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CMS ANNOUNCES PHYSICIAN HOSPITAL COLLABORATION DEMONSTRATION

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Medicare demonstration projects provide opportunities for innovative health care providers and physicians to help shape the future of the Medicare payment system. Recently, the Centers for Medicare & Medicaid Services ("CMS") announced the Physician Hospital Collaboration Demonstration ("MHCQ"). The MHCQ was authorized by Section 646 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). The demonstration will provide CMS with data to facilitate the transition to a Medicare payment system based on evidence-based medicine and an emphasis on quality improvement in patient care. The deadline to apply for participation in the MHCQ is January 6, 2007.

CMS conducts demonstration projects to determine if new programs can beneficially change the Medicare and Medicaid programs. These experimental programs are designed to test and measure the effectiveness of potential program changes. Demonstration projects allow CMS to conduct real world research to affect program changes in advance of implementation on a program-wide basis.

The MMA provides the Secretary of Health and Human Services the ability to waive provisions of the Stark, Anti-kickback, and civil monetary penalties statutes as they relate to the MHCQ applications approved by CMS. CMS continues to maintain that in the absence of this authority, gainsharing is restricted by the Civil Monetary Penalty ("CMP") law.[1] The CMP prohibits hospitals from awarding physicians for reducing services to patients, even if such reductions are limited to duplicative services or otherwise represent improvements in quality.

Even given Congress's authorization to waive certain statutory provisions, however, the Secretary has announced that an applicant may not propose a project that:

- Rewards physicians for the reduction or limiting of services that are medically necessary to a patient entitled to benefits under the Medicare program;
- Provides payments that are based on the volume or value of referrals or business otherwise generated between the hospital and physician;
- Provides payments that are based solely on hospital care; or
- Provides for gainsharing payments that exceed 25% of the Medicare payment amount that is normally made to

[1] The CMP laws prohibit the offering or payment of an inducement to reduce or limit services to patients who receive governmental health care benefits. Gainsharing programs are designed so that providers can share in the savings generated by the reduction in certain services or in the use of certain equipment and supplies.

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physicians for cases included in the gainsharing demonstration.

All in all, payments must be linked to activities that improve overall quality and efficiency and result in cost savings for the episode of care. Given the restrictions noted above, very little latitude is given to project applicants to avoid the applicability of the Stark Law or the Anti-kickback Statute.

Another important consideration is that the Secretary has no authority to waive certain other regulatory issues, such as **anti-trust compliance**. Equally important for **tax-exempt entities** participating in the MHCQ are the questions related to private benefit and private instrument. The Secretary likewise has no authority to waive tax law provisions that may affect the MHCQ participants. We previously discussed these types of regulatory issues related to the operation of pay for performance networks in the March 8, 2006, issue of *Health Industry Online.*

A successful applicant for participation in the MHCQ will likely need to be organized in a corporate structure that is similar to a physician/hospital organization. Tax-exempt entities such as hospitals that provide the operational funding requirements of a PHO may put their tax-exempt status at risk. If physician participants in the PHO do not contribute to the creation or operation of the PHO, the arrangement may also implicate the Stark Law and Anti-kickback Statute to the extent that those laws have not been waived by the Secretary.

When CMS announced the MHCQ it stated that the demonstration:

> *creates an opportunity to implement a demonstration that addresses gaps in care quality and efficiency by combining system redesign—improvements in clinical and non-clinical processes and structures within systems and organizations—with payment changes that alter the financial incentives and disincentives faced by providers. The MHCQ demonstration will test major changes to improve quality of care while increasing efficiency across a delivery system.*

CMS refers to the MHCQ as a “gainsharing” project. However, the focus of this demonstration is not on the traditional gainsharing model in which physicians are able to share in a hospital’s savings that are generated though physicians’ actions that cost reduction efforts rather than quality considerations. The MHCQ is focused on an entire episode of care and not simply the portion of treatment related to a hospitalization. The purpose of the MHCQ is to bring together all of the various elements of patient care in one coherent system.

The existing payment incentives prevent the U.S. from having a health care “system.” The health care treatment patients received by patients in the U.S. is notoriously uncoordinated. The lack of coordination creates inefficiencies and fosters poor quality of care. CMS wants to implement strategies that prevent short and long-term complications in surgical and medical cases. Reducing complications will result in improved quality and eliminate duplication of services. These are some of the most important elements of the business case for the pay for performance model. In other words, CMS is seeking proposals that will create a comprehensive pay for performance model that tracks the care patients receive

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across the spectrum of providers or facilities which provide the care. This outcome tracking will be especially important with respect to those patients who receive care for chronic medical conditions.

Under Section 646 of the MMA, health care groups that are eligible to apply for the MHCQ demonstration are defined as:

- Physician groups;
- Integrated delivery systems (IDSs); or
- An organization representing a coalition of physician groups or IDSs.

CMS will give preference to projects that are implemented by a consortium of physicians and their affiliated hospitals.

The MHCQ represents a substantial step in the development of a pay for performance payment methodology which will govern the way providers and physicians are paid. It is likely that significant changes will be made to the Medicare payment methodology after CMS has studied the results of the MHCQ projects. Potential participants in the MHCQ demonstration will need to be cognizant of the regulatory schemes that will affect the operations of their proposed models to assure that they do not violate the provisions of the Stark Law and Anti-kickback Statute which the Secretary has not waived. Equally as important are tax and anti-trust law which may also be implicated by the creation of a PHO model to participate in the MHCQ demonstration.

A list of active and recently completed demonstration projects that may be of interest are available on the CMS website at: http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/list.asp#TopOfPage.

CMS Issues P4P Advisory Opinion

The OIG issued Advisory Opinion 06-15 on October 6, 2006 concerning a Medicaid waiver project that involves a physician pay performance component. A Medicaid waiver is similar to a demonstration project in that a state is given a waiver from Medicaid regulations in order to attempt an innovative program. The Advisory Opinion is narrowly drawn. The Opinion affirms that there is no violation of federal law when payments to physicians are made on the basis of a P4P program that had been approved through the waiver by CMS. The message is not the limited approval granted in the Advisory Opinion. Rather, the important message is that a P4P program can still violate federal and state regulatory provisions even when the basic structure of the demonstration program or waiver has been approved by CMS.

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