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OIG: joint venture arrangement may violate anti-kickback law

A proposed arrangement that would allow a physician group that provides cancer treatment services to lease space, equipment, and personnel services to urologist groups from which it receives patient referrals could violate the anti-kickback statute and subject the parties involved to sanctions, according to an advisory opinion from the Office of Inspector General (OIG). The OIG concluded that "there is a significant risk that the proposed arrangement would be an improper contractual joint venture that would be used as a vehicle to reward the urologist groups for their referrals."

Arrangement details. Under the proposed arrangement, a physician group that offers among its services intensity-modulated radiation therapy (IMRT) for prostate cancer patients would lease examination and treatment rooms as well as IMRT equipment to urology practice groups that currently refer patients to the physician group for treatment. The physician group would provide the urologist groups with radiation supplies and billing services and individual radiologists associated with the physician group would contract with the urologist groups as independent contractors to oversee IMRT procedures.

In exchange, the urologist groups would pay premises rent, equipment rent, personnel expenses and communication and administrative expenses. The lease amounts would be for fair market value rates fixed in advance and would not vary based on the use of the premises, equipment or services.

Joint ventures. The OIG advisory opinion stated that the proposed arrangement would effectively establish a joint venture between the physician group and the urologist groups.

"The OIG has long-standing concerns about certain problematic joint venture arrangements between those in a position to refer business, such as physicians, and those who furnish items or services for which Medicare or Medicaid pays, especially when all or most of the business of the joint venture is derived from one of the joint venturers," the advisory opinion explained. In 2003, the OIG issued a Special Advisory Bulletin on Contractual Joint Ventures that described and clarified the types of joint ventures that the OIG finds suspect. The OIG said the proposed arrangement shares several elements with the bulletin's example of a suspect joint venture.

Suspect elements. Specifically, the urologist groups would be expanding into a related line of business that is dependent on referrals from those same urology groups. The urologist groups would contract out most of the services associated with performing IMRT and would contribute very little capital or other resources to the IMRT. Thus, they would "be in a position to ensure the success of the busi-

continued on page 2

Wolters Kluwer Law & Business

Anti-Kickback (cont.)

ness, not only by referring to the physician group's facility for IMRT, but by the choice of IMRT over other available therapies for prostate cancer," according to the opinion.

The OIG also noted that the arrangement would allow the technical and professional components of IMRT to be billed to Medicare using the urologist groups' billing numbers. The urologist groups would ultimately retain the difference between the fees collected and amounts owed to the physician group. In the Special Advisory Bulletin, the OIG explained that illegal remuneration can be the difference between the money paid by a referral source to a manager/supplier and the reimbursement received by the referral source from the federal health care programs. The OIG concluded that this arrangement could be a way for the physician group to indirectly reward and compensate the urology groups for a share of the profits from their IMRT referrals.

Anti-kickback statute. The anti-kickback statute makes it unlawful to knowingly and willfully to offer, pay, solicit or receive remuneration to reward referrals of items or services reimbursable by a federal health care program. Remuneration has been construed broadly, including the transfer of anything of value, directly or indirectly.

The OIG could not definitively find that the proposed arrangement violates the anti-kickback statute because to do so would require a determination of the parties' intent. Nonetheless, the advisory opinion stated that the arrangement could potentially generate remuneration prohibited by the statute and that the OIG could impose administrative sanctions in connection with the arrangement. ■

OIG Advisory Opinion, No. 08-10, Aug. 19, 2008, Health Care Compliance Reporter, ¶500,189.

E-Discovery

Early planning is key to avoiding e-discovery headaches

In an age when most information is stored digitally rather than in paper form, one of the biggest mistakes a health care organization can make is not to begin thinking about how to preserve and produce that data until after it receives a subpoena or court order. During a recent teleconference titled "An Overview of the New e-Discovery Rules and Planning for Healthcare Organizations," sponsored by the Health Care Compliance Association, presenters said it is critical for organizations, regardless of their size, to develop litigation response plans as early as possible - hopefully, long before litigation arises.

"It will be absolutely overwhelming unless you've done your due diligence ahead of time and determined where all these records are kept, who the custodians are and what steps you need to take to get your hands on the information," warned Michelle Dougherty, director of practice leadership for the American Health Information Management Association.

During the teleconference, Dougherty and Ronald J. Hedges, an attorney with Nixon Peabody LLP who has written extensively about e-discovery, emphasized just how voluminous electronically stored information (ESI) can be. In addition to information stored within easily accessible servers and databases, an organization could be asked to produce backup tapes, deleted e-mails, and data stored on employees' laptops or personal digital assistants. "ESI is different because it can be available in many different locations, in many different forms," Hedges explained. "It can be an enormous variety of media."

Formulating a plan. The first step for any health care organization developing a litigation response plan, Dougherty and Hedges advised, should be to become familiar with applicable federal, state and local e-discovery rules. Extensive amendments to the Federal Rules of Civil Procedure took effect in December of 2006, creating some degree of uniformity in the way ESI is handled in federal courts. Nearly one-half of states and the District of Columbia have adopted, or are in the process of adopting, e-discovery rules as well, Hedges stated. Although most of those states have approved rules that mirror, in whole or in part, the federal rules, other states have developed their own.

Dougherty and Hedges proposed that the relevant set of e-discovery rules should serve as a starting point for any litigation response plan, and all managers whose

continued on page 3

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E-Discovery (cont.)

departments may be affected by the rules should be educated on what they require. As the planning process begins, Dougherty suggested creating a core litigation response team that includes representatives from the health care organization's legal, information technology and health information management departments, along with any other employees who could provide valuable input.

Consistent standards. Together, she said, the team should create a comprehensive map of the locations where ESI is stored within the organization and the individuals who are in charge of maintaining it. The team should develop protocol for how the organization will coordinate and communicate internally when litigation appears to be likely or when a preservation order is issued by a court. The organization should implement – and more importantly, enforce – standards for how electronic records are to be retained, when they should be destroyed, and in what formats they should be kept, Dougherty recommended.

"The most important thing is to be reasonable," Hedges added. "When you have a policy, you adopt it across the board and follow it consistently."

The 2006 federal rule amendments addressed a range of issues, including parties' obligation to meet and confer about e-discovery early in litigation, in what form information should be produced, and how to allocate the costs associated with discovering information that is not reasonably accessible. ■

CCH Chicago Bureau, Aug. 21, 2008.

Corporate Governance

Metrics effectively present compliance status to board

Compliance officers hold the attention of board members when achievements are measured with clear metrics and communicated with colorful charts, experienced compliance specialists emphasized during a webinar sponsored by the Health Care Compliance Association on August 29. Eric Klavetter, JD, MS, MA, Compliance & Privacy Officer for the Mayo Clinic, Rochester, Minnesota, and José A. Tabuena, JD, CFE, CHC, Vice President, Integrity and Compliance, MedicalEdge Healthcare Group, Inc., Dallas, Texas, provided examples of effective visual tools to create interest and spur action on important issues.

Time and attention. Because the board of directors meets to resolve a wide range of issues, the compliance team competes for time and attention. According to Klavetter, some presentations describe "how the compliance office keeps busy," which might be boring for the board because no reaction or action is required. In contrast, a report that asks the board to judge whether the "compliance program is working and what are the consequences?" stimulates discussion and action. Tabuena commented that recent court decisions say the board has the responsibility to make sure the compliance system is working.

In making a presentation, the compliance officer (CO) needs to be aware of what the board is trying to accomplish for the organization. The CO needs to fit specific compliance issues into the overall plan of where the organization is going. There is no generic plan that will fit every organization.

The first objective for every plan is to have a compliance program "in place," which means the board must agree to specific program outcomes as goals for the program, Klavetter explained. Examples of such goals include whether the program:

- would be considered "effective" by the Department of Justice, the Securities Exchange Commission, and the Office of Inspector General;
- prevents and detects criminal and other misconduct;
- promotes organizational culture that encourages ethical conduct;
- optimizes costs to sustain the program; and
- enhances stakeholder perception of organizational value.

Measurement. Once the program is in place, the question becomes whether that program is effective. The CO should identify the enterprise objective; define program objectives; and measure, identify and improve the outcomes. Measurement works if specific indicators are developed for each outcome and target.

One measurement tool is the Six Sigma Process, which establishes the

continued on page 7

On The Front Lines

Medicare Secondary Payer Statute: Not A Secondary Issue

by Patricia L. Brent, J.D., M.P.H., Health Care Compliance Advisory Board Member

The Medicare Secondary Payer (MSP) statute is an important, but tedious, Medicare reimbursement provision that requires attention because, when not carefully followed, it can lead to serious compliance risks. Under the statute, Medicare becomes the payer of last resort when a beneficiary is covered by an additional, third-party insurer and the obligations of that third-party insurer to cover the beneficiary for a particular service or incident usually must be exhausted prior to any Medicare claims being paid.[1]

Most likely the third-party insurer is an employer-sponsored group health insurance plan, although other insurances, including workers' compensation, automobile liability insurance, or no-fault insurance also are included under the rule.[2]

Although the Medicare Secondary Payer (MSP) provision was adopted in the early 1980s, it is sometimes overlooked by providers who are more concerned about "higher-profile" violations of the False Claims Act, the anti-kickback, or the Stark self-referral statutes. With the current trend of more Medicare-eligible individuals continuing to work past their normal retirement age or having spouses that work and are covered under an employer-sponsored health plan, compliance issues with MSP concerns are likely to increase. This article reviews the MSP provision generally and specifically addresses its role within the context of clinical research billing practices.

Background

Originally, Medicare was designed to be the primary payer for health care services for individuals over 65 years of age but, in 1982, Congress enacted the MSP as one of several measures to help decrease the out-of-control health care spending that was occurring during the late 1970s and early 1980s. This was just prior to Medicare's switch from a cost-based "retrospective" reimbursement system to its current "prospective" payment system (PPS) using diagnostic-related groups (DRGs) as its basis for paying for hospital-based health care services.[3]

The shift from cost-based reimbursement to prospective payment was, in part, another reaction to the high costs of providing inpatient hospital care to Medicare beneficiaries. It was the hope of health policy experts and Congress that the DRG-based PPS, together with the MSP and other measures, would decrease overall hospital care spending as well as provide more comparative data on which to analyze costs and track utilization.

When a Medicare beneficiary is covered by an additional health insurance policy, such as one provided under an employer-sponsored benefit plan, the MSP rule provides that the other insurance must be considered the "primary" policy and Medicare becomes the "secondary" policy only if the primary one fails to pay all the health care costs for a particular encounter.[4]

Under these circumstances, Medicare is used to cover any remaining unpaid charges, after the primary insurance has paid, up to and including the amount of the Medicare allowable charges.

If the primary insurer pays less than the total service charge for an item or service, and the provider is not obligated to accept the primary payer's payment in full, a claim may then be submitted to Medicare to pay the remainder, but the claim may not exceed (1) the amount payable if Medicare was the primary payer; (2) the reasonable cost for the item or service for which payment is based under Medicare rules; and (3) for items authorized as payable on another basis, the greater of the amount payable under the primary plan or the reasonable charge.[5]

The MSP statute creates a role reversal for Medicare - i.e., Medicare pays for co-insurances and deductibles, and any remaining charges, while the "primary" insurance covers the main (and usually higher) costs.

An exception to the MSP rule allows Medicare beneficiaries with end-stage renal disease (ESRD) to be covered using Medicare as the primary insurer and the employer-based health insurance being secondary, but only after a certain period of time (usually 30 months) has elapsed.[6]

Group health care plans of employers with 20 or more employees must provide to an employee or his or her spouse

age 65 or older the same benefits under the same conditions that they provide the benefits to employees and spouses under 65, if those 65 or older are covered under a benefit plan based on the individual's current employment status or the current employment status of a spouse of any age.[7]

This requirement applies regardless of whether the individual or spouse aged 65 or older is entitled to Medicare.[8]

Employers are deemed to meet the "20 or more employees" requirement if an employer has 20 or more full-time or part-time employees for each working day in each of 20 or more calendar weeks in the current or preceding year.[9]

Self-employed individuals who participate in an employer plan are not counted as employees when determining if the "20 or more employees" requirement is met.[10]

Nonetheless, individuals eligible for Medicare are free to reject employer plan coverage, in which case they retain Medicare as their primary coverage. When Medicare is the primary payer, employers cannot offer such employees or their spouses secondary coverage for items and services covered by Medicare. Employers may not sponsor or contribute to individual Medigap or Medicare supplement policies for beneficiaries who have, or whose spouse has, current employment status.

The statute also prevents primary insurers from denying or limiting the payment of claims on the grounds that the beneficiary is covered by Medicare, that Medicare is considered the "primary" insurer, or that a patient is excluded from coverage because his or her policy does not cover employees and spouses who are 65 years of age or older.[11]

MSP: Coordination of Benefits and Claims Submission

The problems created when implementing the MSP rule - and where compliance traps likely are to be the greatest - is in the process of determining which insurance, Medicare or another, is the primary insurance. This process, referred to as the "coordination of benefits," usually occurs in one of several ways: (1) during the initial enrollment period for Medicare, when the beneficiary fills out the Initial Enrollment Questionnaire; (2) during encounters with an employer, such as retiring from the employer or making changes in the health insurance plan; (3) during the admission process when the beneficiary is asked if he or she is covered by other types of health insurance; or (4) if the reason for a health care visit is related to a workers' compensation claim or a liability claim (such as when an automobile accident occurs).

A Coordination of Benefits Contractor (COB) program, established by CMS, is responsible for ensuring the accuracy and timely update of data populated on Medicare's eligibility database regarding other health insurance that may be primary to Medicare. The COB contractor also handles MSP-related inquiries, although not those related to specific claims or recovery attempts. MSP-related claims also can be identified through secondary claim development, self-reporting providers and employers, and trauma-related reporting and data gathering banks. The goal is to quickly identify MSP situations, thus, ensuring correct primary and secondary payments by the responsible party.

Health care providers, including hospitals, physicians and suppliers, are required by the MSP rule to first submit the claim to the primary insurer. The primary payer is required to process and make primary payment on the claim in accordance with the coverage provisions of its contract.[12]

The primary payer may not decline to make primary payment on the grounds that its contract calls for Medicare to pay first.[13]

Then, if the claim is only partially paid by that insurance, the unpaid remainder of the claim can be submitted to Medicare and will be paid according to Medicare coverage rules.

While the MSP statute stipulates that Medicare may not make payment if workers' compensation, no-fault, or liability insurance is the proper primary payer, it authorizes CMS to make a conditional payment to a provider if it is determined that the likely primary payer is workers' compensation, no-fault or liability insurance and will not pay or will not promptly pay.[14]

Such payments are conditioned upon the provider reimbursing the Medicare Trust Fund if it is demonstrated that the workers' compensation, no-fault, or liability insurance has or had the responsibility to make primary payment. It is important that such conditional payments be tracked carefully to assure that timely repayment is made to Medicare once the claim has been paid by the primary insurer. Otherwise, this could result in the provider receiving an overpayment and, if not identified and paid back in a timely manner, could subject the provider to penalties, such as civil monetary penalties.

The Medicare Secondary Payer Rule in Clinical Research Billing

The Clinical Trial Policy/National Coverage Decision (CTP/NCD) provides the rules under which Medicare covers the costs of health care services provided to beneficiaries who participate in clinical trials.[15]

Under the policy, Medicare will pay for "routine costs" associated with patients enrolled in qualified clinical trials, unless these services are otherwise covered or provided free by the clinical trial sponsor.[16]

The policy also covers diagnosis and treatment of complications arising from participation in a clinical trial.[17]

continued on page 6

For research institutions and other health care organizations providing clinical trial services, the current approach to managing reimbursement-related issues begins with the provider conducting, in advance of initiating a trial, a Medicare coverage analysis (MCA). This analysis utilizes the proposed clinical trial protocol, designed by the medical research team, to determine (1) which services and items to be provided during the trial are considered "routine;" and (2) the costs associated with providing these services and items. The research team, together with the provider's patient financial services staff, determine which services will be paid for by third party payers and, then, negotiate with the trial sponsor (usually the drug or medical device manufacturer) to pay for the items and services that likely will not be covered by third-party insurers, including Medicare.

Sometimes a trial sponsor agrees to pay for all of the costs not otherwise covered by the third-party payer, although many clinical trial agreements provide coverage for only those services and items not covered by a participant's insurance policy. In those situations in which the clinical trial participant is a Medicare beneficiary, the common assumption has been that the sponsor would only cover those services and items not covered by other insurances, including Medicare; thus, making the insurer the "primary" payer, with the research sponsor acting as the "secondary" payer. The typical clinical trial agreement also addresses medical complications that may arise as a result of an individual participating in a clinical trial, commonly stating that the sponsor agrees to cover the reasonable and necessary costs of treating complications, when not otherwise paid for by a participant's insurance.

For researchers, sponsors and health care billing personnel, the question of how to treat the costs of complications arising from Medicare beneficiaries' participation in clinical trials, in light of a clinical trial agreement, remains a complex but pressing issue.

For researchers, sponsors and health care billing personnel, the question of how to treat the costs of complications arising from Medicare beneficiaries' participation in clinical trials, in light of a clinical trial agreement, remains a complex but pressing issue. First, the MSP rule does not directly address the status of a clinical trial sponsor, i.e., is the clinical trial sponsor (under its agreement with the provider) considered similar to automobile liability insurance or workers' compensation; thus, making the sponsor the "primary" insurer? Second, although since its inception the CTP/NCD specifically has included coverage for reasonable and necessary services associated with the treatment of medical complications arising from participation in a clinical trial, it does not address its relationship to the MSP rule in these situations. Furthermore, recent changes to the CTP/NCD have not clarified these issues.[18]

Nevertheless, health care institutions that provide clinical trial services to Medicare beneficiaries must comply with both the MSP rule and the CTP/NCD when they submit claims for payment of services or risk billing-related compliance concerns. So, given the above, how does a provider comply with both?

In 2004, CMS responded to a letter inquiring about how to interpret the MSP rule in light of a clinical trial agreement in which the sponsor agrees to pay for coverage of participants' research-related injuries or complications, not otherwise covered by a third-party insurance, including Medicare.[19]

Under the particular situation outlined in the query, CMS cited the MSP rule that the primary insurer must make payment without regard to an individual's Medicare status, and opined that the sponsor, not Medicare, was acting in the role of a primary payer. Thus, CMS suggested that, under certain circumstances, a clinical trial agreement could equate the sponsor with being the primary insurer, as outlined in the MSP provision, therefore, limiting Medicare's financial responsibilities.

Several experts representing providers and the research community, however, have questioned CMS' logic in this interpretation, because the NCD/CTP states that Medicare will pay for items or services provided when related to complications or injuries arising from the participation in a clinical trial. It was the hope of the clinical research community that CMS, in re-issuing it clinical trial policy last year, would address the MSP issue. This did not happen - the CTP/NCD was issued without addressing MSP - and lacking a CMS ruling stating otherwise, or a court's opinion to the contrary, they believe CMS' interpretation in the 2004 is, at best, questionable.[20]

So, the question for providers and research sponsors remains - how does one square the MSP rule with the CTP/NCD and remain compliant with both?

For now, one answer appears to be for researchers and sponsors to include careful terms in their clinical trial agreements that won't unintentionally make the sponsor the primary payer. Possible suggestions include crafting terms in the agreement that (1) limit coverage of payment for complications or injuries to a certain level; (2) limit coverage to only specified complications or injuries; or (3) ensure that participants do not have the sole responsibility for paying the cost of care arising from a complication as a result of participating in a clinical trial. In light of these continuing concerns, some sponsors have decided it is easier to agree to cover all complications; thus, making them the primary payer, even though this choice greatly increases their overall costs for conducting a clinical trial.

Unfortunately, even though the research community continues to raise concern about this issue, CMS has not, to date, clarified the issue. In addition to the compliance risks associated with violating CMS rules, the research community is concerned about what a possible lack of coverage may do to the availability or access to clinical trial services. If clinical trial costs are not covered by insurance (including Medicare) or the trial sponsor, the concern is that the financial burdens of coverage will shift to the provider, or worse, to the participant, leading to a cooling on the willingness of individuals to participate in trials or institutions to support clinical research because of the financial implications.

continued on page 7

Conclusion

Medicare Secondary Payer rules are loaded with possible traps for the uninitiated health care provider or research study sponsor. Compliance with the MSP rule requires that the health care provider submit claims for services and items provided to Medicare beneficiaries first to the insurer that is determined to be the "primary," prior to submitting to any claims to Medicare. To ensure compliance, this requires that all stakeholders, including employers (who offer group health plans), other insurers that provide workers' compensation, no-fault or liability insurance policies, and health care providers effectively coordinate their benefits and claims submission processes. This is especially true when clinical trial services are provided to Medicare beneficiaries, because the role of MSP in clinical trials is not clearly defined. Without carefully crafted terms in the clinical trial agreement regarding the coverage for reasonable and necessary services required to treat complications arising from participation in the trial, providers remain at risk for violating the MSP rule. ■

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1 42 U.S.C. §§1395y(b)(2)(A)(i) and (ii).

2 *Id.*

3 42 U.S.C. §1395y(d).

4 *Supra*, note 1.

5 42 U.S.C. §1395y(b)(4); see *also Medicare Secondary Payer Manual*, Pub. No. 100-05, Chapter 1, §10.8.

6 42 U.S.C. §1395y(b)(1)(C)(ii); see *also Medicare Secondary Payer Manual*, Pub. No. 100-05, Chapter 1, §70.3 and Chapter 2, §§ 20.1.1 and 20.1.4.

7 *42 U.S.C.* § 1395y(b)(1)(A)(i)(II).

8 *Id.*

9 *Id.*

10 *Id.*

11 42 U.S.C. §1395y(b)(1)(A)(i); see *also Medicare Secondary Payer Manual*, Pub. No. 100-05, Chapter 1, §10.7.2.

12 For a detailed explanation of MSP claims processing and submission procedures, refer to the *Medicare Secondary Payer Manual*.

13 *Id.*

14 42 U.S.C. §1395y(b)(2)(B)(i); see *also Medicare Secondary Payer Manual*, Pub. No. 100-05, Chapter 1, §10.7.

15 National Coverage Decision for Routine Costs in Clinical Trials, *Medicare Coverage Determination Manual*, Pub. No. 100-03, July 9, 2007.

16 *Id.*

17 *Id.*

18 *Id.*

19 Letter from Gerald Walters, Director of Financial Services Group, CMS' Office of Financial Management, to Holly Thames Lutz, Esq., dated April 13, 2004.

20 For an interesting and informative discussion of the legal questions associated with the application of the MSP rule to the Clinical Trial Policy/National Coverage Decision, see American Health Lawyers' Association, Health Lawyers' News, March 2008, pp. 9-13, Roger Jansson and Thomas Jeffrey, Jr., authors.

relationship between output (Y) to inputs (Xs) to be used for improvement. The key to the formula Y=f(X) is to identify significant inputs. (The "f" in the formula is the relationship that explains Y in terms of the X's). An example would be Y=7+5X+3X−14X (with a subscript that identifies the variables attached to each X).

The CO should communicate outcomes or results from compliance efforts in ways that are familiar to board members, and this is a metric that is familiar to many boards. As applied to a compliance program, Y could be the percentage of employees with desired attitudes or beliefs. Inputs that produce such attitudes might be corporate goals or employee training. Surveys can measure the effectiveness of such inputs.

Scorecards. Creating a quickly understood scorecard is essential to stimulate board interest and action. Klavetter suggested charts with green, yellow and red indicators of risk for compliance violations, categorized by components of the organization. The CO needs multiple sets of metrics to measure the desired outcome for each area. Tabuena commented that the board is interested in whether the activities of the compliance office make any difference. On the other hand, the board members need to understand what they should care about. In addition, to the scorecard, the CO should further explain identified risk areas so that the board members can focus on areas that require board involvement. Providing comparisons of the organization's compliance performance to national data or survey results also will get the attention of the board.

Strategy. Creating a strategy is different than identifying goals. The risk and compliance infrastructure must be (1) customized to the institution, (2) meaningful to all levels, and (3) easily understood. The tasks for leadership are different than than tasks for operations managers, with details more important for management. The CO translates the objectives of the board to the operations managers and must work closely with operations to develop meaningful metrics to measure outcomes. The metrics the CO uses differs for each of these groups. Ownership metrics are those that would be presented to the board and trustees; operational metrics monitor key processes that help manage risk and would be useful tools for management. ■

CCH Chicago Bureau, Aug. 29, 2008.

Fraud and Abuse

Improper coding due to contradictory instructions rather than fraud

The evidence did not support a reasonable inference that a durable medical equipment supplier knowingly submitted false or fraudulent claims because there was substantial confusion created by contradictory instructions given to the supplier, according to the appellate court.

Coding instructions. The supplier rented special mattress overlays to be used over hospital mattresses as a way to prevent or to relieve patients' bedsore or pressure ulcers. The mattress overlays should have been billed using a miscellaneous code; however, the Medicare carrier instructed the supplier to bill under a more lucrative code usually used for more expensive powered mattresses. Carriers in other states said the power mattress code was not to be used. CMS also issued contradictory and confusing statements as to which code to use.

The supplier attempted to resolve this confusion by writing letters to the durable medical equipment regional carriers (DMERCs) after the transition from carriers to DMERCs for payment, but did not receive clear instruction.

The court concluded that under common law, there was no fraud or taking of advantage necessary to find unjust enrichment. The supplier was given specific authorization to bill using a code for power mattresses.

Attorney fees. With regard to the denial of supplier's attorney fees, the court found that the government did not bring claims "that were either wholly without evidence (False Claims Act) or could not withstand even a cursory review of the admitted evidence (common law claims)." The record showed that the government and the supplier were both legitimately confused during the period before, during, and after the transition, but this did not establish bad faith on the part of the government in bringing claims against the supplier. Therefore, the district court's summary judgment in favor of the supplier was affirmed. ■

U.S. v. Medica Rents Company, Ltd., 5th Cir., Aug. 19, 2008, Health Care Compliance Reporter, ¶800,550.

In the News

Senator dismayed by inaccurate error rate

Upset by findings that a comprehensive error rate testing (CERT) contractor significantly underestimated the number of improper Medicare payments made in 2006, Senator Charles Grassley (R-Iowa), the ranking member of the Senate's Committee on Finance, has asked the Office of Inspector General (OIG) to examine the methodology being used to calculate the 2007 error rate and investigate who within CMS directed the CERT contractor to deviate from established protocol. In a letter to CMS Acting Administrator Kerry Weems, Grassley also requested information about the CERT contractor, AdvanceMed, and assessments of its performance. In its annual report to Congress, the CERT contractor estimated the error rate for durable medical equipment (DME) at 7.5 percent for 2006, or approximately $700 million in improper payments. An OIG report released in August, however, revealed that the true error rate was 28.9 percent. The report also found that CMS orally instructed the CERT contractor to deviate from the agency's written policies by relying on limited medical records available from DME suppliers rather than full medical records from physicians.

Sen. Grassley News Release, Aug. 26, 2008.

California bills seek to protect patient privacy

Two companion California bills would soon create a new Office of Health Information Integrity (AB 211) and a specific administrative penalty (SB 541) for hospitals, home health agencies, hospices and licensed clinics that fail to "prevent unlawful or unauthorized access to, and use or disclosure of, patients' medical information." Under SB 541, a fine of $25,000 per patient, with a cap of $250,000 "per reported event," would be levied by the state Department of Health Services (DHS) for violations. SB 541 also would require the provider to notify both DHS and the patient within five days following the provider's discovery of the unlawful access, use or disclosure. Under AB 211, the new Office of Health Information Integrity would be able to levy administration penalties against individual providers and health care entities not regulated by SB 541 for violations of a new state health and safety code requiring the implementation of administrative, technical, and physical safeguards to protect the privacy of patient medical information. The new office also would have the power to recommend the provider for further investigation or discipline to the state licensing agency.

California Senate Bill 541 and Assembly Bill 211, Sept. 2, 2008.

Hurricane triggers waiver of requirements

The Secretary of HHS has waived certain provider requirements in Hurricane Gustav-affected areas to ensure that health care services are available to meet the needs of Medicare, Medicaid and SCHIP program enrollees and ensure that providers are reimbursed and exempted from sanctions for noncompliance. The waiver includes: (1) certain conditions of participation, certification, program participation or similar requirements; (2) professional licensing; (3) sanctions under the Emergency Medical Treatment and Active Labor Act for redirection of a patient to another location for screening; (4) sanctions for physician referral; (5) limitations on payments for services for Medicare Advantage plan enrollees by out-of-network providers; and (6) sanctions for noncompliance with Health Insurance Portability and Accountability Act of 1996 privacy regulations. Deadlines for performance of required activities also were modified.

HHS Notice, Aug. 31, 2008.