated that the agency will continue to “take a bold approach to reforming regulations.” You can read the full speech [here](#).

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