PUBLICATION

Bill Introduced to Curtail the Stark Law's In-Office Ancillary Services Exception

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On August 1, Rep. Jackie Speier (D-CA) introduced H.R. 2914, the Promoting Integrity in Medicare Act. The legislation would provide that the Stark Law's in-office ancillary services (IOAS) exception is not available for "specified non-ancillary services," which include advanced diagnostic imaging services (currently diagnostic MRI, CT and nuclear medicine, including PET, services), anatomic pathology services, radiation therapy services and supplies, and physical therapy services. The Secretary of Health and Human Services (HHS) would be authorized to expand the list of "specified non-ancillary services" to include other services "not usually provided and completed during an office visit to the physician's office in which the service is determined to be necessary." Increased penalties could be imposed for Stark Law violations relating to "specified non-ancillary services," and increased HHS review and audit activity would be mandated with respect to such services.

Background and Purpose of the Bill

The IOAS exception is the primary vehicle through which referring physician practices are able to provide radiology, clinical laboratory, physical therapy and other ancillary services reimbursed by Medicare. Without this exception, the Stark Law would generally prohibit referring practices, other than practices located in rural areas, from billing Medicare for these services.

A dramatic increase in referring physicians' offerings of ancillary services has been witnessed over recent years. This trend has not gone unnoticed by parties who traditionally provided these services, including independent imaging and laboratory companies, diagnostic and therapeutic radiologists, pathologists and physical therapists. Associations representing these providers have long asserted that physician "self-referral" results in the overutilization of ancillary services and petitioned Congress and HHS to prohibit it.

Although Rep. Speier has twice previously introduced legislation targeting advanced imaging services, congressional response to date has been modest, such as mandating accreditation for advanced diagnostic imaging (in the Medicare Improvements for Patients and Providers Act of 2008) and requiring that patients be provided a list of alternative suppliers when practice physicians order CT, MRI or PET scans (in the Affordable Care Act). Similarly, the Centers for Medicare and Medicaid Services (CMS) has considered imposing additional limitations on referring physician provision of ancillary services, particularly diagnostics, but has failed to take any significant action. Congress and CMS have instead largely opted to address alleged overutilization indirectly – by reducing Medicare reimbursement rates for these services (or imposing other generally applicable limitations) – which has hurt traditional providers as much as or more than referring physicians.

H.R. 2194, by contrast, would radically alter the existing landscape by prohibiting most referring physician practices from providing under Medicare among the most significant of ancillary services. According to the bill's "findings," a "key rationale for the IOAS exception was to permit physicians to provide ancillary services in their offices to better inform diagnosis and treatment decisions at the time of the patient's initial office visit." The legislation is therefore intended to "distinguish between services and procedures that were intended to be covered by the IOAS exception, such as routine clinical laboratory services or simple x-rays that are provided during the patient's initial office visit, and other health care services which were clearly not envisioned to be

covered by that exception because they cannot be performed during the patient's initial office visit." This concept was articulated by CMS in its proposed 2008 Medicare Physician Fee Schedule update, but was never acted upon by the agency. The bill also relies upon studies published by the Government Accountability Office, the Medicare Payment Advisory Commission and Health Affairs, which suggest that self-referral under the IOAS exception has resulted in significant overutilization of ancillary services.

Politics and Prospects

Not surprisingly, passions run high on both sides of H.R. 2914. The Alliance for Integrity in Medicare, a coalition of professional and trade associations representing traditional providers of "specified non-ancillary services," was formed to support the bill. Thirty national medical societies (including the American Medical Association), on the other hand, sent an August 12 letter to members of Congress, in which they denounced the bill's "findings" and argued, among other things, that H.R. 2914 would frustrate the progression to a coordinated, value-based health care system.

The Obama Administration has helped the bill's cause. The Administration's FY 2014 budget proposal seeks to raise revenue by curtailing the IOAS exception for most of the services targeted by H.R. 2914. According to the proposal, which was not submitted in statutory form, it would "encourage more appropriate use of select services by excluding radiation therapy, therapy services and advanced imaging from the in-office ancillary services exception to the prohibition against physician self-referrals….except in cases where a practice meets certain accountability standards" to be defined by the Secretary of HHS.

H.R. 2914 is co-sponsored by Reps. Jim McDermott (D-WA), the ranking Democrat on the House Ways and Means Committee's Health Subcommittee, and Dina Titus (D-NV). The bill has been referred to the Energy and Commerce Committee and the Ways and Means Committee. To become law, the bill must be approved by the full House, the full Senate and the President. The bill's prospects largely depend on whether members of Congress perceive the legislation to be a legitimate means to reduce Medicare expenditures as part of the larger effort to reduce the federal deficit, pursuant to debt limit talks and Sustainable Growth Rate (SGR) replacement legislation, which may occur in the fall of 2013. The Congressional Budget Office (CBO) has not yet published budgetary estimates for H.R. 2914. The CBO and the Obama Administration strongly disagree over how much the Administration's budget proposal would save the Medicare program: the Administration claimed $6.1 billion in savings, compared to CBO's $1.8 billion.

Industry Effects

The effective date of the legislation would generally be one year after its enactment and the bill provides no grandfather for services currently furnished by referring physician practices. If enacted, H.R. 2914 would likely result in massive divestments of ancillary equipment and service lines, or other restructurings. Further, it is likely that states and other private payors will follow Congress' lead and adopt similar positions, which may make structuring viable Medicare carve out arrangements difficult.

H.R. 2914 states that it does not affect Stark's exception for rural providers. Because that exception is narrower than the IOAS exception, however, even referring physician practices located in rural areas (i.e., outside Metropolitan Statistical Areas) may be required to restructure their internal compensation methodologies.

The legislation would not alter Stark's exclusion from "referral" for services recommended by pathologists, diagnostic radiologists and radiation oncologists, pursuant to a "consultation" from another physician. This exclusion does not, however, protect the physician who orders the consultation, who will generally be deemed to refer the ancillary service – even if the performing physician is not so deemed. H.R. 2914 could therefore

result in the breakup of physician practices that include both referring physicians and traditional performing physicians.

From the institutional perspective, the benefits of H.R. 2914 would not be limited to the companies represented by AIM members. Hospitals and other non-physician providers of "specified non-ancillary services" would also benefit from the legislation. The American Hospital Association has not yet weighed in on H.R. 2914.