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MDs had no standing in antitrust suit against medical board

by Sheila Lynch-Afryl, J.D., Contributing Editor

Sherman Act claims brought by a group of emergency medicine physicians against a medical certification board, a residency council, and several hospitals and individuals failed because: (1) under §12 of the Clayton Act; the physicians lacked personal jurisdiction and venue to bring suit in the court where the suit was brought, (2) it was not in the interest of justice to transfer the case to another district; and (3) the physicians failed to establish antitrust standing, according to the U. S. Court of Appeals for the Second Circuit.

Certification of emergency medicine doctors. The physicians claimed that the medical certification board deliberately insisted on the completion of a formal residency program in emergency medicine as a precondition to taking its certification test, which resulted in an artificial restriction on the supply of emergency medicine doctors and an unlawful restraint of trade by placing a premium on such certification. In addition, the physicians alleged that the residency requirements excluded physicians who possessed years of experience but who lacked residency training from being certified in emergency medicine, causing a monopoly on the market by closing the practice track. The physicians further alleged that other physicians who participated in the residency program and received emergency medicine certification by the board received inflated remuneration that resulted in higher medical costs to consumers.

Antitrust standing. To establish antitrust standing, one must show:

(1) an injury in fact to one's business or property,
(2) that the injury is not remote from or duplicative of an injury sustained by a more directly injured party, and
(3) that the injury qualifies as an antitrust injury.

According to the court, the physicians failed to demonstrate that their injuries were ones that the antitrust laws were intended to prevent because they alleged only that they were unable to charge the same super-competitive prices as their emergency medicine colleagues who were certified by the medical board. Furthermore, the physicians did not qualify as efficient enforcers because they, unlike health care insurers, had no natural economic self-interest in reducing the cost of emergency medical care to consumers, the court said. Accordingly, the judgment of the district court was affirmed and the physicians' complaint was dismissed in its entirety. ■

Daniel v. American Board of Emergency Medicine, 2nd Cir., Oct. 7, 2005, CCH Health Care Compliance Reporter, ¶800,064.

Conspiracy convictions stand, sentences remanded

by Susan L. Smith, J.D., M.A., Contributing Editor

Three physicians convicted of conspiracy to distribute controlled substances and conspiracy to commit money laundering were not entitled to a new trial because they were unable to establish that their lawyers provided ineffective assistance or prosecutorial misconduct. There also was substantial evidence to support their convictions of money laundering conspiracy, according to the U.S. Court of Appeals for the Fourth Circuit. The physicians were entitled, however, to resentencing because the sentences were imposed erroneously under the mandatory Sentencing Guidelines standard and the government correctly conceded error on this issue, the court concluded.

The physician owner of a pain management clinic directed the clinic physicians to conduct superficial physical examinations of patients only to make the issuance of prescriptions for controlled substances look like the practice of medicine. At trial, the clinic owner testified that the physicians knowingly and willingly participated in illegal activities related to the clinic's health care fraud scheme and prescription-selling operation in which payments from illicitly obtained funds held by the owner and the clinic were made to the physicians.

Ineffective representation. The physicians contended that their attorneys were constitutionally ineffective and that the prosecutors engaged in prejudicial misconduct based on the attorneys' erroneous and unconstitutional misunderstanding and misapplication of the standard for criminal liability. As a result, the physicians were tried and convicted for civil malpractice rather than for the criminal distribution of drugs. The court stated that the physicians' argument failed, however, because they did not challenge the sufficiency of the evidence, the propriety of the jury instructions, nor did they identify any specific trial error that prejudiced them. Further, the court concluded that the jury was instructed correctly on the differences between the criminal standard, which applies when a licensed physician prescribes controlled substances outside the bounds of his professional medical practice, and the civil standard, which applies when a doctor has departed from the recognized and generally accepted standards, practices and procedures.

Money laundering conspiracy. The court found that there was substantial evidence to support the money laundering conspiracy convictions of the physicians. The physicians had argued that the trial evidence was insufficient to support their convictions. They contended that they must have committed the substantive offense of promotion money laundering to be convicted on the laundering conspiracy charge. According to the court, it was not necessary, however, to prove that the physicians had committed promotion money laundering to convict them of conspiring to do so. In addition, the court stated that the physicians did not assign error to the court's instructions on the charge and did not object to the instructions at the trial. For the jury to convict the physicians on the laundering conspiracy charge, the following elements had to be established:

(1) there was a conspiracy to commit promotion money laundering in existence,
(2) during the conspiracy, the physicians knew that the proceeds used to further the clinic's illicit operations had been derived from an illegal activity and knowingly joined the conspiracy, and
(3) during the conspiracy, a conspirator performed at least one of the overt acts alleged in furtherance of the conspiracy.

Because the court concluded that there was substantial evidence to establish the elements, the convictions were affirmed.

Sentencing guidelines. The physicians challenged their sentences on the basis of the U.S. Supreme Court's decision in *United States v. Booker* (see ¶800,023). In *Booker*, the Court concluded error was plain and warranted reversal when the court imposed sentence under the mandatory Guidelines regime based on judicial fact finding, which resulted in an increase in the sentencing range beyond that which could have been imposed on the basis of facts found by the jury or admitted by the defendant. The challenged sentences were premised on drug quantities neither found by the jury nor admitted by the physicians. Because the sentences were imposed erroneously under the mandatory Sentencing Guidelines standard and the govern-

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Unless otherwise noted, all paragraph references are to the CCH Health Care Compliance Reporter.

ment correctly conceded error on this issue, the physicians were entitled to resentencing. Therefore, the sentences were vacated and remanded.

United States v. Alerre, *4th Cir., Dec. 1, 2005, CCH Health Care Compliance Reporter, ¶800,063.*

Qui Tam suit dismissed for failure to plead with particularity

by Andra Popa, J.D., L.LM, Contributing Editor

A former compliance director's complaint alleging fraudulent billing and retaliatory discharge against an ambulance service company was dismissed because the director failed to plead with sufficient particularity under the *qui tam* provision of the False Claims Act (FCA), the U.S. Appeals Court for the Fifth Circuit concluded.

During the course of the director's work at the ambulance service company, billing supervisors and clerks complained to him that billing statements were submitted for payment without patient signatures. After conducting a company-wide audit, the director found that several company billing offices across the country were noncompliant in the patient signature area. The director reported the results of the audit to the ambulance company's chief compliance officer, distributed the results to several of the company's officers, and presented the results at a compliance retreat. After the director was fired by his supervisor, the director filed a *qui tam* complaint that cited his own audit report and extrapolations, but failed to identify particular invoices.

To withstand a motion to dismiss, claims brought under the FCA must be pleaded with particularity and state the who, what, when, where, and how of the alleged fraud, the court explained. Although this standard may be relaxed if the facts relating to the alleged fraud are within the other party's control, the director did not allege that he tried but failed to obtain sufficient information. Moreover, the director could have contacted the billing clerks, the court said.

The director's retaliatory discharge claim also was dismissed because he did not show that he was engaged in a protected activity, the ambulance company knew he was engaged in this activity, and he was discharged because of it, according to the court. The director's presentations and reports were part of his duties and he did not demonstrate that he was involved in conduct that was inconsistent with his work so that management was on notice. ■

Sealed Appellant I v. Sealed Appellee I, 5th Cir., Nov. 29, 2005, CCH Health Care Compliance Reporter, ¶800,060.

Physicians ordered to cease illegal price fixing against health plans

by Sheila Lynch-Afryl, J.D., Contributing Editor

An association of independent physicians was required to cease and desist from illegal price fixing in its negotiations with payors, including insurance companies and health plans, and terminate pre-existing contracts with payors for physician services, according to a Federal Trade Commission (FTC) order.

The association negotiated and reviewed contract proposals for the services of its members. In negotiation of its non-risk sharing contracts, the association engaged in conduct designed to enhance the collective bargaining power of its members.

Under the FTC order, member physicians are prohibited from exchanging, or facilitating the exchange or transfer, of any information among physicians concerning their willingness to deal with a payor. The association also is required to notify the Secretary for the next three years when it enters into an arrangement with any physicians under which it would act as a messenger or agent with payors regarding contracts. To avoid interference with potential efficiencies, the FTC did not prohibit any agreement involving conduct that is reasonably necessary to further a qualified risk-sharing joint arrangement or a qualified clinically integrated arrangement among physicians. ■

Federal Trade Commission Action, Docket No. 9312, Nov. 29, 2005, CCH Health Care Compliance Reporter, ¶650,035.

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Compliance aspects of the Medicare Part D prescription drug benefit

by Ryan D. Meade, J.D.

The CCH Health Care Compliance Newsletter recently interviewed Ryan Meade on the compliance aspects of Medicare's new Part D prescription drug benefit that took effect January 1, 2006. Mr. Meade is a nationally recognized expert in Medicare law. He negotiated on behalf of Rush University Medical Center what is, as of the date of this interview, the only settlement with the OIG and Department of Justice regarding billing issues arising from the Medicare Clinical Trials National Coverage Decision. Mr. Meade teaches one of the few Medicare Law classes in the country at Loyola University Chicago School of Law and is an assistant professor at Rush University in its College of Health Sciences. He practices law with Meade & Roach, LLP in Chicago and is one of a handful of attorneys in the United States who devotes virtually all of his professional and academic work to Medicare. Mr. Meade can be reached at RMeade@MeadeRoach.com.

What is the biggest compliance myth about Medicare's new Part D prescription drug benefit?

Without a doubt the biggest compliance myth is that Part D does not affect providers and that providers (with the exception of pharmacies) do not need to worry much about Part D. The main compliance burdens do fall on the Part D plan sponsors or perscription drug plans ("PDPs") and the pharmacies, but health systems and practitioners need to understand Part D because their patients will probably look to them first for answers. There also is a tremendous amount of new information that pharmacies are going to need from physicians about the prescriptions they are writing. So there is going to be an indirect, but significant, effect, on non-pharmacy providers.

What sort of information are you talking about that the pharmacies will need?

Well, let's start with the pharmacy filing a claim with the PDP for filling a covered prescription. The Part D drugs must meet the basic standard that all Medicare services must meet – the prescription must be "reasonable and necessary." The burden for determining whether the prescription is reasonable and necessary first falls on the pharmacy. How is the pharmacy going to know this? While it is not spelled out in the new Part D regulations, it seems to me the only way a pharmacy can verify whether a prescription is reasonable and necessary is to check back with the physician who prescribed the drug. This requires the physician to provide the basis and reasoning for the prescription – the easiest way would be for the physician to provide a diagnosis with the prescription.

Are you saying that the Part D rules require physicians to submit ICD-9 codes or written diagnoses with their prescriptions?

No, not at all! Medicare's rules do not require the physician to provide this information, but as a practical matter, how else is a pharmacy going to judge whether a prescription is reasonable and necessary? The pharmacy isn't writing the prescription, the physician is, and only the physician knows the reason for the prescription. I think this information sharing between the physician and pharmacy is going to be something that will develop out of the pharmacies and PDPs implementing the rules.

How does this information from the physician play out with the PDPs?

The PDPs cannot pay for prescription drugs that are not reasonable and necessary just the same as a pharmacy cannot submit a claim for a drug that is not reasonable and necessary, so it makes logical sense that when the PDPs do audits they are going to be looking for the back-up information from the pharmacies that the claims the pharmacy submitted were for drugs that were reasonable and necessary. I think it still comes back to the pharmacy needing to get diagnosis information from the physician. This is going to be a significant culture shift for physicians.

How are physicians taking this?

Well, at this point, I don't think this aspect of Medicare compliance with Part D is getting much discussion, so I don't know if any pharmacies are yet implementing processes to get diagnosis information from physicians. I think physicians, as a profession, have not realized this impact

on them. But I predict that unless there is some alternative means developed for pharmacies to justify claims as reasonable and necessary, pharmacies will ultimately need to develop processes to reach out to the physicians and get the information. E-prescribing would certainly make gathering the information easier.

As a Medicare law professor, how "big" is Part D in the legal structure of Medicare?

You cannot even begin to describe how big a change Part D is from the rest of Medicare. While there are certain basic Medicare compliance rules that will apply to Part D, in scope, structure and operation, it is revolutionary for a government health care program. The biggest departure from traditional Medicare is that Part D allows the patient to choose who will pay his or her Medicare claims and this will affect what basket of benefits the patient will receive. All Medicare beneficiaries will be able to choose a basic plan in their region that will provide a floor of covered benefits with a basic deductible and co-pay schemes. But significantly, rather than have one Medicare contractor for a region, CMS is approving multiple contractors to pay the Medicare claims and the beneficiary must choose which one he or she wants to affiliate with. The PDPs compete with each other for beneficiaries by offering more than the floor of benefits or offering lower premiums for the floor benefits. This is designed to be able to deliver more benefits to the beneficiaries than the Congressionally mandated minimum and at less than the maximum premium. This is a complete departure from Part A and Part B which is moribund in a 40 year legal structure that has not kept up with either the business of health care or how medicine is practiced in 2006. If the structure of Part D is successful, it will offer some exciting opportunities for reforming Part A and Part B.

"Somehow the pharmacies are going to need to know whether a prescription is being given as part of a clinical trial protocol in order to determine whether the research study is a "qualifying clinical trial" and whether the prescription meets the definition of a "routine cost"."

Is Part D's structure working?

That's a tough question. No one knows what will happen until the Part D benefits are in place for several months, but in theory, leading up to implementation, the policy structure of Part D appears to be working. For instance, the statute mandates that a PDP cannot charge a premium greater than $35 per month for the basic package of benefits, but where I live in Chicago, a basic plan can be gotten for as low as $13.32 per month. A variety of plans are offering no deductible options, lower co-pays and "gap coverage." The biggest problem, I think, is that the competition may be working too well – there are 43 plans to choose from in my region. While the policy goal behind Part D was to allow the marketplace to provide more services than the statutory minimum and to empower beneficiaries to choose among plans, 43 plans is a lot to choose from and it can be very confusing for seniors. I've experienced this first hand with family members asking for my help in choosing a plan.

What are the downsides of Part D?

It seems the biggest downside to Part D is the bizarre "donut hole" or "gap" that occurs in the middle of coverage in which under the basic plan structure the beneficiary must pay 100 percent of costs for a while. Some plans are offering gap coverage for additional premiums. I understand that the gap was actuarially required for the already overpriced program, but it is incredibly confusing for beneficiaries. Perhaps future legislation will figure out a way to smooth this out without causing the cost of Part D to rise even further. Another downside is the quickness with which CMS had to roll out Part D from the time the legislation was signed barely two years ago. By all accounts the folks at CMS are working tremendous amounts of overtime to roll this out but there are still many compliance obligations that need to be figured out.

How does Part D affect the self-administered drug rule that prohibits Medicare coverage of most outpatient self-administered drugs?

I don't think Part D affects the self-administered drug rule one bit. To be a covered Part D drug, the drug must be dispensed pursuant to a prescription. If a drug is given in a hospital outpatient clinic or in a physician's office, the drug isn't dispensed with a prescription. The patient doesn't take a pharmacy trip in the middle of an ER visit! The patient is given the oral medication, which he puts in his mouth, rather than a piece of paper, which he takes to the nearest Walgreens or CVS and then returns to the examining room. So oral medication dispensed to a patient in a hospital outpatient setting or a physician's office is still going to be subject to the self-administered drug rule.

Part B has paid for some drugs for years. How is Medicare distinguishing between a Part B covered drug and a Part D drug?

There is a very good document on the CMS website that discusses the differences between Part B and Part D drugs. I would like to refer your readers to that document, which is located at http://new.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/BvsDCoverage_07.27.05.pdf.

Part B has provided for coverage of certain drugs by statute. These have included chemotherapy drugs, other anti-cancer drugs, immunosuppressive drugs, epoetin-alfa for end stage renal disease patients, some respiratory drugs and certain other drugs given in both a hospital outpatient setting,

physician office or through pharmacies that are durable medical equipment suppliers. This Part B coverage essentially stays the same. It is important to keep in mind that this structure is set by statute, and is not a CMS decision. A Part D drug is a drug dispensed pursuant to a prescription and by statute excludes any drugs covered under Part A or Part B.

How does Part D determine whether a drug is "reasonable and necessary"?

The critical factor for a Part D drug to be reasonable and necessary is whether the drug is being used for its Food and Drug Adminstration (FDA) purpose or for a "medically accepted" purpose. By medically accepted, Medicare means an off-label use of a drug that has been approved by certain drug compendia. This is what I was referring to earlier in suggesting that the pharmacies and PDPs will need to know the purposes for which a drug is prescribed. A pharmacy cannot submit a claim for, and a PDP cannot pay for, a drug that is prescribed for a purpose that is not "medically accepted." Physicians may be able to prescribe drugs for off-label purposes but that does not mean that Medicare will pay for all off-label uses of a drug just because a doctor prescribed it.

"This intersection of medical research and Part D is being given far too little attention by the industry. Meanwhile, enforcement of the Clinical Trials National Coverage Determination has been stepped up by the government."

You recently gave a talk at a national Part D compliance conference on the intersection of Part D and medical research. There doesn't seem to be much discussion on this. Could you say a few words about this?

There are bigger issues that CMS has had to worry about than how Part D intersects with research billing rules so it is understandable that CMS has not addressed how to comply with both of these sets of rules. But that doesn't diminish the need of pharmacies and PDPs to understand the impact and the fact that there are specific rules governing billing Medicare during clinical trials. Medicare's National Coverage Decision on Clinical Trials sets out the basic rules for when items and services provided during clinical trials are covered by Medicare. This document explicitly applies to all Medicare benefit categories and now Part D is a new benefit category. The document allows Medicare coverage only for "routine costs" in "qualifying clinical trials." These are defined terms that we do not have time to go in depth on, but suffice it to say that the compliance implications all go back to information sharing between the physician and the pharmacy. Somehow the pharmacies are going to need to know whether a prescription is being given as part of a clinical trial protocol in order to determine whether the research study is a "qualifying clinical trial" and whether the prescription meets the definition of a "routine cost."

The pharmacy also needs to know whether the prescription drug is what is being investigated in the study – there are many studies in which the off-label use of a prescription drug is being investigated. The National Coverage Decision on Clinical Trials contains special rules for whatever item or service is the focus of the investigation. This intersection of medical research and Part D is being given far too little attention by the industry. Meanwhile, enforcement of the National Coverage Decision on Clinical Trials has been stepped up by the government.

Why hasn't CMS come up with a list of drugs that definitively are or are not covered under Part D?

There are lists of certain classes of drugs that are specifically excluded from Part D coverage. Congress took care of that. For instance, barbiturates, benzodiazepines and fertility drugs are some examples. But it seems to be wise that there is not a definitive list of covered drugs because there are always new drugs being approved by the FDA and what is considered "medically accepted" off-label uses of FDA approved drugs is a moving target and constantly changing. While it might be easier to have a specific list, it seems to me that a specific list would stagnate Part D and would create ferocious lobbying to be put on the list – I'm sure CMS has plenty of lobbyists already knocking on its door.

With hundreds of new pages of laws and Medicare affecting organizations that have not been involved with Medicare before, there are probably many entities entering the compliance world for the first time.

That's definitely an understatement. There are thousands of pharmacies that have not had formal compliance programs – or at least not the level of sophistication to their compliance programs that the government has expected of hospitals, physicians and other traditional providers. Additionally, the statute requires the PDPs to have formal compliance programs. On January 1, the health care industry's compliance program obligations made a quantum leap.

Any words of advice to the new compliance programs?

My suggestion to new Part D compliance programs is the same as to any health care organization that has developed a compliance program: don't let your compliance program become static. A compliance program must be dynamic – it must follow the developments in the law, keep an eye on what the government sees as risk areas and enforcement priorities and importantly, the compliance program must audit, audit, audit. The biggest weakness I see in existing compliance programs is their becoming lax in their auditing and monitoring or the organization not understanding that it needs to invest in its compliance auditing and monitoring plan. If an organization does not conduct audits, how does it know that it is complying with the law?

Tax Exempt

IRS tax-exempt bond unit readies for FY 2006

by George Jones, Contributing Editor

Fiscal year (FY) 2006 plans and priorities for the Internal Revenue Service' (IRS) Tax-Exempt Bonds Unit were presented by Clifford Gannett, Acting Director, Charles Andersen, the manager of field operations, and Michael Mertory, acting manager for voluntary compliance at a press briefing in Washington on December 15, 2005. Gannett touted the Tax-Exempt Bond unit's accomplishments over the past year, including closing 483 exams and 57 voluntary closing agreement program (V-CAP) agreements, significantly shortening exam time, and scoring well on the quality of exams conducted.

Operations and focus. While Gannett stated that the tax-exempt bond unit's work plan goals for FY 2006 parallel those of the IRS organization in general (service, enforcement and modernization), Gannett and other staff members focused almost exclusively on enforcement issues.

Gannett highlighted several initiatives on the compliance side for FY 2006. One priority will be in the area of charitable financing. In connection with this priority, Gannett announced the recent addition to its webpage within www.irs.gov of a Compliance Guide document entitled, "Tax-Exempt Bonds for 501(c)(3) Charitable Organizations," which is designed to educate the community on what the IRS believes are the basic requirements with respect to these types of bonds. Gannett reported that a "cadre of agents" is being specially trained to identify different pockets of noncompliance with these types of bonds. After January 30, 2006, the data will be "put to greater use." Gannett reported that about 30 of these 501(c)(3) charitable financing cases are open at the present time.

Voluntary compliance. Gannett also reported that the IRS is seeing an upsurge in issuers coming forward voluntarily through V-CAP to correct problems as the word spreads that examinations are becoming more frequent. Gannett encourages people who are looking at compliance issues with respect to their bonds to come in voluntarily and resolve the problem if they find a violation.

Gannett considered V-CAP to be a huge success. In FY 2004, 51 voluntary closing agreements took place; in FY 2005, 57 were resolved. In the first three months of FY 2006, 23 closing agreements will have taken place and 18 are in the pipeline. The trend is expected to continue as post-issuance compliance work by issuers and borrowers continues to increase.

Gannett noted that the unit is working to finalize IRM 7.2.3, which will contain standardized closing agreement terms. He hopes that the project will be completed in FY 2006.

Conduit borrower cases. "We intend to open more exams addressing a lot of conduit-borrower type issuances that we have not addressed before," Andersen reported. He said that his staff has the names of many participants in these bond deals. According to Andersen, earlier this year a tax lawyer who was representing an issuer and a conduit borrower on a case raised the defense that "everyone else" was following an opinion. When asked who everyone else was, the attorney provided the IRS with a list of several hundred deals listing the law firm, the issuer, and the conduit borrower, allegedly to defend his client. To the chagrin of many bond lawyers, we now have a pretty comprehensive list of these deals out there, Anderson said.

Systemic compliance problem. When asked whether the tax-exempt bond area, and/or certain areas within that general category, were subject to systemic compliance problems, Gannett was careful not to imply that all bond issuers were operating in a legal grey area; but noted that within the small-issue bond area, the level of noncompliance was "shocking." Andersen added that the IRS was about to assess approximately $200 million in IRS Code § 6700 penalties in the near future as to several large issuers. ■

CCH Washington Bureau, Dec. 15, 2005.

Anti-Kickback

OIG seeks to develop new, modify existing safe harbors

by Andra Popa, J.D., LL.M, Contributing Editor

Recommendations for modifying existing safe harbors to the anti-kickback statute and for developing new safe harbors and Special Fraud Alerts have been requested by the Office of Inspector General (OIG). The OIG has requested recommendations beyond those in Appendix F of the OIG's 2005 Semiannual Report (see ¶540,044), which summarized public comments received in response to a December 10, 2004, notice.

The OIG will consider various factors in reviewing proposals for changes or additions to the anti-kickback statute safe harbor provisions, including the extent to which the proposals would increase or decrease: (1) access to health care services, (2) the quality of services, (3) patient freedom of choice among providers, and (4) the cost to federal health care programs. In addition, the OIG will take into account whether a potential financial benefit exists that leads providers or health care professionals to order health care items or services from or arrange for a referral to a particular practitioner or provider.

In considering whether to issue new Special Fraud Alerts, the OIG will consider whether the practices described in the alert (1) result in any of the consequences listed above, and (2) affect the volume and frequency of the targeted conduct. Empirical data or a detailed explanation justifying a suggestion for a safe harbor or Special Fraud Alert should be included in responses to this request for comments. This request and its specifications are required by the Health Insurance Portability and Accountability Act (PubLNo 104-191). Comments must be received no later than February 7, 2006. ■

Notice, 70 FR 73186, Dec. 9, 2005, CCH Health Care Compliance Reporter, ¶760,015.

HIPAA

Health care agent entitled to access medical records

by Gene' Stephens, J.D., Contributing Editor

Although a health care agent did not meet the definition of a "qualified person" under the state public health law, she was entitled to access the medical records of her immediate family member under a different section of the public health law, according to the New York Supreme Court Appellate Division.

A hospital denied a health care agent's request for copies of her mother's medical records on the grounds that the agent was not a qualified person. The agent requested the records so that new caregivers could provide the appropriate treatment to her mother.

Right to Medical Records. The court determined that because the statutory language of one section of the public health law expressly provided the right to request and obtain a patient's medical records only to parents, legally appointed guardians, and to the "individual" patient, the agent did not meet the statutory definition of a qualified person. It concluded, however, that another section of the public health law, which enables an agent to make informed decisions regarding the principal's health care, provided the agent with the right to access the prinicipal's medical and clinical records.

Therefore, the court agreed that the health care agent was entitled to access the requested medical records, but modified the lower court's decision because it disagreed with the lower court's finding that the health care agent was a qualified person. ■

In the Matter of Mougiannis v. North Shore-Long Island Jewish Health System, N.Y. Supreme Court Appellate Division., Nov. 21, 2005, CCH Health Care Compliance Reporter, ¶800,061.

In the News

OIG announces health care program exclusions

Provider and entity exclusions were issued by the Office of Inspector General for November 2005. The notice includes a list of providers and entities excluded for felony convictions of program-related violations, health care fraud, controlled substance distribution and abuse, patient abuse and neglect, license revocation and suspension, and health education assistance loan default. Program payments cannot be made to excluded providers for any item or service; however, program beneficiaries remain free to decide whether they will continue to use the services of an excluded party. ■

Notice, 70 FR 74827, Dec. 16, 2005, ¶760,016.

Use of modifier 25 resulted in improper payments

Thirty-five percent of claims submitted to Medicare in calendar year 2002 using modifier 25 resulted in improper payments totalling $538 million. When a provider performs an evaluation and management (E/M) service that exceeds the usual preoperative or post-operative care performed on the same day, the provider may attach modifier 25 to the claim to allow additional payment for the separate E/M service. The majority improper payments were attributable to the provider's failure to (1) properly document the E/M services or procedure, (2) include necessary identifying information, and (3) respond to requests for information. ■

OIG Report, No.A-07-03-00470, Nov. 1, 2005, CCH Health Care Compliance Reporter, ¶530,327.

Hospital must follow HIPAA disclosure rules

A hospital was compelled to produce a beneficiary's medical billing and refund records subject to a protective order meeting the requirements of the Health Insurance Portability and Accountability Act (HIPAA) (PubLNo 104-191) rather than the more stringent requirements of state law, which would not permit the disclosure of identifying information, because more restrictive state law cannot be used in a federal question action to impede the enforcement of federal law. The parties agreed to abide by the HIPAA requirements that the information be disclosed and used for the purposes of litigation only and that the information be returned at the end of the litigation. ■

United States v.Ancilla Systems, Inc., S.D. Ill., Dec. 22, 2005, CCH Health Care Compliance Reporter, ¶800,067.

E-prescribing final rule corrections

A number of technical corrections have been made to the *Medicare Program E-Prescribing and the Prescription Drug Program* final rule (see ¶700,003 issued on November 7, 2005. CMS corrected words used in erro and added words that were omitted inadvertently. Several references to Web sites in the final rule also have been revised. ■

Final rule,70 FR 76198, Dec. 23, 2005, CCH Health Care Compliance Reporter, ¶700,004.