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Removing the Barriers to Coordinated Care: the Stark Law

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August 10, 2015 was the 22nd anniversary of the expansion of the Medicare self-referral prohibition to include 10 "designated health services" in addition to clinical laboratory tests.[1] This law is the so-called Stark Law. January 1, 2015 was the 20th anniversary of the effective date of these changes. The purpose of the Stark Law was to establish a "bright-line" test separating prohibited self-referrals from referrals that are part of the normal workings of the health care system.[2]

Since enactment, there have been 29 significant regulatory actions taken by the Centers for Medicare & Medicaid Services ("CMS") to interpret and apply the Stark Law. According to former Congressman Fortney "Pete" Stark: "Pretty soon the law got to be as thick as a phonebook for all the exemptions for this, that and the other thing."[3]

On July 15, 2015, the 30th significant regulatory action was taken by CMS when it proposed further rules under the Stark Law.[4] In general, this proposed rule would have many benefits – among other things clarifying points of interpretation within the regulations (the "Stark Rule").[5]

One of the most important aspects of the Proposed Rule is the existing Stark Law and Stark Rule are perceived as barriers to attempts by hospitals, physicians and others to achieve health system reform as envisioned by recent federal actions. CMS stated in the preamble to the Proposed Rule that: "[s]ince the enactment of Section 1877 of the [Social Security] Act in 1989, significant changes in the delivery of health care services and the payment for such services have occurred, both within the Medicare and Medicaid programs and with respect to non-federal payors." [6] Proposed Rule 41927. This is something of an understatement. CMS then stated that it has "engaged in efforts to align payment under the Medicare program with the quality of care provided to our beneficiaries." *Id.* CMS then enumerated the many actions taken by Congress over the last decade and implemented by CMS to achieve this purpose. Proposed Rule 41927-41928. The electronic health records initiative, while not mentioned by CMS, will contribute importantly to achieving these goals. CMS correctly found that stakeholders are concerned whether innovative payment approaches outside of the Medicare Shared Savings Program or CMS-sponsored initiatives and other federal health care initiatives would run afoul of Stark. Proposed Rule 41928-41929. Such concerns extend to arrangements involving non-federal payors because of the broad reach of the Stark Law's definition of a financial arrangement.

Congress and CMS are to be commended for continuing efforts aimed at payment system reform and CMS is to be commended for calling for comments to address this issue (Proposed Rule 41929-41930). However, we do not believe regulatory action will be either sufficient or timely enough to address this issue. Payment system changes that align "payment … with quality of care …" would solve the issue the Stark Law was intended to address – that is, overutilization driven by the prospect of financial gain.[7] Our concern is that CMS does not have sufficient regulatory authority to accomplish these laudatory goals and that the Stark Law, like a 20-year old car, perhaps can be fixed but the better approach is a fresh solution. If repeal is not in the offing, then Congress should enact a broad exception for arrangements that connect payment to health care quality and that seek to reward achieving the so-called "Triple Aim," while at the same time providing for the sunset of the Stark Law.[8] Repeal or sunset of the Stark Law would leave in place many protections against crimes such as theft committed against federal and state programs. These protections include the federal Anti-Kickback Statute and the False Claims Act, although these statutes too will become outdated to be replaced with statutes that focus on quality of care and utility of services.

1 PL 103-66, § 13562 (Aug. 10, 1993); Section 1877 of the Social Security Act.
2 *See, e.g.*, 66 Fed. Reg. 856, 860 (Jan. 4, 2008).
3 Janet Adamy, Wall Street Journal, *Pete Stark: Law Regulating Doctors Mostly Helped Lawyers*, http://blogs.wsj.com/washwire/2014/10/22/pete-stark-law-regulating-doctors-mostly-helped-lawyers/ (Oct. 22, 2014) accessed Aug. 17, 2015.
4 80 Fed. Reg. 41685 (pp. 41909-41930, 41933-41958) (July 15, 2015) ("Proposed Rule").
5 For example, all who have spent time trying to understand the difference that results from the use of the term arrangement in one instance and agreement in another when applying the Stark Rule may soon be relieved of that task. Proposed Rule 41916.
6 1989 was the enactment date of the Stark Law as it related to clinical laboratory services.
7 Of course, the reciprocal concern is the fear that certain payments might encourage reduction of services to Medicare beneficiaries. Notably, as part of Congress's fix of the "sustainable growth rate," Section 1128A((b)(1) limited the applicable civil money penalty to payments to reduce or limit "*medically necessary*" services. PL 114-10, Section 512 (April 15, 2015).
8 The "Triple Aim" or "three-part aim" today includes improving the health of populations, improving the experience of care and reducing per-capita costs of health care.

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