Hospital Incentive Payments to Physicians for Quality and Cost Savings

Implications under the Fraud and Abuse Laws

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I. Stark and Self-Referral Laws

- Stark will apply to an arrangement in which a hospital pays a physician for quality or cost savings performance, if the physician refers patients to the hospital for the provision of DHS. 42 U.S.C. §1395 (a)

Stark and Self-Referral Laws

- CMS has proposed a “shared savings” and incentive payment exception to the Stark regulations, but it is not final or effective. 73 Fed. Reg. 38502 (July 7, 2008)

Stark and Self-Referral Laws

- Three essential elements of the proposed exception:
  (1) transparency, (2) quality controls, and (3) safeguards against payments for referrals

Stark and Self-Referral Laws

- Requirements of the proposed exception:
  - payments with no adverse impact on patient care
  - verifiable quality measures and cost savings supported by credible medical evidence, tracked and monitored

Stark and Self-Referral Laws

- physician must be a member of hospital's medical staff
- independent review of program's impact on quality of patient care
- unrestricted physician access to items, supplies, and devices
- written disclosure to patients
- written agreement detailing incentives; term of one-three years; remuneration set in advance
- payments distributed to qualified "physician pools" of at least five physicians who participate in each performance measure; distribution to individual physicians on a per capita basis

Stark and Self-Referral Laws

- CMS has acknowledged that it would be a challenge for most hospitals to meet the proposed Stark exception
- Status of CMS waiver of Stark requirements

Stark and Self-Referral Laws

- Examples of existing Stark exceptions (42 C.F.R. §§411.355 and 411.357)
  - employment
  - personal services
  - fair market value
  - academic medical centers
  - indirect compensation
  - prepaid plans
  - risk sharing
- Explore structuring arrangement with physicians so there is neither a direct nor indirect compensation arrangement between the hospital and referring physicians – Stark will then not apply

II. Anti-Kickback Laws

- Payments to physicians and others that are intended to induce, or that relate to the volume or value of, patient referrals or generation of business to the hospital, may run afoul of federal and state anti-kickback statutes. See 42 U.S.C. §1320a-7b(b)

Anti-Kickback Laws

- Existing federal anti-kickback safe harbors (42 C.F.R. §1001.952)
  - managed care
  - employment
  - personal services
- Difficult to fit ACO payments into existing safe harbors
- The OIG has not proposed a safe harbor for ACOs or Shared Savings Programs
- The OIG has stated it is not planning to develop a safe harbor for ACOs or shared savings, stating that the Secretary's waiver of kickback prohibitions would be an option for ACO protection

Anti-Kickback Laws

- Failure to meet a safe harbor does not mean that the payment is necessarily illegal
- Fair market payment for quality, value and other objective performance standards will be less likely to violate anti-kickback laws than payments that pay, reward, or relate to the volume or value of patient referrals or the generation of business

Anti-Kickback Laws

- Advisory Opinion 08-16 (October 14, 2008): bonus payments for quality and efficiency standards
- OIG did not impose administrative sanctions under the anti-kickback law because:
  - physicians must be on the medical staff of the hospital for at least a year
  - cap on amounts paid to physicians
  - distributions to physicians on a per capita basis
  - transparency
  - oversight and monitoring of quality targets
  - term of agreement limited to three years

III. Civil Money Penalties Statute

- The federal Civil Money Penalties statute (the "CMP") generally prohibits compensation to physicians to induce them to reduce or limit services to Medicare or Medicaid beneficiaries. 42 U.S.C. §1320a-7a

Civil Money Penalties Statute

- The OIG has issued nine Advisory Opinions from 2005 through 2008 on cost savings measures -- “gainsharing programs” -- implemented by hospitals. Advisory Opinion No. 05-01 (Jan. 28, 2005); Advisory Opinion No. 05-02 (Feb. 10, 2005); Advisory Opinion No. 05-03 (Feb. 10, 2005); Advisory Opinion No. 05-04 (Feb. 10, 2005); Advisory Opinion No. 05-05 (Feb. 18, 2005); Advisory Opinion No. 05-06 (Feb. 18, 2005); Advisory Opinion No. 06-22 (Nov. 9, 2006); Advisory Opinion No. 07-21 (Jan. 14, 2008); Advisory Opinion No. 07-22 (Jan. 14, 2008); Advisory Opinion No. 08-15 (Oct. 14, 2008); Advisory Opinion No. 08-21 (Dec. 8, 2008)

Civil Money Penalties Statute

- OIG did not impose administrative sanctions because:
  - transparency
  - credible medical evidence that payment arrangement would not adversely impact patient care

Civil Money Penalties Statute

- uniform application of savings measures regardless of type of insurance; procedures subject to savings limited to base year
- cap on amounts paid to physicians
- written disclosure to patients
- financial incentives reasonable in amount and duration
- physician group distributes profits on a per capita basis

Civil Money Penalties Statute

- In contrast, the OIG has cited the following characteristics as arousing suspicion of violating the CMP:
  - no connection between compensable physician conduct and a reduction in hospital costs
  - insufficient safeguards that hospital actions other than physician conduct would account for savings compensable to physicians
  - lack of specific written requirements for individual physician conduct; overly general group results as a basis for compensation
  - dubious quality indicators
  - lack of independent verification of cost savings and quality of care indicators

  See, e.g., 73 Fed. Reg. 38,501 (July 7, 2008)

Civil Money Penalties Statute

- The OIG has not ruled on whether cost savings or reduction programs implemented under an ACO are permitted under the CMP
- ACO payments to incentivize quality performance raise issues under the CMP

Civil Money Penalties Statute

- In Advisory Opinion 08-16, the OIG did not impose administrative sanctions for the bonus program under the CMP because:
  - quality targets based on credible medical evidence
  - quality targets reasonably related to practice and patient population of hospital
  - performance measures underlying compensation to physicians clearly and separately identified
  - written disclosure to patients
  - transparency
  - tracking and monitoring of quality targets and measures to prevent inappropriate reductions or limitations in care

Civil Money Penalties Statute

- Additional features of hospital quality incentive payment programs that may reduce risk under the anti-kickback laws and the CMP:
  - independent, third party expertise to help develop program
  - recognized, published standards for quality targets
  - payments tied to meaningful improvements in quality

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Civil Money Penalties Statute

- different payments to improve quality and to maintain improvements; payment to maintain status quo without improvement is riskier
- document payment at fair market value
- quality improvements tied directly to actions of physicians
- payments are for quality only, not for referrals
- tracking and monitoring of quality data and performance; data mining is crucial

See, e.g., OIG Special Advisory Bulletin, Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July, 1999)

IV. Examples of Payment for Quality and Cost Savings

- Establishing quality and cost savings measures and criteria
- Payment methodologies
- Monitoring and evaluating physician performance