TMC
HEALTHCARE

Office of General Counsel

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BY EMAIL ***ACOlegalissues@cms.hhs.gov***

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS–1356–N: ACO Legal Issues

Dear Dr. Berwick:

This letter responds to the request for comments by the Centers for Medicare & Medicaid Services ("CMS") set forth in the above-referenced Federal Register notice ("Notice"), announcing an October 5, 2010 "Workshop Regarding Accountable Care Organizations [ACOs], and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws," 75 Fed. Reg. 57039 (September 17, 2010).

Tucson Medical Center ("TMC") is a 65-year old, 628-bed community hospital that serves more than 30,000 inpatients and 120,000 outpatients each year. TMC is a leading provider in the region for emergency care, women's and maternity care, pediatric care, and many other specialty areas, including cardiac, orthopedic, neuroscience, imaging and senior services. TMC is a strong supporter of the new Medicare Shared Savings Program (the "MSSP"). TMC also is a strong supporter of the application of the ACO model to improve the quality and lower the cost of care furnished to individuals who are enrolled in commercial health insurance plans. Indeed TMC is actively involved in the development of an ACO, as part of the Brookings-Dartmouth collaborative program, and TMC's leaders have met with representatives of CMS and the Federal Trade Commission to discuss this exciting new venture.

Over the past 15 years, the Federal government has devoted substantial resources to enforcing health care fraud and abuse laws, including the Federal health care program anti-kickback law, 42 U.S.C. § 1320a-7b(b) ("Anti-Kickback Law"), and the Federal physician self-referral law, 42 U.S.C. § 1395nn ("Stark Law"). Further, both the

government and private "whistleblowers" have filed hundreds of Federal Civil False Claims Act ("FCA") cases that are founded on alleged violations of the Anti-Kickback and Stark Laws. Concomitantly, and consistent with the repeated recommendations of CMS and the U.S. Department of Health & Human Services ("HHS") Office of Inspector General ("OIG"), providers have developed and implemented comprehensive compliance programs that require adherence to all Federal and State fraud and abuse laws, including (of course) the Anti-Kickback and Stark Laws.

Under these circumstances, TMC questions whether the potential of the MSSP can or will be achieved on a widespread, efficient and cost-effective basis unless and until CMS and the OIG make it clear that where (1) CMS distributes payments to an ACO pursuant to a shared savings, partial capitation or any other model explicitly permitted by Section 3022 of the Accountable Care Act ("MSSP Payments"), and (2) that ACO, in turn, shares such MSSP Payments with participating providers, suppliers and practitioners — all in compliance with HHS' forthcoming MSSP rules and regulations — these MSSP Payments will not implicate or violate the Stark Law, the Anti-Kickback Law, the services reduction civil monetary penalty law ("Services Reduction CMP"), 42 U.S.C. § 1320a-7a(b)(1), or any other similar fraud and abuse law. (For purposes of these comments, we generally will refer to this group of ACO arrangements, which are "downstream" of CMS under the MSSP, as "MSSP ACO arrangements".)

As the Notice correctly observes, "because of the resources and time required to integrate independent provider practices, health care providers are more likely to integrate their care delivery for Medicare and Medicaid beneficiaries if they also use the same delivery systems for patients covered by health insurance in the private market." Consistent with this observation, TMC also questions whether the potential of non-MSSP ACO arrangements can or will be achieved on a widespread, efficient or cost effective basis until and unless the CMS and the OIG make it clear that where (1) a commercial insurer distributes payments to an ACO pursuant to a shared savings, partial capitation or similar model, and (2) the ACO, in turn, shares such payments with participating providers, suppliers and practitioners, these payments will not implicate or violate the Stark Law, the Anti-Kickback Law, or any other similar fraud and abuse law. (For purposes of these comments, we generally will refer to this group of ACO arrangements, which are "downstream" of an insurer, as "Commercial ACO arrangements".)

Stark Law

As CMS has emphasized on numerous occasions, the Stark Law was enacted in order to prevent the overutilization of health care items and services and any concomitant increases in Medicare program costs. The MSSP, on the other hand, is specifically intended to reduce Medicare expenditures and, as such, provides for no incentives (to physicians or any other MSSP Providers) to overutilize Medicare-covered items or services.

Although the MSSP does not implicate the Stark Law's primary policy objective, the Law, by its terms, may implicate many MSSP ACO arrangements. Under the Stark

Law, in the absence of an exception, physicians are not permitted to refer Medicare beneficiaries to providers of "designated health services" ("DHS") — including hospitals — if the physician and DHS entity have a "financial relationship." In many cases, the distribution of MSSP Payments between and among CMS, ACOs and providers will create such "financial relationships." There is no existing Stark Law exception, however, that was specifically designed with MSSP Payments in mind. Because the Stark Law could (given the breadth of its prohibitions) but should not (as a matter of public policy) implicate MSSP Payments, CMS should create a Stark Law exception that clearly and unequivocally provides that where MSSP Payments pass (directly or indirectly) between a physician and a DHS entity, this remuneration will not create a "financial relationship" between the physician and DHS entity for Stark Law purposes.

Importantly, it will not be sufficient for CMS only to protect MSSP ACO arrangements and MSSP Payments. Commercial ACO arrangements also will involve the exchange of shared savings and similar payments between and among commercial insurers, ACOs, and downstream providers, suppliers and practitioners. These arrangements also will create "financial relationships" between physicians and DHS entities that will need to be protected under the Stark Law. (If these financial relationships are not protected, physicians who participate in the ACO will not be able to refer Medicare patients to hospitals and other DHS entities who participate in the ACO, making the ACO, in effect, unviable.) In order to ensure that commercial ACO arrangements do not implicate or violate the Stark Law, CMS should:

- confirm that an ACO qualifies as a managed care organization ("MCO") for purposes of the existing Stark Law exception for "risk-sharing arrangements," 42 C.F.R. § 411.357(n), and make any other conforming and/or necessary changes to this exception to ensure that payments under commercial ACO arrangements do not implicate the Stark Law; and/or

- create a new exception — or expand the exception for MSSP ACO arrangements discussed above — to cover commercial ACO arrangements.

Anti-Kickback Law

Like the Stark Law, the principal policy objective of the Anti-Kickback Law is to prevent the overutilization of items and services reimbursed by Federal health care programs and any concomitant increases in Federal program costs. Also like the Stark Law, however, notwithstanding this policy objective, the Anti-Kickback Law may — by its terms — implicate certain MSSP ACO arrangements and, potentially, certain commercial ACO arrangements.

Under the Anti-Kickback Law, in the absence of an applicable safe harbor, it is unlawful for one party "knowingly and willfully" to provide "remuneration" to another if a purpose of the remuneration is "induce" the referral of Federal health care program patients or business. As noted above, MSSP and commercial ACO arrangements will involve payments between and among health care insurers, providers, suppliers and practitioners, many of whom are in a position to refer Federal health care program patients to each other.

Under these circumstances, and for the same reasons set forth above, TMC believes that it is important for the OIG to provide clear guidance that MSSP and commercial ACO arrangements will not implicate or violate the Anti-Kickback Law. Toward this end, TMC recommends that the OIG create a regulatory safe harbor that will protect all (1) MSSP Payments that pass between and among CMS, ACOs, and downstream providers, suppliers and practitioners, and (2) all similar payments that pass between and among commercial insurers, ACOs and downstream providers, suppliers and practitioners — all provided, of course, that such payments specifically relate to services furnished to individuals enrolled in an ACO.

Services Reduction CMP

Finally, the Services Reduction CMP provides that if a "hospital . . . knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to individuals" who are (1) entitled to Medicare or Medicaid benefits, and (2) "under the direct care of the physician," then the hospital and physician are subject to a CMP for each individual with respect to whom the payment is made.

Under certain ACO arrangements, a hospital may have an ownership interest in an ACO that (1) receives MSSP Payments from CMS, and (2) distributes all or a portion of such Payments to providers, including physicians. TMC requests that the OIG — both pursuant to the MSSP waiver process and more generally — confirm that, under such circumstances, the remuneration flowing from the ACO to the physicians is not (and will not be) considered a "payment" from the hospital to the physicians for purposes of the Services Reduction CMP.

In other cases, MSSP Payments may pass indirectly from CMS through an ACO provider that is a hospital to an ACO provider who is a physician. Again, TMC requests that the OIG — both pursuant to the MSSP waiver process and more generally — confirm that, under such circumstances, the remuneration flowing from the hospital to the physician is not (and will not be) considered a "payment" from the hospital to the physician for purposes of the Services Reduction CMP.

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In closing, TMC would like to thank CMS for providing an opportunity to comment on these important ACO legal issues in advance of the forthcoming workshop on these topics. If you have any questions concerning these comments, or if TMC can provide any additional information, please do not hesitate to contact me.

Sincerely,

Tracy P. Nuckolls, Esq.
Executive Vice President & Chief Legal Officer

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