California Association of Physician Groups

September 27, 2010

BY EMAIL

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") 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).

The California Association of Physician Groups ("CAPG") is the nation's largest professional association of currently operating accountable care organizations representing more than 150 physician groups furnishing health care services to approximately 13 million Californians. Our members are committed to the delivery of coordinated, accountable, clinically integrated health care services. Consistent with this commitment, CAPG is a strong supporter of the new Medicare Shared Savings Program (the "MSSP").

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.

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Under these circumstances, CAPG does not believe that the MSSP can or will be implemented on a widespread, efficient and cost-effective basis unless and until CMS and the OIG make it clear and unequivocal that where (1) CMS distributes payments to an ACO ("MSSP 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) the MSSP ACO, in turn, shares such MSSP Payments with participating providers, suppliers and practitioners ("MSSP Providers") — 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.

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 may, by its terms, implicate many MSSP 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, MSSP ACOs and MSSP 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. Further, as referenced in the Notice,

> 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.

CAPG agrees; and in order to ensure ACO arrangements that cover both Medicare beneficiaries and other types of patients also 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). (CMS also should make any other conforming and/or necessary changes to this exception to ensure that

payments between and among payors, ACOs and/or providers — which payments specifically relate to services furnished to individuals enrolled in an ACO — do not implicate the Stark Law.)

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 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 arrangements will involve payments between and among health care 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, CAPG believes that it also is important for the OIG to provide clear and unequivocal guidance that MSSP arrangements will not implicate or violate the Anti-Kickback Law. Toward this end, CAPG recommends that the OIG create a regulatory safe harbor that will protect all MSSP Payments that pass between and among CMS, MSSP ACOs, and MSSP Providers.

In addition, in order to ensure that ACOs are in a position to enroll both Medicare beneficiaries and other types of patients, the OIG should either amend the "health plan" safe harbor, 42 C.F.R. § 1001.952(m), or create a new safe harbor, that will protect payments between and among payors, ACOs and/or providers, provided 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, MSSP Payments may pass indirectly from CMS through an ACO Provider that is a hospital to an ACO Provider who is a physician. CAPG 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, CAPG 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 CAPG can provide any additional information, please do not hesitate to contact me.

Sincerely,

DONALD H. CRANE
President & CEO
California Association of Physician Groups