September 27, 2010

Donald S. Clark
Secretary
Federal Trade Commission

Donald M. Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services

Daniel R. Levinson
Inspector General

Mail Stop C5–15–12
Centers for Medicare & Medicaid Services
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RE: Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws

Secretary Clark, Administrator Berwick, Inspector General Levinson:

As a collection of not-for-profit, Catholic-sponsored health systems representing diverse regions across the United States and a range of communities spanning nearly all levels of integration between health care providers, we applaud the Obama Administration for its commitment to creating an environment in which the critical delivery system reform provisions of the Patient Protection and Affordable Care Act can be fully realized.

Our systems individually have pursued efforts to partner with physicians and other providers in our communities for the purposes of improving care quality, access and the efficient delivery of services to patients for many years. We supported the inclusion of new payment models such as Accountable Care Organizations (ACOs), bundled payment and the CMS Innovation Center and look forward to serving as a partner with the Administration in the development of a regulatory framework to implement these new models.

To that end, we thank you for the opportunity to provide our perspective on the complex web of law and regulation that while adopted for the purposes of ensuring appropriate utilization, fair market competition and preventing fraud and abuse, also present barriers to the clinical integration vital to widespread adoption of ACOs.

We offer for your consideration a set of specific recommendations for regulatory policy changes that we believe will help clear the path for more rapid adoption of ACOs, as well as bundled payment and other new payment models. The policy recommendations are focused on the Stark, Anti-Kickback and Civil Monetary Penalties laws, anti-trust enforcement and tax policy and licensure/certification requirements.

1. **Exception for Incentive Payment and Shared Savings Programs:** CMS should move forward to streamline and finalize its proposed §411.357(x), published in the CY 2009 Medicare Physician Fee Schedule Update proposed rule, that would establish a new, more inclusive exception under the Stark law for incentive payment and shared savings programs. CMS should reduce the 16 proposed conditions and provide greater flexibility for incentive payment and shared savings programs that improve care quality and reduce unnecessary utilization of services to Medicare beneficiaries.

2. **Regulatory "Safe Harbors":** The OIG and other enforcement agencies have cooperated in establishing specific "Safe Harbors," as well as general guidance on hospital/physician arrangements through the issuance of advisory opinions, bulletins, and other mechanisms. However, advisory opinions and guidance only apply to the specific circumstances under review. We believe there is enough common policy guidance to establish to establish specific "Safe Harbors" for arrangements that meet certain requirements in the following areas, or alternatively, expand existing safe harbors:
   - Under the anti-kickback law on risk sharing for cost savings arrangements, similar to those promulgated to promote e-prescribing and the adoption of Electronic Medical Records (EMR);
   - Under the Civil Monetary Penalties Act for qualifying gainsharing arrangements;
   - Expansion of the "Managed Care Safe Harbor" to include Accountable Care Organizations, such that ACOs would be allowed to operate in a similar capacity to a managed care organization or HMO, creating "downstream" revenue to providers.

3. **Need for Clarification of "Renumeration" restrictions** in light of shared savings arrangements between Not-For-Profit hospitals and for-profit physician groups. The Internal Revenue Service (IRS) and CMS will need to provide guidance regarding the formation and structure of ACO organizations, as well as organizations constructed to participate in the Medicare Bundled Payment pilot program.

4. **Specific Update Language to the DOJ/FTC "Statements of Enforcement" document:** The ACO legislative language could be viewed as restricting physician group participation in ACOs – i.e., a physician group would only be able to participate in one discreet ACO. CMS, as well as DOJ/FTC, will need to clearly define what constitutes a "market" for the purposes of an ACO organization and provide clear guidance on arrangements that effectively "lock up" a large market share to one ACO – particularly if physicians/groups are restricted from participating in multiple ACOs in a single market. While this is a potential problem for all markets, limiting physician participation to one ACO would be especially problematic for small and rural communities. Additionally, we strongly urge the DOJ and FTC to provide greater clarity and guidance within the Statements of Enforcement as to its standard for sufficient clinical integration.

5. **Clarification of an ACO and risk bearing:** CMS will need to provide clarity on whether an ACO is considered the principal risk-bearing entity and as such, would assume responsibilities currently provided to Medicare carriers. If an ACO is considered a risk-

bearing entity, it would then be subject to insurance licensure, liquidity and reserve requirements, depending on state law.

6. **Waiver of Civil Monetary Penalties Beneficiary Inducement Prohibition**. We recommend that this prohibition be waived for ACO organizations as it is necessary to remove risk in circumstances where the ACO wants to encourage loyalty by beneficiaries, or to potentially adjust cost sharing to create incentives intended to maximize outcomes, etc.

Thank you for the opportunity to provide these recommendations to advance the discussion and development of regulatory policy changes to facilitate the implementation of the Affordable Care Act. Please contact Steve Brennan, at (425) 525-3717 or at steve.brennan@providence.org for more detail on any of these recommendations.

Thank you,

Providence Health & Services
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Catholic Health East
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Via Christi Health System
Catholic Health Partners
Trinity Health
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