CCH Health Care Compliance LETTER

Volume 11, Issue 22 health.cch.com October 28, 2008

Six financial arrangements successfully pass OIG scrutiny

In six recently released advisory opinions, the Office of Inspector General (OIG) gave clearance to several programs and financial arrangements, finding that sufficient safeguards had been put in place to prevent violations of the Social Security Act and the anti-kickback statute.

The OIG announced that the following arrangements would not be subject to civil monetary penalties or sanctions:

- a proposed arrangement that would waive cost-sharing obligations for services provided during a government-sponsored clinical trial;
- a proposed arrangement under which a new legal entity would provide purely administrative services for processing and submission of insurance pre-authorizations for various radiology and imaging centers;
- a proposed arrangement between a managed care organization and insurance subsidiaries that would provide policyholders discounts on Medicare inpatient deductibles;
- a program that would provide gift certificates and motivational incentives to reward patients who have met certain goals in substance abuse programs;
- an arrangement under which a hospital would share in savings from cost reductions attributable to changes made by groups of cardiologists who refer patients to the hospital; and
- an arrangement that would allow a hospital to distribute a percentage of bonuses it receives from a private insurer to a physician entity that helps the hospital fulfill certain quality targets.

Waiver of cost-sharing for clinical trial

A proposed arrangement that would waive cost-sharing obligations for clinical services and oxygen therapy provided to Medicare beneficiaries who participate in the Long-term Oxygen Treatment Trial (LOTT), sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and CMS, would not be subject to sanction under the anti-kickback statute or imposition of civil monetary penalties.

The LOTT is a randomized, controlled trial designed to investigate the possible benefits of providing continuous oxygen therapy to patients with chronic obstructive pulmonary disease (COPD) and moderate hypoxemia. The LOTT will consist of two treatment groups: one that will receive continuous oxygen therapy and a control group that will receive no oxygen therapy. Enrolled patients will be allocated to one of these two treatment groups by random assignment in equal numbers. The benefits of continuous oxygen therapy have been demonstrated in patients with severe COPD, but there is insufficient evidence to determine the benefits for patients with milder forms of the disease.

CMS issued a National Coverage Determination (NCD) for home use of oxygen in approved clinical trials extending Medicare coverage to home use of oxygen for

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beneficiaries with moderate hypoxemia who are enrolled subjects in certain approved clinical trials. CMS agreed to pay providers delivering care and other items or services under the LOTT directly for costs that are allowable for Medicare beneficiaries who participate in the trial. Under the proposed arrangement, regional clinical centers and other providers and suppliers participating in the LOTT will waive cost-sharing obligations for protocol-required clinical services and oxygen therapy provided to Medicare beneficiaries who enroll in the LOTT.

The following factors adequately protect the proposed arrangement against the risk of fraud or abuse: (1) the LOTT is a government study that will be closely monitored by NHLBI, CMS and a number of independent entities; (2) the LOTT is neither a commercial study nor product-specific study, and all CMS-approved providers and suppliers that can comply with eligibility criteria are eligible to participate; and (3) the proposed arrangement is a reasonable means of enhancing the likelihood of success of the LOTT.

According to OIG, Medicare beneficiaries may be disinclined to participate fully for the duration of the study if they are required to pay to participate. Waiving cost-sharing obligations is a reasonable means of enhancing patient compliance with study requirements and retaining patients for the entire study period. Waiving cost-sharing obligations also will ensure that low-income patients are not precluded from the study. Lastly, only half the patients will be assigned to oxygen therapy, which will result in a differential of financial burden for study participants if cost-sharing obligations are not waived.

Pre-authorization services

A proposed arrangement under which a newly formed legal entity would provide purely administrative services for processing and submission of insurance pre-authorizations for various radiology and imaging centers would not generate prohibited remuneration under the anti-kickback statute, and the OIG would not impose administrative sanctions.

Under the arrangement, in return for performance of the services, the centers would pay the newly formed entity a "per service" fee for each pre-authorization processed and submitted regardless of whether the patient's insurer ultimately grants the pre-authorization for the procedure. OIG found that the proposed arrangement would not fit in the safe harbor for personal services and management contracts because the entity would be paid on a per service basis; thus, the aggregate compensation would not be set in advance.

OIG concluded that the proposed arrangement would not result in referrals of federal health care program business because: (1) neither the requestor nor the entity (nor their affiliates) is, was, or would be a health care provider, practitioner, or supplier or in any way affiliated with the health care industry (other than through the performance of the services under the proposed arrangement); (2) the proposed arrangement is distinguishable from arrangements involving marketing services because the services are purely administrative and do not involve the promotion of items or services payable under a federal health care program; and (3) the proposed arrangement is distinguishable from potentially problematic arrangements when administrative services are provided by, or on behalf of, a supplier, such as an imaging company or a manufacturer, to an existing or potential referral source.

OIG stated, however, that if a center or other third party (such as a manufacturer) paid the entity to provide the services for or on behalf of a referral source (such as a physician) and, thus, relieved the referral source of the costs of processing and submitting pre-authorizations, then the center or other third party could be providing prohibited remuneration to the referral source in violation of the anti-kickback statute.

Performance-based compensation

A proposed arrangement between a managed care organization (MCO) and insurance subsidiaries of Medicare Supplemental Health Insurance (Medigap) policies offered in almost every state in the country that would provide policy holders discounts of up to 100 percent on Medicare inpatient deductibles incurred at in-network hospitals has sufficient safeguards that it presents a low risk of fraud and abuse. The discounts apply only to Part A inpatient hospital deductibles and not other coinsurance or cost-sharing amounts. No other benefits would be offered by the hospitals to the insurers or their policyholders. When policyholders utilize nonnetwork hospitals, the insurers would have to pay the full Part A hospital deductible.

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CCH Health Care Compliance Letter is published 24 times a year by CCH, a Wolters Kluwer business, 4025 W. Peterson Avenue, Chicago, IL, 60646. Subscription rate is $305 per year. First-class postage paid at Chicago, Illinois, and at additional mailing offices. POSTMASTER: SEND ADDRESS CHANGES TO *CCH Health Care Compliance Letter*, 4025 W. PETERSON AVENUE, CHICAGO, IL 60646. Printed in U.S.A.

As part of the agreement, the insurers would return a portion of the savings from the arrangement to any policyholder who has an inpatient stay at one of the in-network hospitals. The insurers would provide information regarding the savings in written materials given to insureds. The Medigap plan indirectly would contract with hospitals for discounts on other otherwise inapplicable Medicare inpatient deductibles for its policyholders, and reduce the premium for utilizing a network hospital for an inpatient stay.

A safe harbor to the anti-kickback statute at 42 C.F.R. §1001.952(k), permits hospitals to waive the Medicare Part A inpatient deductible in certain circumstances. A second safe harbor at §1001.952(l), allows for reduced premium amounts offered by health plans. Although the arrangement does not constitute grounds for the imposition of civil monetary penalties, it could lead to prohibited remuneration under the anti-kickback statute if there is an intent to induce or reward referrals.

The arrangement, however, represents a low risk of fraud or abuse because the waivers will not increase or affect per service Medicare payments. For example, payments to hospitals under Part A for inpatient services are fixed and unaffected by beneficiary cost-sharing. Also, it is likely that the discounts will not increase utilization. Because membership in the network is available to any accredited, Medicare-certified hospitals that meets applicable state laws, the arrangement does not unfairly affect competition. Last, it is unlikely that professional medical judgment will be affected because a patient's physician or surgeon would not be a recipient of remuneration.

Incentives for drug treatment

Motivational incentives (MIs) consisting of gift certificates of nominal value used to reward a patient's achievement of certain treatment-related goals in a substance abuse program would not constitute grounds for the imposition of civil monetary penalties for providing unlawful inducements to beneficiaries. An outpatient drug abuse treatment center for individuals with psychoactive substance abuse dependence requested an opinion from OIG on the use of MIs because the center believes they might be helpful in achieving abstinence, maintaining attendance, and gaining participation in treatment activities.

The OIG concluded that the MI program poses a low risk of fraud and abuse because: (1) the program follows the therapeutic guidelines of HHS' National Institute on Drug Abuse and Substance Abuse and Mental Health Services Administration; (2) the incentives are of nominal value ($5 to $10) and never take the form of cash; (3) the incentives are clinically indicated for effective treatment under a plan certified as medically necessary and appropriate; (4) the incentives are earned through active, verifiable participation in core elements of treatment, such as providing urine samples and attending sessions; and (5) the incentives are not advertised nor are their potential use discussed with new patients.

While the MI program could generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of federal health care program business were present, the OIG would not impose administrative sanctions in connection with the MI program under the facts and conditions presented.

Sharing cost reduction savings

An existing arrangement in which a hospital shares with groups of physicians a percentage of costs savings arising from certain cost reduction measures implemented by the physicians will not result in civil monetary penalties or sanctions, according to OIG.

An acute care hospital entered into the savings-sharing arrangement with two groups of cardiologists that frequently referred patients to the hospital. Under the arrangement, the hospital paid each cardiology group a share of three years of cost savings directly attributable to specific changes in that group's cardiac catheterization laboratory practices. In developing the arrangement, the hospital hired a program administrator independent from the cardiology groups to identify cost-saving opportunities. The administrator made 30 recommendations that largely involve standardizing the use of medical devices and supplies and curbing inappropriate use or waste.

In this particular arrangement, OIG found that a number of precautionary measures were put in place to ensure that quality of care did not suffer and that federal regulations were not violated.

Under the arrangement, individual cardiologists determined on a patient-by-patient basis the most appropriate

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On The Front Lines

Drug Compounding Activities: Another Risk Area for Compliance

by Michael E. Clark, JD, LLM, Health Care Compliance Editorial Advisory Board Member

As the Food and Drug Administration (FDA) has acknowledged, its regulation of drug compounding activities significantly differs from how it regulates other new drugs.[1] The FDA's position about its authority to regulate drug compounding was recently reiterated in a warning letter issued to a Dallas pharmacy operator. Basically, the agency considers compounded drugs to be ***new drugs****, even if the compounded products are created from FDA-approved ingredients. This two part article provides the laws and regulations, discussion of significant cases, and considerations for health care and compliance professionals to assess.*

The FDA seemed comfortable, for about 50 years, with states taking the lead in regulating drug compounding activities. In 1992, however, when the agency promulgated Compliance Policy Guide No. 7132.16 (now renumbered CPG 460.200),[2] the FDA informed the regulated community not to interpret its willingness to assent to states taking the lead in regulating pharmacy activities to mean that it would not assert its regulatory interests if federal issues are involved. The agency emphasized that "while retail pharmacies are exempted from certain requirements of the [Food, Drug and Cosmetic Act], they are not the subject of any general exemption from the new drug, adulteration, or misbranding provisions."[3]

A few years later, Congress largely adopted the FDA's positions about drug compounding activities by enacting the FDA Modernization Act of 1997 (FDAMA),[4] which ostensibly defined drug compounding activities subject to *federal* regulation.[5] Subsequently, the FDA further explained how it intended to regulate drug compounding activities under the authority given to it by the FDA Modernization Act.

The pharmacy compounding law offers some protections against unsafe and ineffective compounded products, including the following main provisions:

- The compounded product must be individually prescribed for an identified patient;
- A bulk drug substance (basically, the chemical that becomes the drug's active ingredient) can qualify for use in compounding in any of three ways:
  1. It is found in an FDA-approved drug.
  2. It is listed in a book of widely used drug substances published by the United States Pharmacopeial Convention, an independent standard-setting organization.
  3. It is listed in an FDA rule as acceptable for pharmacy compounding (based on the agency's evaluation of the medical literature). A proposed rule, published in the January 7, 1999, *Federal Register*, lists 20 acceptable bulk drugs (myrrh among them), and 10 others that are classified as "under consideration."
- Previously marketed drugs found to be unsafe or ineffective and removed from the market may not be compounded.
- Drug products listed in FDA's regulations as difficult to compound may not be compounded. FDA is making a list of difficult-to-compound drugs for discussion at a future advisory committee meeting.[6]

This regulatory scheme for drug compounding activities, however, proved to be short-lived. In 2002, the FDAMA's restrictions on the ability of pharmacists and pharmacies to advertise about drug compounding were found to be unconstitutional by the U.S. Supreme Court in *Thompson v. Western States Medical Ctr.*[7] Prior to the Court's landmark decision, the Ninth Circuit had persuasively explained why the FDAMA's advertising provisions were not severable from the rest of the legislation.[8]

Significantly, when the government appealed that decision, the Court decided not to reach the severability issue, pointing out that it had not been raised by either party in the appeal.[9]

Medical Center Pharmacy v. Mukasey: The Stage is Set for Certiorari

In a recent decision, the Fifth Circuit expressly disagreed with the Ninth Circuit about the severability of the advertising restrictions in the FDAMA even though the parties suggested that the court should not consider the issue.[10] The Fifth Circuit panel's reasoning appears to be fundamentally flawed. For example, it offered two reasons why

traditional drug compounding activities are not affected by the FDAMA's provisions:

> First, if one considers "compounding" to include creating specialized dosage forms consistent with the instructions on a drug's label, *that...kind of compounding...would not result in a "new drug" under the FDCA's definition*. That sort of on-label compounding would be perfectly permissible even without exempting compounded drugs from the "new drug" definition.
>
> Second, and more significantly, even if compounded drugs are effectively made unlawful by the "new drug" definition and approval requirements, pharmacists still could continue compounding to the *extent allowed by the FDA's enforcement discretion*....[11]

It appears that the panel simply missed the landmark, pre-FDAMA decision in *United States v. Baxter Healthcare Corp.*[12] The type of compounding activities at issue in *Baxter Healthcare Corp.* involved *compounding specialized dosages consistent with the instructions on the drug's label* - the very type of compounding that the court in *Medical Center Pharmacy* said would **not** be a new drug.

> The principal issue...is whether the reconstitution of fully FDA-approved antibiotics in a manner consistent with the labeling directions, using a dilutent meeting the specifications in those directions, and placing the reconstituted antibiotic into an FDA-approved Viaflex plastic container, constitutes the manufacture of a "new" drug...which must be separately approved....[13]

As to the panel's second reason - its comfort that the FDA will properly exercise its enforcement discretion -note that *Baxter Healthcare* had tried to pre-clear its activities and was not criticized by the FDA for years, until, in an about-face, the agency sought an injunction. As the dissenting judge noted, hospitals using this service once again would have to perform the same activities, but at a higher cost because of the majority's decision:

> The single dose preparation technique for intravenous antibiotics is practiced at virtually all hospitals. Many larger hospitals, however, cannot meet their need for intravenous antibiotic drugs through...[this] method. Many of these hospitals have established centralized drug preparation programs...[to] reconstitute, dilute, and repackage the antibiotics in batches. It is not cost-effective for a hospital of more than 300 beds to engage in single dose reconstitution of antibiotics. Hospitals that engage in this type of centralized drug preparation do not necessarily reconstitute the antibiotics in response to an order for a specific patient. Some of these hospitals prepare batches of reconstituted antibiotics sufficient for one day's needs. Other hospitals prepare large batches intended to be used over a relatively long period of time. At least one hospital has prepared as many as 4,000 doses of reconstituted antibiotics at one time.[14]

Perhaps the Fifth Circuit panel also failed to understand the D.C. Circuit's reasoning for invalidating a 1995 guidance in which the FDA proclaimed jurisdiction over activities involving the compounding of drugs used in positron emission tomography (PET) scans.[15] In that case, the D.C. Circuit wrote: "Syncor suggests that if FDA may define "the scope of the regular course of the practice of the profession of pharmacy" so as not to include PET compounding activities, that it may do so for all pharmacists' compounding activities, whether nuclear or not, effectively circumventing the statutory exemption. *FDA's not entirely satisfactory response is that it will exercise its broad jurisdiction wisely.*"[16]

At bottom, *Medical Center Pharmacy* has created an inter-circuit split, which likely will result in a writ of certiorari. Notwithstanding which of the interpretations about the severability of the FDAMA's other provisions proves to be correct, it is important to observe that the FDA's compliance guidance about drug compounding activities is only an *interpretive* guide. As such, it lacks the force and effect of law because the FDA did not promulgate it through the notice-and-comment requirements for legislative rulemaking.[17] This was established by the Fifth Circuit in *Professionals and Patients for Customized Care v. Shalala*, where the court noted that "[a] general statement of policy...does not establish a "binding norm." It is not finally determinative of the issues or rights to which it is addressed. The agency cannot apply or rely upon a general statement of policy as law because a general statement of policy only announces what the agency seeks to establish as policy."[18]

While a pitched battle continues about the longstanding practice of drug compounding between its opponents and proponents, the Government Accountability Office recently indicated that ""[d]rug compounding...is *an important part of the practice of pharmacy* because there is a need for medications tailored to individual patient needs."[19]

Conclusion

Part I of this Article described the current landscape of federal regulatory oversight of compounding and flaws in the Fifth Circuit's decision in *Medical Center Pharmacy* resulting in an inter-circuit split and increasing the likelihood that the issue of compounding will appear before the Supreme Court. Part II of the Article will discuss potential liabilities and compliance considerations for health care professionals engaged in dispensing, marketing, or distributing compounded medications.

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[1] *See* United States v. Baxter Healthcare Corp., 901 F.2d 1401, 1411 (7th Cir. 1990) ("[T]his Court has recognized the logic of the FDA's position that a new drug may be created through the combination of approved drugs. United States v. Articles of Drug, 826 F.2d 564, 566 (1987) (citing 21 C.F.R. § 310.3(h)(2)"). In pertinent part, the FDA's logic on this position is that:

> [c]ompounded drugs are "new drugs" within the meaning of 21 U.S.C. § 321(p), because they are not "generally recognized, among experts... as safe and effective" for their labeled uses. *See* Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 619, 629-30 (1973) (explaining the definition of "new drug"). There is substantial judicial authority supporting FDA's position that compounded drugs are not exempt from the new drug definition. *See* Profls. & Patients for Customized Care v. Shalala, 56 F.3d 592, 593 n.3 (5th Cir. 1995) ("Although the [FDCA] does not expressly exempt 'pharmacies' or 'compounded drugs' from the new drug...provisions, the FDA as a matter of policy has not historically brought enforcement actions against pharmacies engaged in traditional compounding.")

FDA, Dallas District Office, Warning Letter to James Porter (Jan. 7, 2008), at 3; *available at* www.fda.gov/foi/warning_letters/s6698c.pdf. See *also* Baxter Healthcare Corp., 901 F.2d at 1411 ("As a policy choice, Congress has exempted pharmacies and physicians from the registration and inspection requirements that apply to all manufacturers of drugs. 21 U.S.C. §§ 360(g)(1), (2), 374(a)(1), (2). The FDA only follows that lead by focusing on the mass commercial distribution of drugs rather than at the individual level of hospitals and pharmacists.").

[2] CPG 460.200 is available at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html. In relevant part, this guidance lists nine nonexclusive factors that the FDA says it will examine in determining whether to consider an action (such as issuing a warning letter, seizure, injunction, or recommending a prosecution) whenever drug compounding issues are involved:

a. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.
b. Compounding drugs that were withdrawn or removed from the market for safety reasons. Appendix A provides a list of such drugs that will be updated in the future, as appropriate.
c. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. § 355(i) and 21 C.F.R. § 312.
d. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.
e. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.
f. Using commercial scale manufacturing or testing equipment for compounding drug products.
g. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.
h. Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.
i. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

[3] CPG 7132.16, at 1.

[4] FDA Modernization Act of 1997 (PubLNo. 105-115), 111 STAT. 2296 (amending the FDCA in scattered places).

[5] As the Supreme Court has explained, "Section 127(a) of the Food and Drug Administration Modernization Act of 1997..., 21 U.S.C. § 353a, exempts "compounded drugs" from the Food and Drug Administration's standard drug approval requirements as long as the providers of those drugs abide by several restrictions, including that they refrain from advertising or promoting particular compounded drugs. Thompson v. Western States Medical Ctr., 535 U.S. 357, 360 (2002)."

[6] FDA, *Pharmacy Compounding: Customizing Prescription Drugs*, FDA Consumer Magazine (July-Aug. 2000), *available at* www.fda.gov/Fdac/features/2000/400_compound.html.

[7] Thompson, 535 U.S. 357 (2002).

[8] *See* Western States Medical Ctr. v. Shalala, 238 F.3d 1090, 1097 (9th Cir. 2001) ("[e]vidence in the legislative record interpreting the final legislation demonstrates that Congress meant to exempt compounding pharmacists from FDCA requirements *only in return for a prohibition on the promotion of specific compounded drugs*.") (emphasis supplied).

[9] *See* Thompson, 535 U.S. at 366 ("Because neither party petitioned for certiorari on the severability issue, we have no occasion to review that portion of the Court of Appeals decision.").

[10] *See* Medical Ctr. Pharmacy v. Mukasey, 2008 WL 2779229 (5th Cir. July 18, 2008) (Slip. op.)("Neither FDAMA's text nor the inconclusive legislative history amounts to ""strong evidence" that Congress would not have enacted the law without" the advertising provisions.").

[11] *Id.* (emphasis added).

[12] United States v. Baxter Healthcare Corp., 901 F.2d 1401 (7th Cir. 1990) (affirming FDA's actions against a company for compounding hospital drugs, reasoning the activities were more commercial in nature than incidental).

[13] *Id.* at 1412.

[14] *Id.* at 1413.

[15] "On February 25, 1995, FDA announced that PET radiopharmaceuticals "should be regulated" under the drug provisions of the Federal Food, Drug, and Cosmetic Act." Syncor Intern. Corp. v. Shalala, 127 F.3d 90, 92 (D.C. Cir.

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On The Front Lines (cont.)

1997) (holding FDA's rule on PET scans constituted rulemaking subject to APA notice-and-comment to be valid and binding as a legislative rule).

[16] *Id.* at 93, n.3 (emphasis supplied).

[17] See Section 503 of the Administrative Procedures Act, codified at 5 U.S.C. §553.

[18] Professionals and Patients for Customized Care v. Shalala, 56 F.3d 592, 595-596 (5th Cir. 1995).

[19] Statement of Janet Heinrich, Director, Health Care-Public Health Issues, GAO, *PRESCRIPTION DRUGS: State and Federal Oversight of Drug Compounding by Pharmacies* (Testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate), GAO-04-195T, at 1 (Oct. 23, 2003) (emphasis supplied). *See also* Thompson, 535 U.S. at 361 ("[Compounding]...is a traditional component of the practice of pharmacy...and is taught as part of the standard curriculum at most pharmacy schools.... Many States specifically regulate compounding practices as part of their regulation of pharmacies..."). *See generally*, 22 T.A.C. §291.133 ("Pharmacies Compounding Sterile Preparations") for the classification of types of pharmacies and various requirements under state law.

Anti-kickback (cont.)

medical device or supply. Moreover, the full range of devices and supplies would be available to cardiologists and their patients. The arrangement included "floors," beyond which no savings accrue to the cardiology groups. The program administrator also tracked the hospital's performance against quality indicators established by the American College of Cardiology and no cost sharing amounts were allocated to the cardiology groups for procedures that involve reductions in those quality indicators.

To make the arrangement more transparent, the hospital and cardiology groups documented the activities and payment methodology and made such information available to HHS upon request. The hospital and the physician groups also disclose the arrangement to patients in writing and give patients the opportunity to review details of the arrangement, including specific cost saving measures applicable to the patient's procedure.

The OIG noted that because participation in the arrangement has been restricted to cardiologists currently on the medical staff, the likelihood that the arrangement will attract other cardiologists is limited; and the potential savings derived from procedures for federal health care program beneficiaries were capped based on the physicians' prior year's admission of federal health care program beneficiaries. Thus, the incentive to refer patients was reduced, if not eliminated. Under the circumstances, the OIG concluded that the risk of fraud or abuse under the anti-kickback statute was low.

Compensation based on quality

A proposed arrangement that would allow a hospital to share performance-based compensation it received from an insurer with a physician-owned organization was designed with sufficient safeguards for patient care and would not be grounds for sanctions.

A nonprofit corporation that owns an acute care hospital participates in a pay-for-performance program implemented by a private insurer. Under the program, the hospital receives a bonus from the insurer to the extent it meets certain standards of quality and efficiency.

Under the proposed arrangement, the hospital would enter into a quality enhancement professional services agreement with a physician-owned entity whereby the hospital would pay the physician entity a percentage of the bonus it received as a result of meeting the insurer's quality targets. The physician entity would, in turn, distribute its earnings under the agreement to its members, licensed physicians in good standing on the hospital's active medical staff for at least one year and meet certain other criteria.

The hospital certified that it would monitor the quality targets and their implementation throughout the term of the agreement to protect against inappropriate reductions or limitations in patient care services. It also would monitor for changes in physician referral patterns potentially attributable to efforts to meet the quality targets and terminate from the program physicians who have significantly changed their patterns in a manner beneficial to the hospital or the physician entity. All performance records will be available to HHS, and patients who are admitted to the hospital with one of the conditions subject to the quality targets will be informed of the program in writing.

The arrangement has the potential to improve patient care and is unlikely to have adverse effects on it. There was no incentive for a physician to apply a specific standard in medically inappropriate circumstances, and the quality targets were reasonably related to the practices and patient population of the hospital. The OIG also noted that the per capita distribution of compensation under the agreement to members of the physician entity will reduce the risk that the arrangement might be used to reward individual physicians who refer patients to the hospital.

The oversight role of the private insurer provides an additional safeguard, as the insurer has no incentive to overcompensate either the hospital or the physicians. Rather, its incentive is to pay the bonus compensation only as it is earned through the achievement of quality targets. ■

OIG Advisory Opinions, No. 08-11, Sept. 24, 2008, Health Care Compliance Reporter ¶500,195; No. 08-12, Sept. 26, 2008, ¶500,196; No. 08-13, Oct. 2, 2008, ¶500,191; No. 08-14, Oct. 2, 2008, ¶500,192; No. 08-15, Oct. 14, 2008, ¶500,193; No. 08-16, Oct. 14, 2008, ¶500,194; respectively.

Fraud & Abuse

False statement within claim does not result in liability under FCA

A provider's certification of compliance with Medicare statutes and regulations as stated in an annual cost report does not render all claims submitted for reimbursement by that provider false under the False Claims Act (FCA) if that statement is not true.

A physician employed by the provider alleged that the certification of compliance submitted by the provider for services rendered was false because the provider was not in compliance with numerous conditions of participation. The certification of compliance statement within the annual cost report, however, does not condition Medicare payment on perfect compliance with any particular law or regulation.

Liability under the FCA does not occur because a false statement is included within a claim, but rather the claim itself must be false or fraudulent. Under 42 C.F.R. Part 488, providers must undergo inspections and accreditation to remain in compliance within the Medicare program. There are various methods in place to assure compliance with those conditions of participation (COPs).

A provider is not making a false claim when it certifies it is in compliance with all the conditions of participation, even when the provider is not in compliance with all COPs. An actual false claim for payment must be submitted for there to be a false claim. A broader interpretation of a certification of compliance statement would undermine the administrative scheme in place for ensuring that providers remain in compliance.

The appellate court also rejected an anti-kickback allegation because the provider's attempt to broker a private compromise with the physician who was dissatisfied with the hospital's accommodations was not a solicitation for a kickback within the meaning of the FCA. The provider's motion to dismiss was affirmed. ■

U.S. ex rel. Conner v. Salina Regional Health Center, Inc., 10th Cir., Oct. 2, 2008, Health Care Compliance Reporter ¶800,566

In the News

New law requires mental health parity

Mental health parity legislation that prohibits employer group health plans from imposing higher copayments and deductibles on benefits for mental health services became law after years of struggle by advocates in the medical community. The bipartisan parity measure was attached to the $700 billion economic rescue package passed by Congress and signed by President Bush on October 3. Rep. Patrick Kennedy (D-Rhode Island), a sponsor of the parity legislation, said the measure marks the "end of mental health discrimination." Senate lawmakers attached the legislation to the rescue package in an attempt to win House support. Under the bill, insurance companies that provide mental health benefits would be required to do so on the same terms as care for physical ailments. Group health plans would not be required to offer mental health benefits under the bill, but those that do would have to offer similar terms and conditions as they offer for medical and surgical benefits. Employers with fewer than 50 employees would be exempt from the act's requirements.

CCH Washington Bureau, Oct. 3, 2008

MedPAC weighs financial relationship reporting

The Medicare Payment Advisory Commission (MedPAC) is considering options for requiring public reporting of physicians' financial relationships. At its October meeting, the commission discussed several draft recommendations, which it plans to vote on during its November meeting. Under the draft recommendations, manufacturers of drugs, biologics, medical devices or supplies and their subsidies would have to report their financial relationship with physicians, hospitals, research organizations and other types of organizations. HHS would be required to put the information on a searchable database with much of the information available to the public. Other information, including the provider's Medicare billing number, would only be available to researchers under certain circumstances. Hospitals and ambulatory surgery centers (except those that are publicly traded) and certain provider groups would have to report each physician who directly or indirectly owns an interest in the hospital or surgery center. Finally, the Secretary would be required to submit a report to Congress on the prevalence of financial arrangements between hospitals and physicians.

CCH Washington Bureau, Oct. 6, 2008

HHS issues interim guidance for PSOs

HHS has begun implementing the protections of the Patient Safety and Quality Improvement Act by developing new interim guidance that outlines how to become a Patient Safety Organization (PSO). The Act authorized the creation of PSOs to improve safety through the collection and analysis of data on patient safety events. By providing both privilege and confidentiality, PSOs will create a secure environment in which clinicians and health care organizations can voluntarily collect, aggregate and analyze data that enable the identification and reduction of risks and hazards. The interim guidance allows HHS' Agency for Healthcare Research and Quality to begin receiving applications from qualified entities that wish to become PSOs. This guidance will remain effective until HHS issues a final rule for PSOs, which is expected by the end of 2008. The proposed rule was published in February 2008. Information about the certification process is available at: www.pso.ahrq.gov.

CCH Chicago Bureau, Oct. 8, 2008