The Seniors' Access to Critical Medications Act of 2023 (H.R. 5526)

Sponsored by U.S. Representatives Diana Harshbarger (TN-01) and Debbie Wasserman Schultz (FL-25)

Present Law

A physician who makes a referral of a Designated Health Service ("DHS") to an individual or entity with whom the physician has a financial relationship may be in violation of the physician self-referral law (commonly known as the "Stark law") unless the referral falls under an exception. The most common Stark exception for prescribing physicians is the In-Office Ancillary Services (IOAS) exception, which allows physicians to dispense outpatient drugs from their practice or practice-owned pharmacy.

The Secretary of Health and Human Services, acting through the Centers for Medicare & Medicaid Services (CMS), has interpreted the IOAS exception to permit patients to receive oral cancer drugs and other medications in-person from their physician at the physician's office. However, CMS' interpretation does not permit physicians to mail, send by courier, Federal Express, or otherwise deliver oral prescription drugs to their patients. In addition to prohibiting sending medicines by mail, CMS' interpretation also prohibits a spouse, family member, or caregiver from picking up the medication at the physician's office on behalf of the patient.

CMS' interpretation of a Stark violation in these scenarios is misguided, especially as Medicare transitions from a fee-for-service environment to value-based models. How can it be a Stark violation when there is no referral when a drug is simply delivered or picked by someone other than a patient? The impact of this CMS interpretation is dire and can compromise the well-being of cancer patients and others with serious diseases who are too sick to pick up their medications in person, who live in rural areas distant from their physicians, or who simply do not have transportation.

During the COVID public health emergency (PHE), CMS issued a Stark waiver that allowed delivery or pickup of prescription drugs, temporarily lifting the restrictions that hindered patient access to these crucial medications. Upon expiration of the PHE, CMS issued two FAQs stating that the Stark waiver also expired. As a result, Medicare patients' ability to access their prescription drugs was put in jeopardy, as physicians and their practices face a Stark violation if they continue to deliver drugs to their patients or allow someone other than a patient to pickup drugs from the medical practice — as they had been doing throughout the pandemic with no issues.

Over the last few years, CMS has commendably made reducing health disparities one of its

foremost priorities, as outlined in their recently updated Framework for Health Equity. Unfortunately, this CMS interpretation is counterintuitive after nearly three years of success in helping people that face social, physical, and economic challenges that often prevent them from obtaining their medication.

Bill Summary

The Seniors' Access to Critical Medications Act is very simple and straightforward. It would amend section 1877 of the Social Security Act to clarify that delivering medicines by mail, courier or other methods, or allowing a family member or caregiver to pick up medicines on behalf of a patient would **not** violate the Stark law and would fall within the scope of Stark's IOAS exception. The bill would thus require CMS to revise its interpretation of current law that prohibits delivery of medicines to patients who are not physically present in the physician's office. The bill would also rescind the two FAQs issued by CMS on this matter.

Effective Date

The bill is effective for services consisting of drugs, and any supplies necessary to administer such drugs, furnished on or after May 11, 2023. This is the date that the PHE expired and the Stark waiver related to this issue also expired.