



Sisters of Charity of Leavenworth Health System

September 25, 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
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws

Secretaries Clark, Berwick; Inspector General Levinson:

As a member of the Sisters of Charity of Leavenworth Healthcare system representing 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 system physician-hospital organizations individually have pursued efforts to partner with 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 strongly 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 Medicare Conditions of Participation 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, targeted 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, through the evolution of advisory opinions and guidance on individual hospital/physician arrangements, developed enough consistent policy direction 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 “Remuneration” restrictions** in light of shared savings arrangements between Not-For-Profit hospitals and for-profit physician groups. The Internal Revenue Service (IRS) 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 appears to restrict physician 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. This especially critical for small and rural communities.
5. **Clarification of an ACO and risk bearing:** CMS will need to provide clarity on whether an ACO is considered in “first line” position regarding risk and assume responsibilities currently provided to Medicare carriers. If an ACO is considered “first line,” it would



Sisters of Charity of Leavenworth Health System

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

6. **Waiver of Civil Monetary Penalties prohibition of giving something of value to a Medicare or state healthcare program beneficiary** that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider or practitioner for services that may be paid in whole or part by Medicare or state healthcare programs. This is needed to remove risk 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 me at 406-237-3105 for more detail on any of these recommendations.

Thank you,



Mike Schweitzer, M.D., MBA

Regional Chief Medical Officer
Holy Rosary (Miles City, MT)/St. Vincent Healthcare
VP Medical Affairs, St. Vincent Healthcare (Billings, MT)