HEALTH CARE & THE LAW

TROUTMAN SANDERS OBTAINS FEDERAL GAINSHARING APPROVAL

Robert E. DeWitt
404-885-3184
rob.dewitt@troutmansanders.com

The Troutman Sanders Health Care Practice Group has successfully provided legal services related to the Department of Health and Human Services, Office of Inspector General ("OIG") advisory opinion (OIG Advisory Opinion No. 01-1) that approves a "gainsharing" arrangement between St. Joseph's Hospital in Atlanta, Peachtree Cardiovascular and Thoracic Surgeons, P.A., and Goodroe Healthcare Solutions, a noted Atlanta-based national health care consulting firm. This opinion is of significant national importance because it allows health care providers to proceed with this innovative collaborative initiative that can result in significant institutional savings and increased physician compensation while maintaining the highest quality patient care.

"Gainsharing" is a term broadly defined by the OIG as an “arrangement in which a hospital gives physicians a percentage share of certain reductions in the hospital’s cost for patient care attributable in part to the physician efforts.”

This is the second positive OIG opinion for the Troutman Sanders Health Care Practice Group within the past year making the Group a national leader in this area. These OIG advisory opinions are characteristic of Troutman Sanders’ creative solutions to complex problems.

Background

As growing financial pressures in the late 1990’s focused hospitals on cost reform, gainsharing evolved as an effective means for engaging physicians in cost saving initiatives. As physicians control approximately 80% of hospital costs, many hospitals viewed gainsharing as the ideal answer to their budgetary woes. However, a July 1999 OIG Advisory Bulletin entitled “Gainsharing Violates Federal Law” dealt a major setback to the gainsharing initiative, and arrangements across the country were terminated or their development halted. Troutman Sanders and its clients, Peachtree Cardiovascular and Goodroe Healthcare Solutions, did not view the 1999 Advisory Bulletin as a “no” from the OIG, but rather an opportunity to continue to design adequate safeguards needed to meet federal guidelines. While the OIG acknowledged in 1999 the potential value of such arrangements in reducing health care costs, the Advisory Bulletin contended that gainsharing violated a provision of the Civil Money Penalties Law of the Social Security Act which prohibits hospitals from “knowingly making a direct or indirect payment to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under the direct care of the physician.” The OIG also raised

(Continued on page 2)
Mission Statement:
The Troutman Sanders Health Care Practice Group represents a broad spectrum of health care providers and organizations that provide health care products, services, and technology to the health care industry. There are over 20 lawyers in our Health Care Practice Group, including those experienced in health care regulation, mergers and acquisitions of health care entities, managed care, medical technology and intellectual properties, capital financing for health care entities, physician employment and related arrangements, and health care legislation. In addition, other practice areas in the firm such as litigation, labor and employment, and tax and estate planning provide invaluable assistance to our health care clients.

concerns that the cost savings arrangements actually could violate the anti-kickback and self-referral statutes.

Approved Gainsharing Model

Despite the 1999 OIG Advisory Bulletin, Troutman Sanders and its clients reformulated their model and continued to petition the OIG for approval. This particular model is the first and only to elicit a favorable ruling from the regulatory agency. Under the approved arrangement, the hospital will pay cardiac surgeons at the hospital 50% of the cost savings achieved through changes in 19 specific operating room practices, classified into three groups: “open as needed” items; supply substitution; and drug use limitation. At the end of the first year of the program, savings to be shared are calculated by subtracting actual costs—adjusted to reflect only utilization meeting predetermined clinical benchmarks—from historic costs for comparable procedures. In all its aspects, the model is dependent upon a cardiac information system for detailed costs and outcomes tracking. The software captures costs directly attributable to actions covered under the gainsharing arrangement to insure that generated savings are achieved in accordance with appropriate clinical indicators and benchmarks. The favorable OIG Advisory Opinion notes that the combined features of the newly structured gainsharing model provides sufficient safeguards against improper reductions in services and poses a low risk of fraud or abuse under physician referral laws. The significant features of the model are as follows:

- Cost savings measures and resultant savings clearly and separately identifiable, with direct connections between individual actions and cost reductions.
- Written disclosure of gainsharing arrangement provided to patients undergoing procedures covered under the model.
- Objective clinical indicators establish baseline thresholds below which no savings accrue.
- Financial incentives limited in duration and amount.
- Credible clinical data and research supports the position that patient care is not adversely affected by re-engineered practices.
- Payments based on all surgeries regardless of patient insurance coverage.
- Cost savings do not accrue for procedures above and beyond historical patient volumes.
- Case mix, ages, and payors of patient population monitored; individual surgeons exhibiting significant deviation from historical measures are dropped from the gainsharing arrangement.

Ramifications

It is anticipated that many cardiac programs around the country will move forward with the development of gainsharing models given this positive regulatory development. In addition, it is anticipated that programs will be developed in other clinical areas utilizing the same principles announced in the OIG Advisory Opinion. It is important to note that all programs must obtain their own favorable advisory opinion from the OIG to implement a gainsharing model. Although tremendous effort is involved in crafting and implementing gainsharing programs, the potential for substantial (multi-million dollar) benefit for both hospitals and physicians exists.
On August 17, 2000 the Health Care Financing Administration ("HCFA") published final regulations establishing standards for electronic health care transactions, pursuant to the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act ("HIPAA"). Covered entities are required to comply with the standard implementation specifications and standard medical and non-medical data code sets established by the regulations when performing electronic health care transactions. Entities failing to do so may face civil monetary penalties.

HCFA expects that the adoption of standard electronic transactions will result in greater efficiency and administrative ease for the health care system, and, according to HCFA, should result in a $29.9 billion in savings over a ten year period. It is estimated that entities will spend $7 billion converting to the use of the standard specifications and code sets. The steep costs associated with this undertaking help explain the 17,000 comments that HCFA received during the 60 day comment period following the publication of the proposed regulations. This article summarizes the regulations which became final as of October 16, 2000.

Health care Transactions

Health care “Transactions” are those in which parties exchange financial or administrative information related to health care, and include, without limitation: (1) health care claims or equivalent and counter information; (2) health care pay-
ment and remittance advice; (3) coordination of benefits; (4) health care claim status; (5) enrollment and disenrollment in a health plan; (6) eligibility for health plan; (7) health plan premium payments; (8) referral certification and authorization; (9) first report of injury; and (10) health claims attachments. The regulations set forth standards specifying the format, data elements, and data content, including designated code sets for each type of electronic health care Transaction. Implementation specifications are available by written request.

Covered Entities

Pursuant to HIPAA, the regulations define Covered Entities as Health Plans (including group health plans, health insurance issuers, HMOs, and issuers of long term care policies, among others) and health care Clearinghouses (including billing companies, value-added networks and switches, and any other entity which processes or facilitates the processing of health care information received from another entity). Covered Entities also include any health care Provider (including hospitals, skilled nursing facilities, outpatient rehabilitation agencies, home health agencies, residential facilities, pharmacies, medical and dental laboratories, durable medical equipment suppliers, medical doctors, osteopaths, dentists, podiatrists, chiropractors, and optometrists) that electronically transmits a health care Transaction.

Health Plans and Clearinghouses are required to electronically transmit, in accordance with the adopted standards, all health care Transactions between Covered Entities. In addition, a Health Plan is required to electronically transmit a health care Transaction if any entity requests that it does so, whether or not such entity is a Covered Entity. Health care Providers are able to continue to transmit health care Transactions in the traditional paper method, without regard to the standards established by the regulations. However, if a health care Provider does electronically transmit a health care Transaction with a Covered Entity, it must do so in accordance with the standards established by the regulations.

While the proposed regulations created an exception for health care Transactions within a corporate entity, HCFA did not include this exception in the final regulations. Thus, Health Plans and Clearinghouses are required to electronically transmit health care Transactions in accordance with the adopted standards within their own organization, as well as when transmitting to a distinct Covered Entity. In addition, to the extent a Provider electronically transmits a health care Transaction within its own organization, it also must do so in accordance with the adopted standards.

Health care Clearinghouses, Health Plans, and Providers may use “business associates” or “third party administrators” to conduct health care Transactions on their behalf, but if they do so, they must require the business associate, and any agent or subcontractor of the business associate, to comply with all applicable requirements of the regulations.

Risks of Non-Compliance

Covered Entities, with the exception of small Health Plans, are required to begin complying with the regulations by October 16, 2002. HIPAA provides that persons are subject to fines of $100 per occurrence, up to $25,000 per violation of an identical requirement or prohibition for a calendar year. Thus, Covered Entities that fail to adopt the standards in a timely manner could potentially face up to $25,000 in fines for each requirement or prohibition violated, with no ceiling for failing to com-
Conclusion

HCFA’s final regulations concerning standard electronic health care Transactions were the first in a series of final regulations expected from HCFA pursuant to the Administrative Simplification provisions of HIPAA. These regulations will likely be costly to institute. The requirements are being compared to Y2K compliance projects in scope and cost for the health care industry. While the regulations offer entities two years to become compliant, covered entities should begin the process now, to avoid a “mad dash” in the period just prior to October, 2002. Entities failing to do so could face significant civil monetary penalties.

COMPLIANCE PROGRAMS FOR PHYSICIAN PRACTICES

Christopher L. Coffin, J.D., R.N.
404-885-3827
christopher.coffin@troutmansanders.com

Introduction

As part of the Federal Government’s efforts to reduce health care fraud and abuse in the United States, the Department of Health and Human Services (HHS), Office of Inspector General (OIG), has encouraged health care providers to create corporate compliance plans for their practices. Over the past three and one half years, to assist providers with the development of these plans, the OIG has established general guidelines for various providers that describe elements fundamental to an effective corporate compliance plan. To date, the OIG has issued compliance program guidelines for hospitals, clinical laboratories, home health agencies, durable medical equipment suppliers, third-party medical billing companies, hospices, Medicare +Choice organizations offering coordinated care plans, nursing facilities, and most recently, individual and small group physician practices.

Guidelines for Physician Plans

The OIG released the final version of its Compliance Guidance for Individual and Small Group Physician Practices (“Compliance Guidelines”) on September 25, 2000. In these guidelines the OIG has focused on individual and small group practices developing meaningful compliance programs that comply with applicable laws, statutes, and regulations. By following these Compliance Guidelines and implementing a corporate compliance plan, physicians will not only increase legal compliance within their practices, but they will also improve

(Continued on page 6)
the quality of care rendered through improvement in patient care documentation and efficiencies in billing and reimbursement. Therefore, physicians are encouraged to use the Compliance Guidelines to implement a corporate compliance plan that will help identify regulatory risks and reduce improper conduct while streamlining business operations.

As the OIG has stated, there is no “one size fits all compliance program for physician practices.” However, the Compliance Guidelines include seven steps that physician practices may consider when implementing a corporate compliance plan. The seven suggested steps include (1) conducting internal monitoring and auditing through performance of periodic audits; (2) implementing compliance and practice standards through the development of written standards and procedures; (3) designating a compliance officer or contact(s) to monitor compliance efforts and enforce practice standards; (4) conducting appropriate training and education on practice standards and procedures; (5) responding appropriately to detect violations through the investigation of allegations and the disclosure of incidents to the appropriate Government entities; (6) developing open lines of communication, such as (a) discussion with staff regarding how to avoid erroneous or fraudulent conduct and (b) using community bulletin boards to keep practice employees updated regarding compliance activities; and (7) enforcing disciplinary standards through well-published guidelines. Each step in the Compliance Guidelines is briefly summarized in the following paragraphs.

Step One: Auditing and Monitoring

In this initial step, the OIG suggest that the physician practice conduct a risk-identifying audit. The purpose of this audit is for the physician practice to determine whether it is engaging in activities that create a regulatory risk. Such risks may present themselves in many different areas that are covered in the steps below. Once the physician practice identifies potential risks, it must be sure to appropriately respond.

The OIG suggests that physician practices initially complete a base line audit and conduct periodic audits thereafter. Physician practices should consider completing audits on a yearly basis.

Step Two: Practice Standards and Procedures

In considering the standards and procedures that physician practices should develop, the OIG has noted potential risk areas affecting physician practices. These potential risk areas include (1) coding and billing; (2) reasonable and necessary services; (3) documentation; and (4) improper inducements, kickbacks and self-referrals. In addition to these four major risk areas, the Compliance Guidelines list “additional risk areas” for physician practices to consider when implementing a corporate compliance plan.

Step Three: Designation of a Compliance Officer/Contact(s)

Once the physician practice has completed audits and identified risks, it should appoint one or more members of the practice to accept responsibility for compliance monitoring, developing any necessary corrective action plans, and overseeing the practice’s adherence to those plans. The OIG notes that the practice may appoint one person to be responsible for all compliance activities, or it may designate multiple persons to implement the compliance program.
Step Four: Conducting Appropriate Training and Education

The OIG emphasizes that education is a critical component of any compliance program. The Compliance Guidelines list three basic steps for setting up educational objectives: (1) determining who needs training in the areas of coding and billing and compliance; (2) determining the type of training that best suits the practice’s needs; and (3) determining when and how often education is needed and how much each person should receive. In addition, the Compliance Guidelines provide physician practices with a variety of means through which education and training may be accomplished. Physician practices should consider the specific suggestions that the OIG has presented when creating training and education programs.

Step Five: Responding to Detected Offenses and Developing Corrective Action Initiatives

Each corporate compliance plan should include a section that outlines appropriate responses to problems within the practice. Such responses may include contacting legal counsel and creating corrective action plans. Because a physician practice’s response to a detected offense can adversely affect the practice, providers should carefully consider these issues.

Step Six: Developing Open Lines of Communication

Physician practices should implement a system of communication that encourages frank discussion about problems and risks that exist within the practice. The OIG encourages the use of several forms of communication between the compliance contact(s), office staff and provider personnel. Depending on the size and structure of the physician practice, informal communication techniques may be implemented to successfully achieve compliance. The Compliance Guidelines offer examples of both formal and informal communication techniques that physician practices may consider.

Step Seven: Enforcing Disciplinary Standards Through Well-Publicized Guidelines

The final step a physician practice should take in creating a compliance program is ensuring that employees understand the consequences for non-compliance. The Compliance Guidelines state that an effective physician practice compliance program should include procedures for enforcing and disciplining individuals who violate the practice’s compliance or other practice standards. The OIG has recommended specific enforcement and disciplinary procedures for physician practices to consider.

Conclusion

Given the health care enforcement environment and the OIG’s continuing emphasis on compliance programs, physician practices must carefully consider implementing a corporate compliance plan. Providers can use the Compliance Guidelines as a valuable tool in developing and implementing practical and cost-effective compliance measures in their practices. In addition, by implementing an effective compliance program and incorporating compliance principles into the practice environment, providers will improve their business practices and decrease their exposure to future regulatory risks. ◆
In addition to this Review, Troutman Sanders LLP also publishes seven other newsletters:

**Employee Benefits & The Law** discusses current developments in the law and current issues in the administration of employee benefits and executive compensation.

**Employment & The Law** details current federal and state labor issues that impact the relationship between employers and employees.

**Environment & The Law** tracks developing trends in environmental law, including air and water quality and hazardous substances.

**Intellectual Property & The Law** covers current issues in intellectual property/high tech areas, including copyrights, trademarks, patents, trade secrets, employment agreements and tax issues applicable to the development of technology.

**International Business & The Law** details current issues that impact international business transactions, trade in merchandise and services, and international investment opportunities.

**Real Estate & The Law** provides up-to-date information on legal developments affecting real estate including opportunities for readers to protect their properties, and provides general insights into related areas of interest.

**Transportation & The Law** addresses issues of interest to trucking companies, railroads, logistics companies, shippers with transportation needs and others with an interest in transportation issues.

Please contact the Office of Practice Development at 404-885-2525 if you would like to receive any of these publications.

---

**Out & About**

**Tom Baker** gave a presentation on Medicare fraud and abuse issues for rehabilitation service providers at Rehab 2001: A Medicare Payment Odyssey conference by Dixon-Kanary & Company in Las Vegas, Nevada on January 18, 2001. In addition, Tom has been serving as the Chairman of the monthly meetings of the Georgia Electronic Commerce Association, eHealth Working Group.

**Rob DeWitt** helped clients of the Health Care Practice Group to obtain OIG Advisory Opinion No. 01-1 which permits a hospital-physician gainsharing arrangement. The OIG Opinion, Troutman’s clients, and Rob were featured in the March, 2001 edition of Health Lawyers News, a publication of the American Health Lawyers Association.

**Joe Mandarino** participated in a working group of the American Health Lawyers Association that produced a “member briefing” titled “IRS Intermediate Sanctions Temporary Regulations” that was issued in March. Joe also published an article titled “IRS Publishes Long-Awaited Intermediate Sanctions Regulations” that will appear in the next issue of the Tax & Finance Newsletter of the American Health Lawyers Association.