
CLIENT NEWSLETTER

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OIG Reviews Prompt Pay Discounts

The Office of Inspector General (“OIG”) of the United States Department of Health and Human Services recently issued an advisory opinion (Advisory Opinion 08-03) in which it approved a proposed arrangement involving a health system offering discounts to all patients, including Medicare and Medicaid patients, based on their prompt payment of their cost-sharing amounts and amounts owed for non-covered services. Although such an arrangement could violate the Anti-Kickback Statute or Civil Monetary Penalty Act, the OIG concluded that it would not impose sanctions.

Proposed Arrangement

The proposed arrangement in Advisory Opinion 08-03 provides that the health system would provide 5% to 15% discounts to patients for prompt payment of their cost-sharing amounts and amounts owed for non-covered services. The discount would apply to both inpatient and outpatient services. The health system certified that it would take the following steps associated with the arrangement: (1) not claim the waived amounts as bad debt or otherwise attempt to shift the burden to Medicare or Medicaid programs, other third party payors, or individuals; (2) not use the program as part of a price reduction agreement between the health system and a third party payor; (3) offer the program without regard to the patient’s reason for admission, length of stay, or diagnostic-related group; (4) bear all costs associated with administering the program; and (5) certify that the amount of the discount would

bear a reasonable relationship to the system's avoided collection costs.

OIG Analysis

The arrangement raised a concern that the discounts offered by the health system could potentially be considered payments to induce patients to obtain services at the health system's facilities. Such an inducement could result in penalties under the Anti-Kickback Statute. The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer to pay, solicit or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. The OIG concluded that based upon the certified steps the health system was willing to take as part of the arrangement, the Anti-Kickback Statute Safe Harbor for waivers of beneficiary co-insurance and deductible amounts for inpatient services (42 C.F.R. § 1001.952(k)) would be met. However, discounts for outpatient services are not covered under a specific Anti-Kickback Statute safe harbor. Nevertheless, the OIG held that as to discounts for outpatient services, the arrangement was a legitimate prompt payment incentive and there was minimal risk that the arrangement would induce patients to self-refer to the health system for services. The finding of "minimal risk" was based in large part upon the health system's certified steps to be taken as part of the arrangement.

Conclusion

Despite the OIG's ruling in Advisory Opinion 08-03, any discount arrangement needs to be reviewed by counsel to ensure it is appropriately structured to avoid any potential fraud and abuse liability exposure. The Rogers Law Firm is available to review any such proposed arrangement.

CMS Sets Limits for Non-Monetary Compensation and Medical Staff Incidental Benefits for 2008

The Centers for Medicare and Medicaid Services ("CMS") recently issued the limits that hospitals and other health care entities could spend on physicians for calendar year 2008 under the non-monetary compensation and medical staff benefits exceptions to the Stark Law. Specifically, hospitals and other health care entities will be permitted to provide non-monetary compensation to physicians up to an aggregate amount of \$338.00. Furthermore, hospitals will be able to provide medical staff incidental benefits (i.e. meals, parking, other items or services used on the hospital's campus) of no more than \$29.00 per occurrence (i.e. providing a meal to a physician of not more than \$29.00 each time the physician is on-campus providing services to patients who are hospitalized).

The Stark Law provides that a physician may not refer an individual for a designated health service to an entity with which the physician, or a member of his or her immediate family, has a financial relationship. A "financial relationship" includes all forms of

remuneration between a hospital and physician. The Stark Law, however, does contain an exception to “financial relationships” for non-monetary compensation and medical staff incidental benefits provided by a hospital or health care entity to a physician (42 C.F.R. § 411.357). Each year the amount of non-monetary compensation and medical staff incidental benefits is adjusted by CMS in accordance with the Consumer Price Index-Urban All Items (CPI-U) for the 12 month period ending the preceding September 30th.

Under the Stark Law exception there are other provisions which must be met by a hospital or health care entity providing non-monetary compensation or medical staff incidental benefits to physicians. Such provisions include, but are not limited to, the following: the compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician; the compensation may not be solicited by the physician or the physician’s practice; the compensation arrangement does not violate the Anti-Kickback Statute or any Federal or State law or regulation. As to medical staff incidental benefits, it is important to point out that the compensation must be offered to all members of the medical staff practicing in the same specialty and the compensation must be provided by the hospital and used by the medical staff members on the hospital’s campus.

In addition to the above limitations regarding non-monetary compensation or medical staff incidental benefits, a hospital or health care entity may have a policy or compliance manual which precludes providing such compensation. A hospital or health care entity should carefully review any proposed non-monetary compensation or medical staff incidental benefits with legal counsel before providing such compensation.

If you have any questions regarding non-monetary compensation or medical staff incidental benefits, please do not hesitate to contact any of The Rogers Law Firm.

HHS Proposes Rule Implementing Patient Safety Act

On February 12, 2008, the United States Department of Health and Human Services (“HHS”) published a proposed rule in the Federal Register which is intended to improve the quality and safety of health care for patients by encouraging the establishment of Patient Safety Organizations (“PSOs”). PSOs are private entities recognized by the Secretary of HHS to collect and analyze patient safety events reported by health care providers. PSOs would be new and separate from all currently existing entities charged with addressing health care quality.

HHS states that PSOs would allow for the voluntary reporting of patient safety events without fear of new tort liability. In addition, they would encourage clinicians and health care organizations to voluntarily share data on patient safety events more freely and consistently. Under the proposal, PSOs can collect, aggregate and analyze data and provide feedback to help clinicians and health care organizations improve health care quality.

The authority to list and formally recognize PSOs was established by the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41). While the statute makes patient safety event reporting privileged and confidential, it does not relieve clinicians or health care organizations from meeting reporting requirements under federal, state or local laws. However, the statute and the proposed rule address an important barrier that currently exists, namely, the fear of legal liability or sanctions that can result from discussing and analyzing patient safety events.

The proposed rule describes the following:

- the process whereby an organization may become a PSO;
- how clinicians will be able to report patient safety events confidentially;
- the restricted methods in which these data will be shared with others engaging in patient safety work while remaining privileged and confidential; and,
- how clinicians will receive feedback on ways to improve patient safety.

HHS considers strong confidentiality provisions as the key to voluntary reporting, and breaches of these confidentiality provisions may result in the imposition of civil monetary penalties.

The Agency for Healthcare Research and Quality (“AHRQ”) of HHS will administer the rules for listing qualified PSOs, and the Office for Civil Rights of HHS will be responsible for enforcing the confidentiality provisions of the statute. Further, HHS plans to issue guidance allowing entities to be listed as PSOs, consistent with the statute, prior to publication of the final rule. After collecting and analyzing sufficient non-identifiable data, AHRQ will publish information on national and regional statistics, including trends and patterns of patient safety events, which will be published in AHRQ’s annual *National Healthcare Quality Report*.

The public comment period for the proposed regulation lasts until April 14, 2008. The proposed regulation can be viewed online at:

<http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064803acce8&disposition=attachment&contentType=html>. The Rogers Law Firm will continue to monitor the proposed regulation implementing the Patient Safety Act and will provide updates accordingly.

OIG Issues Advisory Opinions Approving Certain Gainsharing Arrangements

The Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) posted two new advisory opinions January 14, 2008, approving certain gainsharing arrangements between acute care hospitals and physician groups.

Background

Advisory Opinion 07-21. This opinion applies to an acute care hospital that entered into a gainsharing arrangement with a group consisting only of cardiac surgeons, all of whom had medical staff privileges at the hospital. In the arrangement, the hospital agreed to pay the surgical group a 50% share of the hospital’s cost savings directly attributable to changes made by the surgeons in the operating room. The cost savings were calculated by subtracting the actual costs while enforcing the recommendations from the historic costs for the same items in the year prior to entering into the arrangement (base year costs – contract year costs = cost savings).

Twenty-five specific cost-saving recommendations were made, based on a study by the Program Administrator, who analyzed the historic practices of the hospital’s cardiac surgery department. The Program Administrator was hired for this specific, “arms-length” transaction for a certified fair market value fixed fee, and his assessments and position had no ties to the cost savings. Those specific recommendations were set forth in four categories: “Disposable Cell Saver Components” (surgeons to refrain from opening disposable components of the cell saver unit until a patient experiences excessive bleeding); “Use as Needed Supplies” (limit the use of certain surgical supplies to an “as needed” basis); “Product Substitutions” (substitution, in whole or in part, of less costly items for items then being used by the surgeons); and “Product Standardization” (group to standardize the use of certain cardiac devices and supplies where medically appropriate). These cost-saving recommendations were based on the study examining historical and clinical measures “reasonably related to the practices and the patient population at the hospital, and, in some cases, national data to establish ‘floors’ below which no savings would accrue to the surgical group.”

Advisory Opinion 07-22. This opinion discusses an arrangement between an acute care hospital and an anesthesiology group who would receive a 50% share of the hospital’s cost savings directly attributable to changes made by the anesthesiologists. This arrangement consisted of specific recommendations categorized as follows: “Use as Needed Items” (use as needed policy regarding use of a specific drug and a specific device used to monitor patients’ brain function); “Product Substitutions” (substituting less costly items for those being used); and “Product Standardization” (group to standardize the use of certain fluid warming hot lines where medically appropriate).

OIG Analysis

In examining both of these arrangements, the OIG identified several concerns that these arrangements create: cutting too much on patient care; “cherry picking” health patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; payments in exchange for patient referrals; and unfair competition (“race to

the bottom”) among hospitals offering cost savings programs to foster physician loyalty and attract more referrals.

More importantly however, the OIG addressed how these proposed gainsharing arrangements would be analyzed under the Civil Monetary Penalty Act and the Anti-Kickback Statute. The Civil Monetary Penalty Act provides for a civil monetary penalty against any hospital that knowingly makes a payment directly or indirectly to a physician (and the physician receives that payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician’s direct care. The OIG determined that the proposed gainsharing arrangements in Advisory Opinions 07-21 and 07-22 have sufficient safeguards so that the OIG would not seek sanctions under the Civil Monetary Penalty Act. These safeguards include the following:

1. Clearly and separately identifying specific cost-saving actions and the resulting savings.
2. Implementing the recommendations did not adversely affect patient care.
3. Amount to be paid under the arrangement was calculated based on all surgeries regardless of patients’ insurance coverage and subject to the cap on payment for Federal health care program procedures.
4. Utilizing historical and clinical measures to establish baseline thresholds to protect against inappropriate reductions in services.
5. Ensuring that individual physicians maintain the same selection of devices and supplies before and after the implementation of the arrangement.
6. Providing written disclosures of their involvement in the arrangement to patients whose care may have been affected by the arrangement and providing patients an opportunity to review the cost-savings prior to admission to the hospital.
7. Making financial incentives reasonably limited in duration and amount.
8. Distributing savings by the group to its members on a *per capita* basis (mitigating incentive for an individual physician to generate disproportionate cost savings).

The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. The OIG concluded that it would not seek sanctions under the Anti-Kickback Statute in relation to the proposed gainsharing arrangements in Advisory Opinions 07-21 and 07-22, based on the following safeguards which were in place:

1. Limiting participation in the arrangement to physicians already on medical staff.
2. Capping potential savings derived from procedures for Federal health care program beneficiaries.

3. Limiting the contract to one year.
4. Structuring the arrangement so that in each, that group was the sole participant and the profits are distributed on a *per capita* basis.
5. Setting out with specificity the particular actions that generated the cost savings on which payments were based.

Conclusion

Although the OIG determined that both proposed gainsharing arrangements could bring potential violations under the Civil Monetary Penalty and the Anti-Kickback Statute, the OIG stated that it would not impose sanctions based on the safeguards in place in each arrangement. The Opinions indicate that the structure and scope of these arrangements is such that the potential abuse of the benefits to physicians is eliminated, allowing a mutual benefit in cost-savings to the entity as well as its staff, while maintaining standard levels of patient care.

Any proposed gainsharing arrangements should be reviewed by legal counsel to ensure it is appropriately structured to avoid any potential fraud and abuse liability exposure. The Rogers Law Firm is available to review any such proposed arrangement.

HIPAA Security Audits – OIG and CMS: Being Prepared for Possible Review by Two Enforcement Agencies

In March of 2007, Piedmont Hospital in Atlanta became the first institution in the country to be audited for compliance with the Security Rule of the Health Insurance Portability and Accountability Act (“HIPAA”). The Office of the Inspector General (“OIG”) of the U.S. Department of Health and Human Services (“HHS”) conducted the audit, which some consider predictive of audits to be held at other institutions this year. Neither the hospital nor the inspection officials have spoken about the audit, but *Computerworld* published what it claims to be a document from a reliable source that lists 42 items to which HHS officials wanted responses from the hospital within 10 days.

Most of the list pertains solely to the handling, housing, and protection of electronic Protected Health Information (“ePHI”) and the risk and safety measures in place to protect ePHI. There were 24 requests to Piedmont Hospital for policies and procedures regarding ePHI related items, followed by 18 requests for various lists of information pertaining to the structure and security of the ePHI data. The scope of the information requested provides insight as to how HHS conducts audits regarding the secure handling and protection process of ePHI within a hospital. The following is the list which was provided by *Computerworld*:

Requested Information and Policy	
*Establishing and terminating access to systems housing electronic patient health information (ePHI)	*Recording/examining activity in information systems that house or process ePHI data
*Inactive computer sessions	*Emergency access to ePHI systems
*Risk assessments/analyses of relevant systems that house ePHI	*Preventing, detecting, containing / correcting security violations
*Employee violations (sanctions)	*Electronically transmitting ePHI
*Regularly reviewing records of information system activity (audit logs, access reports, and incident tracking)	*Creating, documenting and reviewing exception reports or logs. Provide examples of security violation logging
*Physical access to electronic information systems and facility in which they are housed	*Creating, documenting and reviewing exception reports or logs. Provide examples of security violation logging
*Monitoring systems/network, including listing of all network perimeter devices	*Remote access activity (network infrastructure, access servers, etc.)
*Internet usage	*Wireless security
*Terminating electronic session and encrypting / decrypting ePHI	*Maintenance/repairs of hardware, walls, floors, and locks
*Firewalls, routers and switches	*Transmitting ePHI
*Password and server configurations	*Antivirus software
*Network remote access	*Computer patch management

Requested Lists	
All information systems that house ePHI	Transmission methods for ePHI
Terminated and new employees	Organizational charts
Encryption mechanisms used for ePHI	Entity wide security program plans
Authentication methods used to clarify users authorized to access ePHI	All users with access to ePHI database, their access rights and privileges.
Outsourced/contracted individuals with access to ePHI data	Systems administrators, backup operators, and users
Antivirus software used for desktop and other devices including their versions	Software used to manage and control access to internet
Users with remote access capabilities	Antivirus servers (including versions)
Database security requirements and settings	Primary Domain Controllers (PDC) and servers

In addition to a HIPAA Security Rule audit by the OIG, covered entities may also be faced with an audit by the Centers for Medicare & Medicaid Services (“CMS”) for HIPAA compliance. CMS has extended a contract with PricewaterhouseCoopers to assist in conducting “compliance reviews” under HIPAA in what it delineates as a completely separate and unrelated audit from those done by the OIG. The likely targets for these audits will be those entities which CMS has already investigated under the HIPAA Security Rule. CMS representatives claim that these audits are part of a learning process and they will re-examine the security for those entities to ensure that the proper changes have been addressed subsequent to the original complaints.

Although the results of the reviews will be shared with the health care community, the findings will not be associated by entity name. With the Security Rule, CMS retains the authority to impose fines for serious violations of compliance and may require action plans to

remedy the issues. A set of guidelines for these reviews is to be posted by CMS in the early part of 2008.

The Rogers Law Firm will continue to monitor this matter and will provide updates accordingly. In the meantime if you have any questions or concerns regarding the HIPAA Security Rule, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

CMS Issues New Stark Law FAQs

The Centers for Medicare & Medicaid Services (“CMS”) of the United States Department of Health and Human Services has published answers on its website to a new set of frequently asked questions (“FAQs”) concerning the Physician Self-Referral Law, commonly referred to as the “Stark Law” (42 U.S.C. § 1395nn). The Stark Law precludes a provider from referring Medicare/Medicaid beneficiaries for designated health services to entities with which they, or members of their immediate family, have a direct or indirect financial relationship. These FAQs responses are intended to provide some clarification of CMS’s interpretation of certain gray areas in the most recent Stark Law Regulations (“Phase III”).

One of the issues considered is whether the Phase III “stand in the shoes” “grandfathering” provision applies to an arrangement that, as of September 5, 2007, did not meet the definition of an “indirect compensation arrangement” (and was not directly between a physician and a DHS entity) but would have satisfied the requirements of the exception for indirect compensation arrangements in 42 CFR § 411.357(p) if it had been applicable. CMS stated that it would not, as the only arrangements that qualify for the “grandfathering” provision in § 411.354(c)(3)(ii) are those that, as of September 5, 2007, both (1) met the definition of an “indirect compensation arrangement set forth in §411.354; and (2) satisfied the requirements of the exception for indirect compensation arrangements in §411.357(p). CMS added that if an arrangement satisfies both of these criteria, it need not be amended during its original term or the current renewal term (as of September 5, 2007) to comply with the requirements of another exception.¹ The FAQs topics also include the following:

- Examples of organizations, providers, or other entities that are NOT “physician organizations” as defined at 42 CFR §411.351;
- Services that qualify for the in-office ancillary exception in 42 CFR § 411.355(b);
- What constitutes a "physician practice" within the definition of "physician organization" under 42 CFR § 411.351;
- Whether provisions regarding termination or amendment of leases apply to personal service arrangements;
- Whether a hospital that directly employs or contracts with physicians to provide physician services to hospital patients is considered a “physician organization”;

¹ See 72 FR 51028.

- Physician recruitment arrangements;
- Fair market value compensation for medical directors of dialysis facilities;
- Whether implanted brachytherapy sources qualify for the Stark exception for implants furnished by an ASC;
- What constitutes a “physician organization” under Regulation 42 CFR § 411.351; and
- Group practice billing for ancillary services provided in shared office space with shared equipment.

The new CMS Stark Law FAQs can be viewed online at:

http://www.cms.hhs.gov/PhysicianSelfReferral/05a_FAQs.asp#TopOfPage. If you should have any questions regarding these FAQs, please contact any of the attorneys at The Rogers Law Firm.

April 1st Deadline Approaching for Tamper-Resistant Medicaid Prescriptions

Pursuant to Section 7002(b) of the United States Troop Readiness, Veterans’ Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 (the “Act”), as of April 1, 2008, all written prescriptions for out-patient drugs must be executed on tamper-resistant prescription pads in order to be reimbursable by the Medicaid program. The Act provides that in order to qualify as tamper-resistant, a prescription pad must contain an industry-recognized feature to prevent one of the following problems by April 1, 2008, and all three of the following problems by October 1, 2008: (1) unauthorized copying of a completed or blank form; (2) erasure or modification of information written by the prescriber; and (3) the use of counterfeit prescription forms. Any industry-recognized feature which is designed to prevent these problems is permissible under the Act.

The requirement for utilization of tamper-resistant prescriptions under the Act does not apply to the following types of prescriptions: those paid for by Medicaid managed care organizations; electronic, faxed or verbal prescriptions; and refills of prescriptions presented to a pharmacy before April 1, 2008.

The Rogers law Firm is available to answer any questions regarding the process for meeting the requirements of the Act.

This Newsletter is published by The Rogers Law Firm to keep its clients informed of developments in health law. The Newsletter should not be construed or relied upon as legal advice or legal opinion on any specific facts or circumstances. If you have any questions or concerns regarding the articles contained in the Newsletter or would like legal advice or legal opinion concerning a specific matter, please do not hesitate to contact any of the attorneys at The Rogers Law Firm, at (617)723-1100.