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Federal Trade Commission  
Office of the Secretary  
Room H-113 (Annex W)  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

Re: Proposed Statement of Antitrust Enforcement Policy Regarding  
ACOs Participating in the Medicare Shared Savings Program  
Matter V100017

To Whom It May Concern:

The Affordable Care Act seeks to change the healthcare landscape by introducing new payment and service delivery systems for all U.S. citizens. It calls for the creation of Accountable Care Organizations (ACOs) as one means of accomplishing this change. ACOs are designed to closely connect groups of providers who are willing and able to take responsibility for improving the overall health status, care efficiency and experience for a defined population. The alignment of incentives within ACOs will support the clinical integration and collaboration among doctors, hospitals and other care providers that is needed to “bend the cost curve” and revolutionize how care is provided, paid for and received, across all payors, both public and private.

Iowa Health System (IHS) fully supports the goals of the Affordable Care Act and applauds the efforts of the Centers for Medicare & Medicaid Service (CMS) and the Office of Inspector General (OIG) in proposing broad waivers of the Physician Self-Referral Law and the Anti-Kickback Statute in connection with the Medicare Shared Savings Program (MSSP) and payment and service delivery models developed by the Innovation Center. These waivers will be an essential step toward reducing the legal and regulatory barriers to achievement of the important health reform goals of the Affordable Care Act, and the grants the Secretary full authority to waive or modify the Physician Self-Referral Law and Anti-Kickback Statute as necessary to promote the Congressional intent underlying the Act. Further, under the Act and the proposed MSSP regulations, ACO participants will be required to submit all data that CMS and other regulators would need to identify occurrences of fraud and abuse and each MSSP ACO contract will be for a finite, three-year term and presumably terminable by CMS for cause in the event that the data indicates that such fraud and abuse has occurred. Accordingly, IHS encourages CMS and the OIG to accommodate the following recommendations for clarifying, refining and improving the effectiveness of the proposed waivers, which IHS believes are consistent with and supportive of the Congressional intent to foster the development of ACO's.

## **Proposed Physician Self-Referral Law Waiver**

### **Applicability of the Proposed Waiver to Distributions of Shared Savings to Other than ACO Participants and ACO Providers/Suppliers**

IHS urges CMS to expressly state that shared savings arrangements with providers and suppliers who are not participants in the ACO (“Other Providers/Suppliers”) would be considered “necessary for and directly related to” an ACO’s participation in and operations under the MSSP and thereby covered by the second prong of the proposed waiver under the Physician Self-Referral law that applies to distribution of shared savings to third parties. The ability to align incentives with Other Providers/Suppliers will be critical to facilitating the formation and successful operation of ACOs that elect to participate in the MSSP. This will be particularly true in the inaugural years of the MSSP because many providers may choose not to become full-fledged ACO participants until the MSSP and other CMS pilot programs have a track record of success. Of course, such an express statement should limit applicability to shared savings arrangements with non-ACO participants and non-ACO providers in which payment is contingent, in whole or in part, upon achievement of improvements in the quality and/or cost efficiency of, and/or patient and caregiver satisfaction with, services furnished to fee-for-service Medicare beneficiaries, and/or upon adherence to evidence-based clinical protocols, care coordination guidelines and/or treatment models in connection with furnishing such services. Such a qualifier would assure consistency with CMS’ stated intent that the scope of the Physician Self-Referral Law waiver be limited, in the case of distribution of shared savings outside the ACO, to those activities that relate “closely to the requirements for an ACO under section 1899 of the Act, including achieving the quality and savings goals of the Medicare Shared Savings Program.”

### **Applicability of the Proposed Waiver to Financial Arrangements other than Shared Savings Arrangements**

IHS urges CMS to extend the proposed Physician Self-Referral Law Waiver to cover financial arrangements with Other Providers/Suppliers, other than the distribution of shared savings, that meet the criteria described in the preceding paragraph and are thereby designed to align incentives in treating Medicare fee-for-service beneficiaries and achieve improvements in cost efficiency, quality and patient and caregiver satisfaction. Such alternative forms of alignment will indirectly contribute to achievement of the care integration, coordination and accountability that will be needed to realize the goals of the MSSP and thus to an ACO’s ability to qualify for shared savings bonuses under the MSSP.

### **Applicability of the Proposed Waiver to Provider/Supplier Arrangements Under Commercial Payor Programs**

ACOs will need to make substantial capital and other resource investments to build an accountable care delivery system that will support participation in the MSSP and other innovative CMS payment and delivery system models. To remain financially viable, ACOs that make such an investment will also likely need to establish a variety of accountable care arrangements with commercial payors. Such arrangements will also involve financial relationships among ACOs, ACO participants and ACO provider/suppliers that indirectly implicate the Physician Self-Referral Law when they involve physicians and entities to which the ACOs and their participants also make referrals for the furnishing of Medicare designated health services. Therefore, IHS urges CMS to expressly provide that the proposed Physician Self-Referral Law waiver applies to financial relationships among ACOs, ACO participants and ACO provider/suppliers that are necessary for and directly related to an ACO’s participation in and operations under any commercial payor program to the extent that they make payment contingent, in whole or in part, upon achievement of improvements in the quality and/or cost efficiency of, and/or patient and caregiver satisfaction with, services furnished to enrollees covered under the program, and/or upon adherence to evidence-based clinical protocols, care coordination guidelines and/or treatment models in connection with furnishing such services.

### Applicability of the Proposed Waiver To Funding ACO Infrastructure Investments

As noted above, participation in the MSSP and other innovative CMS payment and delivery system models will require substantial capital investment on the part of ACOs. In general, many providers participating in an ACO will be unable to contribute to the funding of such investments. IHS recognizes the long-held and valid concerns that CMS and the OIG have concerning the provision of free or discounted items and services to referral sources. On the other hand, if funding of such investments by hospitals and health systems on behalf of ACO participants and ACO provider/suppliers who cannot afford to do so is not covered by the proposed waiver, then only a relatively small number of highly integrated delivery systems will be in a position to apply for participation in the MSSP. Accordingly, IHS urges CMS to extend the proposed Physician Self-Referral Law waiver to cover the payment of infrastructure costs and consulting, actuarial and legal expenses by an ACO, and/or by one or more ACO participants, on behalf of other ACO participants or ACO provider/suppliers.

### **Proposed Anti-Kickback Statute Waiver**

#### Enhancing Access and Patient Compliance

An essential ingredient of any ACO's formula for earning shared savings under the MSSP and other innovative CMS payment approaches will be facilitating access to needed care and encouraging patients to comply with their treatment plans. ACOs will need to be able to provide incentives to beneficiaries who need assistance, such as free screenings or wellness items, co-pay and deductible waivers, and transportation vouchers. These types of incentives could implicate the Anti-Kickback Statute. The Accountable Care Act provides an exception to the CMP law for remuneration that "promotes access to care and poses a low risk of harm to patient and federal health care programs" as designated by the Secretary under regulations. IHS urges the OIG to extend the Anti-Kickback Statute waiver to permit the furnishing by ACOs, ACO participants and ACO provider/suppliers of free or discounted items and services to Medicare fee-for-service beneficiaries that are necessary for and directly related to promoting participation in and access to an ACO and/or medical home, including transportation, outreach, email access, health screenings, education and the waiver of copayments and deductibles.

### **Electronic Health Records Stark Anti-Referral Exception and Anti-Kickback Statute Safe Harbor – Extension or Removal of Sunset Provision**

In 2006, CMS and the OIG promulgated an exception to the Physician Self-Referral Law and a safe harbor under the Anti-Kickback Statute for hospitals to make donations of certain EHR technology items and services to physicians. Both the exception and the safe harbor set a deadline of December 31, 2013 as the date by which the donations must be completed ("Sunset Date"). This Sunset Date will occur well before the end of even the term covered by the initial 3-year agreements under the MSSP. The use of electronic health records (EHR) is an essential tool for care coordination. CMS' recognition of the important role of EHR technology in achieving the goals of health reform is evident, in part, in the requirement that ACOs participating in the MSSP demonstrate meaningful use of EHR technology. Accordingly, IHS urges CMS to extend (until at least the end of the 3-year terms of the initial agreements CMS enters into under the MSSP) or eliminate the Sunset Date on both the Physician Self-Referral Law exception and the Anti-Kickback Statute Safe Harbor.

### **Need for Federal Pre-Emption**

IHS suggests that CMS and the OIG use the ACA's broad grant of authority to fully occupy this area of health care regulation and clearly communicate the federal government's intent to pre-empt the field. Otherwise, providers' plans to organize as ACO's to comply with the MSSP may raise compliance questions with various state law provisions that simulate the federal physician self-referral law or anti-kickback statute.

### **Timing of Threshold Qualification for Proposed Waivers**

IHS suggests that the Physician Self-Referral Law, anti-kickback statute and Gainsharing CMP waivers include the investment in legal, consulting, personnel, and technology needed to build an ACO. Because much planning and investment needs to occur before an ACO is contracted with CMS in the MSSP, the investment should be protected as well. For instance, an ACO will need to require its participants to provide information about patients to the ACO and other ACO participants and ACO providers/suppliers. This information exchange will need information technology programs to permit the exchange. The exchange is directly related to ACO operations. Even though ACO participants and ACO providers/suppliers may incidentally benefit from this planning and investment, if the investment is necessary for and directly related to the ACO's MSSP operations, the waivers should apply.

Thank you for the opportunity to submit comments to the Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program. Questions regarding these comments can be directed to [rosenesc@ihs.org](mailto:rosenesc@ihs.org).

Sincerely,

Sabra Rosener