Pursuant to the Federal Register notice, I submit the questions below for inclusion in the discussion among the agencies in consideration of the antitrust, self-referral, civil money penalty and other issues inherent in the formation of Accountable Care Organizations (ACOs). I have categorized the various questions.

ACO Payments to Physicians

Compensation by ACOs to physicians through distribution of shared savings and remuneration in the form of administrative and management service implicate AKS and Stark laws. A proposed solution to these issues is to create a new AKS safe harbor and Stark exception (or expansion of the proposed physician incentive plan exception or exception for risk sharing arrangements) permitting ACOs to require and/or incentivize physicians to direct referrals within the ACO network and to reward them financially for their participation in the ACO (through shared savings, payments for services, and nonmonetary compensation integral to the operations of the ACO). Such a safe harbor/exception should define fair market value in the context of ACO payments for shared services, and *expressly permit payments that vary with aggregate volume or value of referrals to designated health services ("DHS") providers* in the ACO.

- If shared savings are paid to a group practice, how may the savings be distributed within the group practice?

- Can payments be distributed in proportion to DHS referrals?

- If shared savings are not distributed to employed physicians on the basis of personally performed clinical and/or non-clinical services, to what extent can the employer allocate payments based on other indicia of performance that may take into account efficiencies created through referral relationships or that otherwise vary with the aggregate volume or value of DHS services referred to other providers participating in the ACO?

- What types of bonus payments will be permitted?

- If the employer is a DHS entity, is a distribution to employed physicians of shared savings from the ACO considered an impermissible sharing of profits?

- To what extent are ACO administrative functions and overhead considered a benefit (nonmonetary compensation) to independent physicians?

For example, if the ACO employs nurse coordinators, do we need to charge independent physicians for those services? How do we calculate the value of these services to independent physicians?

- Can physician employees be paid a percentage of a hospital's Medicare-related cost savings (or step-up in payment for quality) under the Stark employment exception without a volume/value problem?

- If the Stark Law employment exception is limited to compensation "for identifiable services," are changes in clinical and administrative conduct "identifiable services?" If so, what is the fair market value of the changes and/or how is this determined?

- Will OIG/CMS address the fair market value of data sharing and tracking in exchange for distribution of shared savings?

CMP laws prohibit hospitals from knowingly making a payment to a physician to limit or reduce items or services furnished to Medicare or Medicaid beneficiaries.

- Does the CMP law prevent making any physician employment compensation contingent on a reduction in LOS and readmission rates?

- If savings are based on participation in the ACO, there may be a financial incentive to limit treatment and increase referrals to providers who control the incentive payments, both of which are appropriate within the context of an ACO where both treatments and costs are evaluated together, but which would otherwise not be acceptable practices. Co-management, bundled payments and gainsharing agreements generally intend to improve efficiency by reducing services. Are any "gainsharing arrangements" or similar "pay for performance" compensation arrangements (including risk-sharing arrangements) structured to meet the CMP Law as interpreted by applicable OIG advisory opinions?

- Must there be an independent valuation for any quality incentive or shared savings payments?

Electronic Health Record ("EHR")

EHR technology and applications will be essential to capturing quality data and supporting care protocols. The Stark and AKS exceptions and safe harbors for EHR support are narrow.

- Will CMS and the OIG expand these protections so that hospitals can supply ACO participating physicians with hardware and software

necessary to accomplish clinical integration and report quality data? For example, the Stark exception for electronic health records and services requires that software donated be interoperable; the receipt of the items or services cannot be conditioned on doing business with the donor; the donee's eligibility and the nature of the donation cannot be determined in a manner that directly takes into account the volume or value of referrals to the donor or other business generated between the parties; and the exception is available only until December 31, 2013.

- ACO software may be proprietary, and therefore not intended to be interoperable; an ACO must encourage referral relationships among participants in order to be effective; the 2013 sunset date is too soon. Will CMS facilitate the ability of an ACO to enhance reporting capabilities and interoperative connectivity with independent physicians and/or physician groups that will not or do not have the means to otherwise make the investment in technology?

ACOs Engaging in Joint Contract Negotiations With Payors

There is a need for clear guidelines as to level and types of clinical integration that will support joint contracting without running afoul of antitrust laws.

- Will it be necessary to show efficiencies and cost savings to avoid potential antitrust issues? If so, how will this be measured and how will the ACO know when "sufficient" efficiencies and cost savings are achieved?

- Should there be a grace period from antitrust enforcement while ACOs organize and begin operations?

- Will the FTC create any safe harbors associated with horizontal and vertical integration activities associated with creating ACOs or update the 1996 Health Care Statements issued by the FTC in conjunction with the Department of Justice to reflect the new ACO structures and include guidance as to their appropriate structures that agencies and courts will use to evaluate arrangements?

- Alternatively, would the FTC (and Department of Justice) issue guidance that providers who are members of an ACO are financially integrated so that further analysis as to their clinical integration is unnecessary in

evaluating joint contracting arrangements with payors? In other words, if CMS approves an ACO's application for participation as a Medicare ACO, will that be deemed sufficient for antitrust financial integration purposes?

Payment of Shared Savings to ACOs

There remain many questions around the method and manner for CMS to make "shared savings" payments to ACOs and whether the formalities necessary for a provider to participate in the Medicare program will apply to ACOs. It is not clear which current CMS rules and formalities, if any, will apply to ACOs.

- Will CMS require ACOs to have a National Provider Identifier **(**NPI**)** and/or to complete a provider enrollment application in order to receive shared savings from Medicare?

- If an ACO is an administrative organization that contracts with affiliated providers, will the affiliated providers receive the shared savings payment directly or can the ACO entity receive the shared savings payments from CMS and then allocate the savings to its participating providers? If the ACO is permitted to receive the shared savings payments directly from CMS, must there be a "reassignment" from the ACO's participating providers?

- Will CMS issue guidance as to the appropriate division of shared savings?

- Is it appropriate for an administrative ACO organization to charge an administrative fee to offset additional costs associated with coordinating care for ACO beneficiaries?

Membership in an ACO & Referral Patterns

It is not clear what requirements will be imposed, if any, on providers who desire to join an ACO.

- Will CMS issue guidance regarding what percentage of services must be performed within the ACO to qualify an individual as an ACO participant?

- Is an ACO able to provide penalties or incentives to physicians to encourage referrals within an ACO (and to other providers who participate in the same ACO) for a participant without violating the AKS Law?

- How does CMS expect an ACO to enhance quality and value for patients if there is no ability to facilitate the patient's care within and among providers who all participate in the same ACO?

ACO Providers Sharing Data & Application of HIPAA

Under ACA, CMS will require reports of quality data associated with ACOs.

- How will benchmarks regarding quality measures be developed?

- Will any reported quality and performance measures be made available to the public or to other ACOs?

- Will CMS take existing state statutes regarding the confidentiality of peer review data into account in developing mechanisms for quality reporting?

- Will CMS, the OIG, and FTC engage the Office of Civil Rights to evaluate the sharing of patient data in the context of the Health Insurance Portability and Accountability Act of 1996 as amended ("HIPAA")? Specifically, is data collection and sharing in the context of an ACO consistent with the definitions of "treatment," "health care operations," and "payment"?

- What type of agreements, if any, will be necessary to comply with applicable arrangements for receiving and sharing protected health information with third party affiliated health care providers?

- If treatment, payment, and operations are more integrated in one organization, is there a clear delineation as to when data becomes protected health information under HIPAA?

ACO Tax Exemption Requirements

Due to variations in the structure of ACOs, it is not clear how the Internal Revenue Service will treat ACO's for tax purposes in the event an organization desires its ACO to be considered tax exempt.

- Will CMS, the OIG, and FTC engage the Internal Revenue Service to provide guidance regarding tax exemption issues related to the formation of ACOs?

- Given that many of the nation's hospitals and health systems are tax-exempt organizations under IRC 501(c)(3), will there be guidance on maintaining tax exempt status while operating an ACO; *e.g.*, distributing shared savings payments to for-profit physician groups?

- Under what circumstances can an ACO qualify as a 501(c)(3) charitable organization?

ACOs Accepting Capitation & State Law Issues

The ability of an ACO to accept bundled, capitated or other types of payments may be subject to applicable state law. ACO's that operate in states that do not regulate or permit more flexibility in regulating the business of insurance may be at an advantage.

- Has there been any consideration of adopting federal law that would preempt state insurance statutes that might hinder development of provider-based ACOs?

  State laws regarding the bearing of risk by an ACO and associated regulations may require an ACO to obtain a health plan or other managed care organization license or certificate in order to receive global capitation for inpatient, outpatient and physician services, or similar risk payments from health plans. Is CMS contemplating working with the Department of Labor, IRS and other federal agencies to create a preemption from state insurance regulation for ACOs so they can be treated uniformly across all 50 states for purposes of: (i) accepting bundled/capitated receiving and allocating shared savings?; and (ii) engaging in what some states may view as the business of accepting insurance risk?

Thank you in advance for considering these issues.

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