CCH Health Care Compliance LETTER

Volume 9, Issue 2 health.cch.com January 23, 2006

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Inquiry into QIO activities raises critical concerns

by Michelle Oxman, J.D. LL.M., Contributing Editor

A review of the activities of Quality Improvement Organizations (QIOs) investigating quality-of-care complaints and evaluating Medicare contractors has led Sen. Charles Grassley (R. Ia.) to question the relationships between QIOs and CMS staff and the extent to which QIOs and key CMS staff actually are investigating beneficiaries' quality-of-care complaints.

Initial concerns. Grassley launched his inquiry in the summer of 2005 after the *Washington Post* reported that QIOs appear to do too little to fulfill their mandate of investigating complaints about poor care of Medicare patients providers. In addition, the *Post* reported that QIOs receive little scrutiny; are barred from sharing most of their findings with patients; and provide lavish pay and "perks" to executives. In August 2005, Grassley requested documentation of certain transactions between CMS and QIOs in three regions.

Noting that CMS pays QIOs $300 million per year, Grassley stated that the documents and photographs received in response to the August request raise "a number of critical concerns," including the management of government funds. The senator has requested that both the Office of Inspector General and the Government Accountability Office "review the activities [of the QIOs] in more depth."

Focus on conferences, key employees. In a January 4th letter to CMS Administrator Mark McClellan, Grassley focused on the annual Triregional QIO Conference, held in 2005 at a Florida beach resort. According to Grassley's letter, photographs of the conference "suggest a cruise ship atmosphere rather than that of a government working meeting.... The pictures depict a luxurious resort, lavish dinners, dessert buffets, and Hawaiian dance parties—all in a tropical beach locale." Grassley requested a detailed accounting of the costs for the past four conferences, including detailed information on the source and amount of funding.

Describing his concerns, "you wonder if these contractors are going to luaus and playing golf instead of investigating patient complaints about poor Medicare quality," Grassley said. "And then you have to wonder whether the federal employees who are supposed to make sure the contractors are doing the job we pay them to do are instead going to luaus and playing golf themselves."

The senator also requested detailed documents on the travel, awards received, and use of QIO property by two key employees from September 2000 through December 31, 2005, and on other travel by CMS staff during the past three years. Grassley set a deadline of January 19, 2006, for Dr. McClellan's response. In addition, he plans to contact QIOs directly for information.

CCH Chicago Bureau, Jan. 12, 2006. ■

Nuclear medicine exception to Stark rules ends

by Stacey Fahrner, J.D., MPH, Contributing Editor

The regulations implementing the Stark Law (PubLNo. 92-603) have been amended to expand the definition of designated health services (DHS) to include diagnostic and therapeutic nuclear medicine services (see 42 C.F.R. §411.351). The new rule will affect many physicians who invested heavily in nuclear medicine ventures based on previous CMS guidance, particularly in the Phase I final rule, which specifically excluded nuclear medicine services as DHS.

Under Stark, physician ownership and investment interests in DHS are severely limited to prevent over utilization of those services and unnecessary expense to the Medicare and Medicaid programs. Compliance with the new rule will require physicians to divest their ownership or investment interests in nuclear medicine equipment and ventures, or be precluded from submitting claims to Medicare for nuclear medicine services, according to the final rule. Other concerns with the expanded definition expressed in comments to the proposed rule include disruptions in care due to changing business structures and lower quality of care from facilities owned by non-physicians.

Future of physician investments. The impact on physician involvement in nuclear medicine ventures is the most immediate concern. Commenters worried that an immediate need to sell would prompt "bargain basement" sales, and physicians would not be able to recover their capital investments. Suggestions included a three to five year phase in or grandfathering existing arrangements. To address these concerns, CMS had delayed the effective date of the rule until January 1, 2007. According to CMS, the delayed date should provide adequate time for physicians to divest their ownership interests or to restructure financial arrangements. CMS noted that physician self-referrals to nuclear medicine services are arrangements that can be abused, and exceptions such as grandfather clauses can be created only when the arrangement in question poses no risk of abuse.

Impact on beneficiary access and quality of care. In response to concerns that the new rule would limit beneficiary access and disrupt patient care, CMS stated that while the rule may affect the ability of a physician to refer to an entity in which he or she has a financial relationship, there should be alternate entities available or alternative business structures that would allow a physician to continue furnishing services to his or her patients. Furthermore, physicians may continue to perform and interpret imaging tests in their own offices when those arrangements qualify for protection under the Stark statutory or regulatory exceptions, such as the in-office ancillary services exception, CMS explained.

CMS also disagreed with comments suggesting that the new prohibition on self-referrals to nuclear imaging facilities would reduce the quality of care provided by physician owned facilities. In particular, the comment focused on the timeliness of diagnosis and initiation of therapy. CMS countered that there was no data or anecdotal evidence to support the idea that facilities owned by non-physicians furnished lower quality of care.

The rule is characterized by CMS as a reflection of the changing view of nuclear medicine in the health care community. In addition, the final rule is based on studies and comments suggesting that referral and utilization patterns are closely tied to a physician's financial interest in the entity providing the services and supplies. The expanded definition includes therapeutic nuclear medicine services as DHS under "radiation therapy services and supplies," and includes diagnostic nuclear medicine services as DHS under "radiology and certain other imaging services." The rule, however, does not include any diagnostic nuclear medicine services that are not imaging services. For example, the performance of a radioimmuno assay or the irradiation of blood products would not be considered DHS under the expanded definition. Also included under the new definition are positron emission tomography (PET) scanners, which constitute an important share of Medicare-covered nuclear imaging.

The new Stark prohibition on physician self-referral to nuclear medicine services was included in the final rule for the 2006 physician fee schedule under Part 5. ■

Final rule, 70 FR 70116, 70283–70298, Nov. 21, 2005, CCH Health Care Compliance Reporter, ¶700,005.

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CCH Health Care Compliance Letter is published 24 times a year by CCH INCORPORATED, 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.

Hospitals, nursing homes need to determine Medicare Part D role

by Catherine Hubbard, Contributing Editor

Although the new Medicare Part D prescription drug benefit was written with retail pharmacies in mind, the program will affect hospitals and nursing homes, according to Day Egusquiza, president of "Finding HealthCare Solutions... together," Twin Falls, Idaho. Unfortunately, many of these facilities aren't sure how to implement the new program, he said during a January 5, 2006, Healthcare Financial Management Association audiocast.

The Part D benefit. "Only prescription medicines are impacted by the patient's Part D coverage," Egusquiza said, adding that over-the-counter drugs will not be impacted. Although the program is geared toward large dose and 30-day supplies rather than single doses like those given in an emergency room, the benefit will impact facilities that provide oral medicines in an outpatient setting as well as those that previously billed outpatient medicines to Medicaid and now must bill them to Medicare Part D for payment, Egusquiza explained. Because outpatient medicines currently covered under Part A and Part B will continue to be covered that way, the new Part D benefit only applies to outpatient oral, self-administered medications. Even drugs that are covered under Part D are considered non-covered for an out-of- network provider, which includes most hospitals and nursing homes, he noted.

Plans of action. Facilities need to aggressively review self-administered drug pricing, determine the real cash impact of any change and the cost of doing nothing, determine what kind of help to offer the Medicare patients in the area and develop an information reference pool or handout for each Medicare outpatient registration, Egusquiza said. He recommended that facilities develop an action plan, which includes determining whether to: (1) keep the status quo and continue to bill patients for self-administered drugs, (2) become a participating retail pharmacy, or (3) remain out of network and explore ways to assist the beneficiary through the process.

If facility chooses to continue current practices, it will continue to declare all self-administered drugs as non-covered for Part A and Part B and screen for financial hardship or collect in full, Egusquiza said. He cautioned facilities that pursue this course of action to "be prepared for backlash of confused patients as to ask why, with the Part D premiums beneficiaries are paying, the facility's medications are not covered."

If the facility wants to become a retail pharmacy, it will have to meet the definition of a retail/community pharmacy, which, according to CMS, is a pharmacy where patients walk in off the street, provide a prescription slip, and have it filled regardless of whether the prescription is associated with a visit or procedure at that facility. The facility should support plan-specific formularies for each prescription drug plan (PDP) in the area and surrounding states, keep pharmacist coverage to an adequate level to meet drug quality review service requirements, and keep Part D registrations and billing separate from Part A and Part B. To bill on behalf of the patients for the Part D drugs, the hospital should contract with each PDP being sold in the area, he added.

If the hospital decides to become a patient advocate, there are many ways to help beneficiaries, Egusquiza said. In addition to providing help with filing claims to the PDP, facilities should make beneficiaries aware that there will be prescription drugs and over-the-counter medicines that will not be covered by their chosen PDP. Facilities also should encourage beneficiaries who haven't enrolled in Part D to do so to avoid late penalties. They should distribute a Part D explanatory letter, explain out of network issues, and explain, when applicable, what the MediGap supplemental plans cover and how they affect copays and deductibles, he added. ■

CCH Washington Bureau, Jan. 12, 2006.

Definition of "Claim" Under the False Claims Act

by Andrew Ruskin, J.D., Contributing Editor

A recent decision by the Sixth Circuit Court highlights an issue that has been subject to some controversy–whether False Claims Act liability can attach to interim payments that are subject to reconciliation during settlement of the Medicare cost report. The issue in this case concerned outpatient billing for anesthesia medication prior to the implementation of the outpatient prospective payment system. The court determined that, notwithstanding the reconciliation of payments occurring through the cost report settlement process, liability could still attach to an interim payment that is false. The court's holding, however, gives short shrift to the elaborate process used to ensure the accuracy of final payments and relies on case law that is not applicable.

Avoiding False Claims Act liability has been a high priority in the health care industry due to the disproportionate nature of its penalties. False Claims Act liability attaches under a number of circumstances, including when a person or entity "knowingly presents, or causes to be presented, to...the United States Government...a false or fraudulent claim for payment or approval.[1] For the purposes of this statute, "knowingly" means either actual knowledge, deliberate ignorance, or reckless disregard for the truth or falsity of the information in question.[2] Also defined in the statute is the term "claim," which includes "any request or demand...for money [that results in reimbursement by the Government]."[3] Violations of the False Claims Act lead to penalties of up to $11,000 per claim and treble damages.[4] For items reimbursed through the cost report, determining what constitutes the "claim" is critical. For instance, hospitals may receive interim disproportionate share hospital (DSH) or indirect medical education (IME) payments on a per claim basis, which are then finalized through the cost report settlement process. If a hospital's interim DSH or IME rate is based on faulty information, it can later be corrected on the submitted cost report. Any overpayments received on an interim basis would be reconciled to the final settlement upon audit.

Under these circumstances, if each individual payment is considered a claim for purposes of the False Claims Act, a hospital's liability could be enormous, even though the hospital ultimately receives no overpayment. At a minimum, the hospital would incur penalties of $11,000 for each interim claim submitted, likely resulting in millions of dollars of liability. If the final cost report is deemed the claim, however, and is correct, there would be no liability.

The *Battle Creek* case

In *United States ex rel. Schell v. Battle Creek Health System*,[5] the court considered whether the defendant hospital's billing methodology for anesthetic medication resulted in False Claims Act liability. As alleged by the relator in this case, the hospital purportedly included charges for a full vial of medication on each Medicare outpatient claim when only a portion of the vial had been administered.[6]

The hospital, on the other hand, maintained that it had adopted a flat-fee method of charging for anesthetic medication, which did not involve making any representations as to the amount of drug administered in a given encounter.[7] The court noted, however, that the record contained evidence that the hospital had not followed a uniform, flat-fee charging methodology.[8] Rather, some of the claims reviewed by the court reflected charges for multiple units of certain medications on a single claim form.[9]

As explained by the court, the charges on each such outpatient claim were multiplied by a historic cost-to-charge ratio to derive an interim payment.[10] The court acknowledged that these interim payments are then reconciled to a final settlement amount upon audit of the hospital's cost report.[11]

Court's holding

Because the court could not conclude that the hospital had not been overpaid based on the current record, it determined that it could not grant the hospital's request to dismiss the case at the state.[12] In reaching this decision, the court rejected the hospital's argument that any interim overpayments would be corrected during the settelment of the cost report.[13]

The court determined that the hospital is not insulated from False Claims Act liability simply by virtue of the fact that the fiscal intermediary would later review the hospital's claim during audit.[14] The court found support for this proposition in its holding to a case it had decided earlier.[15]

In that prior case, a home health agency had submitted a cost report with inflated pension costs, which had ultimately been disallowed by the intermediary during audit.[16] Although the home health agency had argued that there should be no False Claims Act liability because it did not retain the overpayment, the court disagreed. As stated by the court in the earlier opinion and quoted in the *Battle Creek* opinion:[17]

> A party cannot file a knowingly false claim on the assumption that the fiscal intermediary will correctly calculate the value in the review process. Such a result would shift the burden of cost calculation from the provider to the fiscal intermediary and encourage the filing of false claims, which is directly at odds with the stated goal of the FCA.

Notwithstanding the distinctions between an interim claim and a submitted cost report, the court found that the cost report settlement process did not shield the hospital in the *Battle Creek* case from False Claims Act liability.

The court also questioned whether the ultimate payment to the hospital was accurate.[18] Summarizing the statements of the hospital's expert witnesses, the court posited that proper Medicare payment hinged upon uniform billing practices.[19] Since the court identified variances in anesthetic medication charges among the claims reviewed, it determined that there was a possibility that Medicare had overpaid for these medications.[20]

In the *Battle Creek* case, the court found that the cost report settlement process did not shield the hospital from False Claims Act liability.

Court holding raises questions

The recent court holding raises several questions, among them, should individual claims be considered claims under the False Claims Act when payment is subject to reconciliation through the cost report? Although the *Battle Creek* court concluded that False Claims Act liability attaches to interim claims, such a holding is not necessarily compelled by the statute. As used in the False Claims Act statute, a claim is essentially a demand for payment. While it is true that even interim claims result in a hospital's receipt of funds, neither the hospital nor the intermediary consider the hospital's entitlement to these funds to be unqualified.

For cost reimbursed services, the Medicare program's true liability cannot be discerned until the hospital has information regarding costs incurred over the course of the entire cost reporting period. All payments received prior to cost report settlement are merely estimates, usually based on historic data. The only true claim for payment for expenses reimbursed through the cost report is the cost report itself.

No accuracy expectation with interim payments

Rather than paying providers only upon the submission of their annual cost reports, Congress has recognized that hospitals need reimbursement on a more frequent basis. As stated in the Medicare statute, the Secretary of the Department of Health and Human Services is to "periodically determine the amount which should be paid under [the Medicare program] to each provider of services...and the provider of services shall be paid, at such time or times as [the Secretary] believes appropriate (but not less often than monthly) ... the amounts so determined, with necessary adjustments on account of previously made overpayments or underpayments."[21]

In other words, to ensure adequate cash flow to hospitals, Congress has chosen to forego absolute accuracy in initial payments, and has provided for an end-of-year reconciliation. Since Congress has determined that adjustments for overpayments are integral to the Medicare reimbursement process, it simply could not have intended that hospitals incur False Claims Act exposure for each interim payment resulting in an overpayment.

CMS has implemented its statutory mandate by allowing hospitals to receive interim payments based on historic costs. As a baseline for current costs, Medicare uses the costs reported on a hospital's most recently audited cost report.[22] To convert this estimate of reimbursement to an actual amount owed a hospital, the intermediary audits the hospital's cost report and makes any necessary adjustments.[23]

Accordingly, it is not until the final audit is complete that the final liability of the government and the hospital to one another is established. Up until that point, it is anticipated that there will be some inaccuracies in the amounts that are paid because there has not yet been any sort of reconciliation of the provider's records.

Consistent with the inchoate nature of interim payments, hospitals have no appeal rights prior to an intermediary's final determination. One statutory prerequisite to Provider Reimbursement Review Board (PRRB) jurisdiction over a hospital appeal is the hospital's receipt of the intermediary's final determination of reimbursement due the hospital for a given cost reporting period.[24] An intermediary can only make such a determination upon "the close of the provider's cost reporting period...."[25] Since all payments made prior to the conclusion of the cost reporting period are merely estimates, there is no need to attach any appeal rights to those payments.

Other rights as well only attach upon settlement of the cost report. Interest can only be assessed on overpayments or underpayments determined through the cost report settlement process.[26] Further, the cost report settlement allows intermediaries to recoup overpayments from future interim payments.[27] The Medicare program is intentionally structured so that these rights do not attach prior to this point because it would be inequitable to impose liability based only upon estimated payments.

No finality until cost report settlement

Courts reviewing the regulatory framework surrounding Medicare payments have understood and accepted that only an intermediary's final determination represents the actual payment by the Medicare program to a hospital.[28] For example, in *Robert's Nursing Home, Inc.*, the Seventh Circuit considered when the statute of limitations began to run for the recovery of overpayments made to a provider participating in the Medicare program.[29] The Court held that liability for overpayments only accrues after the intermediary's final audit.

The Court explained that the Medicare "regulatory scheme allows interim payments to be made based on estimated costs, but provides that the final liability of the provider and the government under the program will not be determined until an audit of the cost reports of the provider is completed."[30] The Court reiterated the point by noting, "only after the audit by the fiscal intermediary could either party be liable to another. Prior to the time of the audit, neither party had a cause of action against the other."[31] Likewise, in *Hughes House Nursing Home*, the First Circuit as well examined when the statute of limitations begins to run in a Medicare overpayment case.[32] The court held that liability for Medicare reimbursement did not accrue until the intermediary's settlement of the cost report, which is when the government first has the right to demand money from the provider for any overpayments.[33] Essentially, neither the provider nor the intermediary has a claim against the other until cost report settlement.

Interim payments, final settlement one transaction

In light of their interdependency, courts attempting to determine the rights of the Medicare program with respect to bankrupt providers have deemed interim payments and the cost report settlement to be part of the "same transaction." In bankruptcy, a creditor is not allowed to take any action to reclaim amounts owed by a debtor, unless an exception applies.[34]

One such exception is the doctrine of equitable recoupment, which requires that the claim to recoupment of amounts owed the creditor arises from the same transaction that gave rise to the liability to the debtor that is protected in bankruptcy.[35] In one Ninth Circuit case, the court examined Medicare's continuous payment and reconciliation process to determine whether the Medicare program was entitled to recoup overpayments from a bankrupt provider and stated that:[36]

> In light of these protracted billing procedures governing the ongoing relationship between Medicare and its providers, it is clear that the payments at issue "logically relate" to one another; while this exchange of funds may stretch over an extended period of time, it remains part of a continuous balancing process between the parties.

Accordingly, the court highlighted the constant act of assessing and adjusting payments as the nexus between the obligations to justify finding a logical relationship sufficient to satisfy the "same transaction" test. Similarly, upon examination of the Medicare payment system, the DC Circuit has also held that "Congress rather clearly indicated that it wanted a provider's stream of services to be considered one transaction for purposes of any claim the government would have against the provider."[37]

As is made clear by these holdings, no one payment to a hospital can be examined in isolation. Rather, all the payments, the actual cost report, and the subsequent recoupment of overpayments, if any, all are components of one payment transaction. This transaction culminates in the settled cost report, which alone represents a hospital's "claim" to the government for payment.

Were *Battle Creek* claims "false"?

To support its skepticism regarding whether the Battle Creek hospital's anesthetic medication charge practices actually resulted in proper Medicare payment, the court mistakenly focused on whether a single anesthetic charge was applied across-the-board to each hospital patient.[38] Although, as the court points out, hospitals must have uniform charge practices to ensure proper Medicare payment, the uniformity need not result in a one-charge-fits-all system that ignores actual patient utilization of resources.

For items reimbursed on a cost basis, Medicare uses charges as a statistic to allocate costs between Medicare and non-Medicare patients.[39] Therefore, the relationship between charges and costs must be consistent across the payor spectrum.[40] Based on this principle, the *Battle Creek* court should have focused on whether the hospital's anesthetic medication charge structure was applied uniformly to Medicare and non-Medicare patients alike. If so, it would be irrelevant if patients with differing use of these medications were charged different amounts in proportion to their utilization, provided that similarly situated patients were treated the same.

As the factual summary in this case does not describe whether there were any differences between the Medicare and non-Medicare charge practices, it cannot be determined whether there had been any distortion in Medicare payment. Accordingly, contrary to the court's assertion, it is impossible to discern whether the hospital's charge structure raises the specter of any false claims.

Battle Creek, Medshares distinctions

As noted above, the court found support for its *Battle Creek* decision from its earlier decision in the *Medshares* case. In placing this reliance on the earlier decision, however, the court overlooks a very important distinction between the cases.

Although the *Medshares* case involved home health agency costs included on a submitted cost report, the *Battle Creek* case involves only outpatient charges submitted on an interim claim. For both home health agency and outpatient services during the period in question, Medicare reimbursed providers on the basis of cost and charge data aggregated over the course of the entire year.

Only upon the accrual of this data on the cost report could a provider properly allocate its costs to Medicare and non-Medicare payors. Accordingly, interim claims for payment for these services could never result in a final determination of payment standing alone, and any payment made on the basis of such a claim necessarily must be an estimate.

The *Battle Creek* court sets problematic precedent by extending its earlier holding, which attached liability to submitted cost reports subject only to intermediary audit, to interim claims for payment, which are submitted while relevant data are still being accrued. Because this opinion thus upsets the payment scheme carefully crafted by Congress and CMS, other courts should be wary of finding any precedential value to this decision. ■

This article has been reprinted from the November 2005 issue of Dennis Barry's Reimbursement Advisor, Volume 21, No. 3, (Aspen Publishers). Andrew Ruskin is an attorney in the Washington, D.C. office of Vinson & Elkins, LLP.

1 31 U.S.C. §3729(a)(1).
2 31 U.S.C. §3729(b).
3 31 U.S.C. §3729(c).
4 31 U.S.C. §3729(a).
5 419 F.3d 535 (Aug. 22, 2005), CCH Health Care Compliance Reporter, ¶800,015.
6 *Id.*
7 *Id.*
8 *Id.*
9 *Id.* For instance, one claim had two separate charges for Midazolam 2mg/2mL, two separate charges for Propofol 200mg/20mL, and a charge for Midazolam 2mg/2mL with a quantity listing of two, totaling $535.25, but another claim had two separate charges for Lidocaine 1%20mL as part of total claim for pharmacy charges of $210.75. Notably, the court does not identify whether Medicare or some other payor is responsible for payment for any of the claims it had reviewed.
10 *Id.*
11 *Id.*
12 *Id.*
13 *Id.*
14 *Id.*
15 *Id.* (*citing* to A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc., 400 F.3d 428, 445 (6th Cir. 2005)).
16 *Medshares*, 400 F.3d at 438-439.
17 *Battle Creek*, 419 F.3d 535 (*citing Medshares*, 400 F.3d at 447).
18 *Battle Creek*, 419 F.3d 535.
19 *Id.*
20 *Id.*
21 42 U.S.C. §1395g(a).
22 42 C.F.R. §413.64(e).
23 42 C.F.R. §413.64(f).
24 42 U.S.C. §1395oo(a)(1)(A)(i).
25 42 C.F.R. §405.1801.
26 42 C.F.R. §405.378.
27 42 C.F.R. §405.1803.
28 *See United States v. Gravette Manor Homes*, Inc., 642 F.2d 231, 234 (8th Cir. 1981); *accord United States v. Robert's Nursing Home, Inc.*, 710 F.2d 1275, 1278 (7th Cir. 1983); *United States v. Hughes House Nursing Home*, 710 F.2d 891 (1st Cir. 1983); *Phillips Petroleum Co. v. Lujan*, 4 F.3d 858, 860 (10th Cir. 1993); *United States v. Home Health Agency, Inc.* , 862 F. Supp. 129, 135 (N.D. Tex. 1994) (*stating*, in a Medicare overpayment recoupment case, "no cause of action could accrue based upon payments that are mere estimates" (internal citation omitted)).
29 710 F.2d at 1276.
30 *Id.*
31 *Id.* at 1278 (*citing United States v. Withrow,* 593 F.2d 802 (7th Cir. 1979)) (emphasis added).
32 710 F.2d at 892-893.
33 710 F.2d at 894.
34 11 U.S.C. §362.
35 *In re TLC Hospitals, Inc.*, 224 F.3d 1008, 1011 (9th Cir. 2000).
36 *Id.* at 1012 (*quoting the lower court's opinion*).
37 *United States v. Consumer Health Serv. of America*, Inc., 108 F.3d 390, 395 (D.C. Cir. 1997).
38 *Battle Creek*, 419 F.3d 535.
39 *Provider Reimbursement Manual*, §2203.
40 42 C.F.R. §413.53(b).

Evidence supports DME owners' conviction for falsifying CMNs

by Gené Stephens, J.D., Contributing Editor

The convictions of two durable medical equipment (DME) company owners charged with defrauding Medicare were affirmed because there was sufficient evidence that the owners had conspired with medical clinics and pharmacies to provide patients with false certifications for unnecessary medical equipment, according to the U.S. Court of Appeals for the Eleventh Circuit.

DME scheme. In operation of the scheme, the owners obtained and payed recruiters to locate Medicare-eligible persons to serve as patients. The patients were then paid by the owners to visit the clinics where a physician or physician's assistants would falsely certify a diagnosis of chronic obstructive pulmonary disease and prescribe unnecessary medical equipment and respiratory medications. Pharmacies that participated in the scheme later would compound the medications for the DME companies.

Sufficiency of evidence. The owners alleged that there was insufficient evidence to support their convictions and that the district court committed an error in calculating the amount of loss and sentencing attributable to each member of the conspiracy. The government, however, submitted sufficient evidence and documentation to establish the involvement of each owner and conspirator. In addition, the district court did not commit error in its loss calculation and sentencing of the owners because, according to the United States Sentencing Guidelines, "each person who undertakes a criminal activity is responsible for all reasonably foreseeable acts and omissions in furtherance of the jointly undertaken criminal activity" (U.S.S.G. §1B1.3(a)(1)(B)).

Refusal to inform jury. The district court did err, however, by refusing to inform the jury that one of the physicians withdrew from the conspiracy. Additional evidence supported the conclusion that the physician affirmatively withdrew from the DME fraud conspiracy more than five years before the government brought charges against him, and that his communication of his withdrawal to the other conspirators was successful. Therefore, the physician was entitled to a jury instruction on his withdrawal from the conspiracy, and his conviction was vacated. ■

United States v. Arias, 11th Cir., Nos. 03-12185, 03-14589, 04-14839, Dec. 12, 2005, ¶800,069.

Fraud and Abuse (cont.)

MD settles allegations of improper billing for vaccinations

by Stacey Fahrner, J.D., M.P.H., Contributing Editor

A physician and a pediatric clinic have entered into a civil settlement agreement regarding federal government allegations that they violated the False Claims Act by billing the Medicaid program and other insurance plans for the administration of childhood vaccines received free of charge through the Vaccines For Children program (VCF). The government also alleged that the physician and clinic improperly billed Medicaid for office visits that were coded at a higher or more complex level of service than were provided by the clinic.

Agreement. The physician and the clinic have agreed to pay double damages to the United States and the state of Connecticut in the amount of $206,274.28, and they will enter into payment plans with the private insurance plans for the approximately $27,000 billed for the administration of free vaccines. The settlement also includes an integrity agreement with HHS designed to ensure future compliance with the requirements of the Medicare and Medicaid programs.

Operation free shot. This case is part of a continuing investigation known as "Operation Free Shot," which focuses on Connecticut health care providers who bill Medicaid and other insurance programs for vaccines received through the VFC program, a joint federal and state program that provides childhood immunizations. Under the program, the Department of Public Health distributes free vaccines to providers who agree not to bill Medicaid or any third party for the cost of the vaccines.

"We will not tolerate providers who misuse the VCF program for financial gain and will make every effort to recover VCF funds and impose multiple damages and penalties where appropriate," U.S. Attorney for the District of Connecticut, Kevin O'Conner, stated. ■

DoJ Press Release, Jan. 5, 2006.

In the News

New standards requiring patient safety initiatives released

A focused effort on enhancing patient safety is a specific area of emphasis in the new standards for clinical accreditation announced by URAC, an independent, nonprofit organization offering accreditation and certification programs. The new standards include a Consumer Safety Quality Improvement Project as one requirement for organizations seeking accreditation. The changes to the standards, which became effective January 1, 2006, improve consistency and efficiency between the core standards and each of the accreditation program modules, according to Douglas Metz, chairman of URAC's Standards Committee and chief health services officer for American Specialty Health. For further information go to www.urac.org. ■

URAC News Release, Jan. 9, 2006.

VNA manager sentenced for fraudulent billing

The former senior manager of a visiting nurse association was sentenced to 15 months imprisonment for submitting fraudulent invoices to the association for health care services that were never provided. The former senior manager pled guilty to one count of health care fraud after he admitted entering into agreements with two outside vendors to assist in the implementation of the fraudulent billing scheme. Further evidence revealed that between October 2000 and September 2004, the former senior manager caused losses to the association of more than $900,000, of which more than $450,000 was paid by Medicaid and over $40,000 was paid by Medicare. In addition to the repayment of government health care program funds, the court ordered the former senior manager to pay a remaining restitution balance of $303,993. ■

DoJ Press Release, Jan. 3, 2006.

State senator pleads guilty to fraud charges

A Rhode Island state senator has pleaded guilty to charges that he was employed by three health care executives to advance in the General Assembly the interests of a Rhode Island medical center. He also has agreed to cooperate in the ongoing investigation of the three executives who have been indicted on 38 counts, including conspiracy to deprive citizens of the senator's honest services and using the mails to do so. During the time period covered by the indictments, the senator was a member of two committees having jurisdiction over legislation affecting health care facilities. ■

DoJ Press Release, Jan. 5, 2006.

DME supplier settles Medicare FCA claims

An owner of a diabetic supply company has agreed to pay over $1.6 million to the Department of Justice (DoJ) to settle allegations of submitting false claims to Medicare, as part of a settlement agreement. An investigation by the DoJ, HHS, and the Office of Inspector General revealed that claims submitted to Medicare for diabetic supplies included claims for services that were not rendered, equipment that was not ordered or accepted by the beneficiary, and supplies that were sent after the beneficiaries' deaths. Other allegations included that an employee forged physician and beneficiary signatures and unsolicited telemarketing calls to beneficiaries in violation of Medicare law. As part of the settlement agreement, the owner and the company have agreed to be permanently excluded from all federal health care programs. ■

DoJ Press Release, Dec. 6, 2005.