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by Dennis M. Barry, J.D.

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Revised Common Formats for collecting safety data issued

The availability of an expanded and enhanced Common Formats Version 1.0 and the process for its continued development and refinement have been announced by the Agency for Healthcare Research and Quality (AHRQ). As authorized by HHS, the AHRQ coordinates the development of a set of common definitions and reporting formats (Common Formats) that allow healthcare providers to voluntarily collect and submit standardized information regarding patient safety events. The initial release of the formats, Version 0.1 Beta, was announced in the *Federal Register* on August 29, 2008 (73 FR 50974-50976). The Common Formats can be accessed electronically at <http://www.pso.ahrq.gov/index.html>.

Reporting framework. The Patient Safety Act (42 U.S.C. §299b-21 to b-26) and Patient Safety Rule (42 C.F.R. Part 3) establish a framework by which doctors, hospitals, and other healthcare providers may voluntarily report information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to patient safety organizations (PSOs) and the information received and analyzed by PSOs—called “patient safety work product”—is privileged and confidential. Patient safety work product is used to identify events, patterns of care, and unsafe conditions that increase risks and hazards to patients.

Regulatory requirements. The Patient Safety Act and Patient Safety Rule require PSOs to collect patient safety work product from providers in a standardized manner in order to permit valid comparisons of similar cases among similar providers. The collection of patient safety work product allows the aggregation of sufficient data to identify and address underlying causal factors of patient safety problems. In order to facilitate standardized data collection, the Secretary of HHS authorized AHRQ to develop and maintain the Common Formats to improve the safety and quality of healthcare delivery.

Common Formats. AHRQ's Common Formats include: (1) descriptions of patient safety events and unsafe conditions to be reported, (2) delineation of data elements to be collected for specific types of events, (3) specifications for patient safety population reports, (4) technical specifications for electronic data collection and reporting, and (5) a user's guide.

Scope of Common Formats. The scope of Common Formats applies to all patient safety concerns, including: (1) incidents—patient safety events that reached the patient, whether or not there was harm, (2) near misses or close calls—patient safety events that did not reach the patient, and (3) unsafe conditions—circumstances that increase the probability of a patient safety event.

Format types. Version 1.0 includes generic and event-specific formats. The three generic formats pertain to all patient safety concerns and include: a

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healthcare event reporting form, a patient information form, and a summary of initial report. The eight event-specific formats pertain to frequently-occurring and serious patient safety events, including: blood or blood product, device or medical/surgical supply, fall, health-care-associated infection, medication or other substance, perinatal, pressure ulcer, and surgery or anesthesia.

Acute care hospital focus. The Common Formats Version 1.0 focuses on patient safety reporting for acute care hospitals. The AHRQ anticipates expanding future versions of the Common Formats to include other settings such as: nursing homes and other bedded facilities; ambulatory surgery centers; other ambulatory care settings, including community health centers, rehabilitation centers, and hemodialysis centers; physician and practitioner offices; and retail establishments such as pharmacies.

The AHRQ welcomes industry feedback. Information on the feedback process can be obtained at <http://www.pso.ahrq.gov/index.html>. ■

AHRQ Notice, 74 FR 45457, Sept. 2, 2009

Hospice claims in nursing facilities found noncompliant, OIG

Eighty-two percent of hospice claims for beneficiaries in nursing facilities in 2006 did not meet at least one Medicare coverage requirement, according to the Office of Inspector General (OIG). In 2006, Medicare paid approximately \$1.8 billion for these claims. Eighty-one percent of the claims did not meet at least one Medicare coverage requirement relating to election statements, plans of care, services or certifications of terminal illness, and an additional one percent of the claims were undocumented (i.e., the hospices did not submit any records to support the claims, as required).

Election statements. Terminally-ill individuals who are entitled to Medicare Part A may elect hospice care by filing election statements. For hospice services to be covered by Medicare, election statements must meet certain federal regulations. The regulations aim to ensure that

beneficiaries understand the services they will be receiving and foregoing as a result of the hospice benefit. Informed consent for hospice election is particularly important given that beneficiaries may be foregoing life-saving therapies.

Thirty-three percent of hospice claims did not meet election requirements. There were no election statements for four percent of the hospice claims. For another 29 percent of the claims, the election statements did not comply with one or more regulations. In most instances, the election statements did not explain that hospice care was palliative, rather than curative, or explain that the beneficiaries waived Medicare coverage of certain services related to their terminal illnesses.

Plan of care. A plan of care must be established pursuant to federal regulations for each hospice beneficiary in order for hospice services to be covered by Medicare. The plan of care ensures that the individuals involved in hospice care know precisely what is supposed to be done, by whom, at what time, and for what purpose.

Sixty-three percent of the claims did not meet plan of care requirements. The hospices did not establish plans of care for beneficiaries in one percent of the claims. For another 62 percent of the claims, the plans did not meet at least one federal requirement. These plans of care were not established by interdisciplinary groups; did not include necessary components, such as detailed descriptions of scope and frequency of services; or did not specify intervals for review, as required.

Certification of terminal illness. For hospice services to be covered by Medicare, a certification that the individual is terminally ill must be completed pursuant to regulations. In four percent of hospice claims, the certifications were missing or did not meet one or more federal requirements. Some deficiencies included: failure to specify that the individual's prognosis was for a life expectancy of six months or less if the terminal illness ran its normal course; absence of supporting clinical information or other documentation in the medical record; or absence of physician signatures.

Recommendations. The OIG recommended that CMS: (1) educate hospices about coverage requirements and their importance in ensuring quality of care; (2) provide tools and guidance to hospices to help them meet the coverage requirements; and (3) strengthen its monitoring practices regarding hospice claims. CMS concurred with all of the recommendations. ■

OIG Report, No. OEI-02-06-00221, Sept. 8, 2009



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EMTALA inapplicable to later-discovered emergency medical conditions

The U.S. District Court for the Eastern District of Pennsylvania properly ruled in favor of several hospitals and doctors who allegedly violated the Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. § 1395dd, by failing to stabilize and inappropriately transferring a patient, when the patient in question did not present herself in an emergent state and was not in an emergent state until she began to undergo monitoring at the primary hospital.

One of the plaintiffs was a woman whose pregnancy was considered high risk due to her diabetes. On the morning of her child's birth, she went to a routine outpatient fetal monitoring appointment at a perinatal facility. When she arrived, she complained of discomfort, yet was not alarmed about her condition and did not feel she was in an emergent state. She was subsequently administered a non-stress test, during which she began to experience increased pain and contractions. Based on the preliminary test results and her diabetic condition, her doctor terminated the non-stress test and sent her to her primary hospital for extended perinatal monitoring.

At her primary hospital, she waited approximately 15 to 20 minutes for a room and was examined. Upon review of the woman's preliminary results, the woman was rushed into surgery and gave birth to a severely brain damaged child.

The child's parents filed suit, asserting, among other things, that the hospitals and doctors violated EMTALA by failing to stabilize the mother's emergency condition and inappropriately transferring her from the perinatal facility to her primary hospital.

EMTALA. EMTALA requires hospitals to give certain types of medical care to individuals presented for emergency treatment: (1) appropriate medical screening, (2) stabilization of known emergency medical conditions and labor,

and (3) restrictions on transfer of unstabilized individuals to outside hospital facilities. Congress enacted EMTALA based on concerns that hospitals were either refusing to treat certain emergency room patients or transferring them to other institutions. The practice is known as "patient-dumping."

Excluded patients. EMTALA's requirements are triggered when an "individual comes to the emergency department," 42 C.F.R. § 489.24(a)(1). Such an "individual" can only "come" to the emergency department if that person is not already a patient of the hospital. Under 42 C.F.R. § 489.24(b), a patient is defined as "an individual who has begun to receive outpatient services as part of an encounter . . . other than an encounter that the hospital is obligated by this section to provide." EMTALA does not apply to outpatients, even if during an outpatient encounter, they are later found to have an emergency medical condition and are transported to the hospital's emergency department.

The Third Circuit Court of Appeals held that, contrary to the parents' assertion, the mother did not come to the hospital with an emergency medical condition. The mother was not in an emergent state until after she began the monitoring at the primary hospital and her condition quickly changed. Neither her previous complaints of discomfort

nor her high-risk pregnancy amounted to an emergency under EMTALA. The circumstances failed to trigger EMTALA, and therefore precluded the parents' EMTALA claim.

Actual knowledge requirement. The parents were moreover required to prove that: (1) the mother had an emergency medical condition, (2) the hospital actually knew of the condition, and (3) the patient was not stabilized before being transferred. Under EMTALA, hospitals are not held accountable for failing to stabilize conditions of which they are unaware, or even conditions of which they should have been aware. The parents' EMTALA claim failed because they did not satisfy the requirement of actual knowledge. For example, there was no evidence that any of the hospital staff at the perinatal facility actually knew that the mother's condition was an emergency before directing her to her primary hospital for further monitoring. She did not present herself as an emergency patient, and did not herself believe her condition was emergent until after her arrival at her primary hospital. The Third Circuit accordingly held that the parents' EMTALA claim was properly dismissed. ■

Torretti v. Main Line Hospitals, Inc., 3rd Cir., Sept. 2, 2009, *Health Care Compliance Reporter*, ¶800,724

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Stark Case on Exclusive Contract with Physicians in a Hospital Outpatient Department: *Narrow Interpretation of Stark Exception*

by Dennis M. Barry, J.D.

The Third Circuit Court of Appeals has sent shock waves throughout the hospital community with a January 2009 decision in the case of United States ex rel. Kosenske v. Carlisle HMA, Inc.¹ The court's opinion is not perfectly clear on the facts and, therefore, it is not perfectly clear what the court's decision means.

Facts

This case is a *qui tam* (whistleblower) case brought under the False Claims Act. The whistleblower is an anesthesiologist. The government did not intervene in this case, so the litigation was handled by the whistleblower and his counsel.² It is not stated in the case, but it appears that the whistleblower was making a back door challenge to an exclusive contract for a pain clinic that an anesthesiology group had with the defendant hospital.³ The relator had previously been a member of the anesthesiology group that held that exclusive contract, but, for reasons not explained in the court's opinion, he no longer was a member of that group.

The anesthesiology group and Carlisle Hospital negotiated an exclusive contract for anesthesiology services in 1992. Under the contract, the anesthesiology group agreed to furnish medical services as needed, and the hospital agreed to grant exclusivity to the anesthesiology group and also agreed to furnish office space and clerical support. Neither party paid any cash compensation to the other. The whistleblower was the lead physician in the anesthesiology group at the time that the 1992 contract was negotiated.

At the time that the contract was negotiated, the hospital did not offer pain management services, but the parties contemplated offering those services in the future, and, thus, pain management services were expressly included in the scope of medical services to be furnished under the contract.⁴ The contract also stated:

In the event that Hospital or [the Hospital's parent organization] obtains, opens, or operates another facility or location at which anesthesiology or pain management services are required or offered, Hospital and [the Hospital's parent organization] shall offer [the anesthesiology group] the opportunity to provide exclusive anesthesiology and pain management services at such new facility or location under the same terms and conditions as provided in this agreement to the fullest extent that the Hospital and/or [the Hospital's parent organization] is able to contract with [the anesthesiology group] to provide such services

on the same terms and conditions as set forth herein. Should Hospital and/or [the Hospital's parent organization] be unable, for any lawful reason, to enter into a contract with [the anesthesiology group] to provide such services on the same terms and conditions....⁵

In 1998, while the 1992 contract was still in place, the hospital built a new off-campus facility that included a pain management clinic (in addition to an ambulatory surgery area). The new site was approximately three miles from the main hospital. The court's opinion assumed that the hospital had an exclusive arrangement with the anesthesiology group for furnishing pain management services at the new pain management clinic.⁶ The whistleblower remained with the anesthesiology group for at least two years after 1998, and thus, as a member of the group, benefited from the exclusivity that the hospital afforded to the anesthesiology group up to that time.

The off-campus site was treated as a provider-based site by the hospital, and there do not appear to be any allegations in the case that the site did not qualify for provider-based status. As one would expect for a provider-based site, the hospital bore the costs for the facility, personnel, and supplies, and did not charge the anesthesiologists rent or otherwise collect any amounts from the anesthesiologists for access to the hospital's facility, personnel, or supplies for treating patients.

The anesthesiologists billed for their professional services and retained the revenue from such billing. The court's opinion is silent on what CPT-4 (Current Procedural Terminology, 4th Edition) codes the anesthesiologists used for their services. The court's opinion also is silent on what site of service the anesthesiologists used on their bills.

The Whistleblower's Allegations

The whistleblower anesthesiologist argued that the exclusive contract arrangement between the hospital and the anesthesiology group violated both the illegal remuneration statute and the Stark law, and, hence, all hospital bills to Medicare for services ordered by the anesthesiologists were false claims within the meaning of the False Claims Act. The whistle-

blower contrasted pain management services with traditional anesthesiology services by noting that anesthesiologists were the source of orders for hospital services for pain management patients, in contrast to surgical anesthesia where other physicians were the source of the original referral.

The lower court concluded that the anesthesiologists "received numerous benefits" under the contract, including exclusivity and "office space, medical equipment, and clerical personnel without charge."⁷ Thus, the lower court held that there was a "financial relationship" within the meaning of the Stark law.

The lower court, however, went on to hold that the relationship met a Stark exception because there was a written contract for fair market value.⁸ The lower court also held that the contract met the personal services exception to the illegal remuneration statute.⁹

The Appellate Court's Opinion

The Third Circuit Court of Appeals reversed the district court decision, and remanded to the district court for further proceedings. There are five elements of the court's opinion that are noteworthy:

- (1) the court held that exclusivity has value and, thus, an exclusive contract creates a financial relationship that must fit within a Stark exception;
- (2) the court also held that the office space furnished to provider-based physicians had value and created a "financial relationship" for which a Stark exception was required;
- (3) the fact, alone, that a contract between a hospital and referring physicians is the product of arms-length negotiations does not necessarily mean that the arrangement is at "fair market value;"
- (4) the hospital in this instance erred in not obtaining payment from physicians for the use of hospital space; and
- (5) the court was stringent and unforgiving in determining whether a Stark exception had been met.

The fourth item listed above is the most controversial and, along with the other elements of the court's opinion, is discussed below.

Exclusivity

It is common for hospitals to have exclusive arrangements with hospital-based physicians. Hospitals benefit from such an arrangement because it assures physician coverage necessary for services that are part and parcel of operating a hospital, such as pathologists for laboratory supervision and surgical pathology services, anesthesiologists for surgical services, and radiologists for imaging services.¹⁰ Other benefits that hospitals typically obtain from exclusive contracts include assistance in training hospital personnel, assurance of satisfactory quality, and participation by physicians in departmental management and other hospital administrative activities.

Neither the lower court nor the Third Circuit criticized exclusive contracts. Instead, the courts concluded that there is value in such contracts, even if that value is noncash value. There is no need under the Stark law for there to be payment of money for there to be a financial relationship.

While the court's holding that exclusivity has value, and that the existence of such value creates a "financial relationship," may startle some hospital executives and physicians, it is not, as a practical matter, a troubling finding. Exclusivity almost always is created by a written contract.¹¹ Thus, the same contract that creates the financial relationship will, in most instances, be a contract that satisfies a Stark exception based on a personal services contract that is in writing.¹²

There is, however, an unusual quirk in the *Carlisle* case. The Third Circuit interpreted the contract as creating exclusivity in the pain management clinic at the same time that it held that the contract did not extend to the physician services furnished in that clinic. While this has certainly created a problem for the hospital in this case, this is a very unusual situation.

Office Space for Hospital-Based Physicians

The Third Circuit also held that the anesthesiology group received value from the hospital in the form of "office space, medical equipment and personnel."¹³ This finding is a bit unsettling. The very nature of a physician furnishing services to patients in a hospital entails the use of hospital resources. In this instance, the court may have thought that the resources made available to the physicians differed qualitatively or quantitatively from those made available to noncontracting members of the medical staff.

Hospitals typically, if not universally, make office space available to hospital-based physicians. For example, a pathologist will typically have space including a microscope, a computer terminal, and dictation equipment. The pathologist needs that space and equipment to furnish professional pathology services. Medicare physician fees take into account the physician's personally furnished work, but also take into account the resources needed by the physician to do his or her work. For the services of hospital-based physicians, the physician fees do not reflect practice expenses at the level of physicians practicing in the community.

Does the *Carlisle* decision mean that a "financial relationship" is created when a hospital furnishes office space, dictation equipment, or similar assistance to a hospital-based physician? The answer is not clear. In part, the court distinguished the pain clinic setting from the typical hospital-based physician arrangement.¹⁴ In this instance, the contracting physicians do refer patients to the hospital and order tests from the hospital. That is distinguishable from many hospital-based physicians who refer no patients and whose ordering is entirely derivative of work sent to them by reason of being a hospital-based physician.

The Third Circuit also referred to the "free use of the Pain Clinic facilities."¹⁵ As discussed below, the court appears to

have been concerned about the anesthesiologists' access to hospital patient care space and equipment and not the more narrow issue of furnishing a small amount of utilitarian office space.

The conservative course is to have written contracts with all hospital-based physicians who receive office space or similar resources. To the extent that there is a need for a valuation opinion, it should take into account such office space and other resources, although the value assigned to it may not necessarily be very high. Because offering office space and similar resources for hospital-based physicians is nearly universal, there should not be an issue of fair market value.

Determination of Fair Market Value

The lower court found that the financial relationship that it found to exist because of the exclusivity of the arrangement, as well as the hospital furnishing to the anesthesiologists office space and related services, met a Stark exception for written contracts at fair market value.¹⁶ The Third Circuit concluded that this exception did not apply because the written contract predated the creation of the pain clinic and, by its terms, did not extend to services furnished in the pain clinic.

The Third Circuit did not leave the matter there, however, but went on to criticize the lower court's finding that the arrangement was at fair market value. In the lower court proceedings, the defendant hospital had not tendered any evidence of the fair market value of the space, equipment, and staff services furnished to the anesthesiologists or of the mutual exclusivity provisions of the contract. The lower court found such evidence unnecessary because the agreement was the result of negotiation between unrelated parties and "by definition, reflected fair market value."¹⁷ The appellate court disagreed on the ground that the anesthesiologists and the hospital were "in a position to generate business for each other" and the regulatory definition of "fair market value" is the amount that would be paid by parties "who are not otherwise in a position to generate business for the other party."¹⁸

To the extent that parties need to address fair market value in an arrangement like this, the court was correct that the Centers for Medicare and Medicaid Services' (CMS's) regulation would not give rise to an inference that value negotiated at arms-length is fair market value. The hospital's argument, however, was that it was erroneous to view the arrangement as the hospital furnishing space, equipment, supplies, or personnel to the anesthesiologists as discussed below.

Hospital Must Receive Value in Exchange for Exclusive Access

The hospital argued that permitting physicians to practice in a patient care area for which the hospital billed separately for the technical component services was not giving any value to the physicians. The other side of the coin was that the physicians did not receive any value because they billed only for their personally furnished services and that payment to them did not include payment for "facility" services.

The Medicare physician fee schedule has separate and lower payments for services furnished in a hospital outpatient department

that eliminates from payment to the physician reimbursement for the technical component of the service that are furnished by the hospital.¹⁹ Indeed, under the Medicare "prohibition against unbundling," only the hospital could bill for the technical component of services furnished to hospital-registered patients, and the physicians could not bill or receive value from Medicare for those services.²⁰ The Third Circuit, however, concluded that it still could not ignore "the current arrangement under which [the anesthesiology group] is receiving the free use of the Pain Clinic facilities and apparently the exclusive right to practice pain management there."²¹

The court has not made it easy to determine the breadth of its opinion. A logical extension of the court's opinion is that all hospitals should be charging all physicians for access to any hospital service when the physician also bills for his or her services furnished in connection with the hospital service. This would not be limited to hospital-based specialties and would not be limited to departments for which there is exclusivity. Neither CMS nor any court has concluded that medical staff privileges, which entail access to hospital facilities, have value for which a hospital must receive remuneration. Presumably, this is not what the court believes is required by the Stark law (although the court, itself, never expressly ruled out such a logical extension of its decision). What the court did say was that access to hospital facilities "and apparently the exclusive right to practice" in the department created the problem.²²

The court's conclusion that there is value in an exclusive contract for a hospital department that must be paid to the hospital cannot be reconciled with the Department of Health and Human Services Office of Inspector General's (OIG's) view of this same issue because the OIG has made it absolutely clear that a hospital may not properly extract value from physicians in exchange for an exclusive contract for the department.²³ Not only does the Third Circuit's opinion conflict with the OIG's interpretation of the law, but the facts (except as discussed below) do not support the court's decision. As noted above, physician access to hospital facilities, equipment, personnel, and supplies does not create revenue for physicians and, thus, does not create value for physicians because physician payment does not include payment for the technical component of hospital services.

There is one circumstance when physicians may possibly receive value for access to a hospital outpatient clinic. For Medicare patients, there must be split billing for services furnished in a hospital outpatient department. Indeed, it is an "obligation" of provider-based status to have split billing of technical and professional components for all Medicare patients seen in a provider-based clinic.²⁴

Most nongovernmental payers, however, do not follow Medicare rules with respect to services furnished in hospital outpatient clinics. For physician visit services,²⁵ those payers will not honor a hospital bill for technical component services. On the other hand, those nongovernmental payers usually will not reduce the payment for the physician service for the so-called "site of service differential."

Thus, for some services, an undifferentiated portion of the payment to the physician by nongovernmental payers may include payment for a component of the service furnished by the hospital, i.e., the facility, equipment, personnel, and supplies. If

the physician is receiving payment from nongovernmental payers for services for which the costs were borne in part by the hospital, then the physician is receiving a benefit from the hospital. This is easily remedied by the physician remitting to the hospital a portion of his or her collections from nongovernmental payers whose payments to the physician include full payment for the technical component of the service.²⁶

Narrow Interpretation of Stark Exception

The lower court in the *Carlisle* case found that there was a financial relationship between the hospital and the anesthesiology group based on exclusivity and the use of hospital facilities, but held that the arrangement was covered by a written contract at fair market value. The contract was confusing. The definition of "medical services" in the contract included pain management services.

On the other hand, in a portion of the contract quoted by the Third Circuit, the parties referred to the possibility of opening a pain management clinic in the future and extending the agreement to that clinic. It appears that the parties conformed to the terms of the contract with respect to the pain management clinic and, accordingly, if there had been contract litigation between the parties, a court may very well have found the agreement to apply to the pain management clinic.

Yet the Third Circuit did not show any flexibility in interpreting the contract. This approach is consistent with CMS's most recent Stark regulations. Parties are well-advised to be sure that their contracts are up to date, cover all aspects of the arrangement, and that the payments made and services furnished are consistent with the terms of the written contract.

Recommendations

Given the decision in this case, as well as other authorities, providers should consider the following recommendations:

- Do not charge physicians for exclusive contracts; doing so violates clear OIG guidance.
- Do have written contracts with hospital-based physicians. To the extent that the hospital furnishes office space, clerical support, or similar resources to the physicians, include that in the contract as consideration (or additional consideration) for the physician's agreement to furnish administrative services and to provide coverage for the department for the agreed-upon hours.
- Be certain that all physician contracts are signed, have not lapsed, cover all aspects of the arrangement, and are followed by both parties
- If you are in a hospital under the jurisdiction of the Third Circuit (New Jersey, Delaware, Maryland, and Pennsylvania), consult with counsel on what additional steps, if any, are appropriate.

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¹ 554 F.3d 88 (3rd Cir. 2009), petition for rehearing pending. The Third Circuit hears appeals from federal district courts in the states of New Jersey, Pennsylvania, Maryland, and Delaware.

² As a legal matter, no inferences can be drawn from the government's decision not to intervene. It is uncommon, however, for the government not to intervene in a large case.

³ The case books are full of cases in which physicians have challenged exclusive contracts on the grounds that such contracts violate a hospital's own medical staff bylaws or are an illegal restraint in trade in violation of federal and state antitrust laws. Physicians rarely succeed in such cases. The courts have made plain that there are good business and clinical reasons for exclusive contracts, particularly in the traditional "hospital-based" specialties.

⁴ District court opinion at 23, No. 1:05-CV-2184 (Nov. 14, 2007).

⁵ 554 F.3d at 92.

⁶ The opinion is silent on what other physicians, if any, sought privileges to furnish patient care services in the pain management clinic.

⁷ District court opinion at 16.

⁸ *Id.* at 17-28.

⁹ *Id.* at 32.

¹⁰ There are other departments where hospitals may find exclusive contracts to be useful, but for these three specialties, exclusive contracts are very common.

¹¹ Some hospitals with open medical staffs have not expressly created exclusivity by contract or otherwise but everyone assumes that the arrangement is exclusive. Unless the hospital would deny privileges to a physician who otherwise qualifies for medical staff membership and privileges in an area, the arrangement is not exclusive.

¹² A limitation on this statement may be that the Third Circuit may not agree that the agreement is at fair market value unless the physicians are paying for access to hospital facilities. This is discussed below.

¹³ 554 F.3d at 96, quoting 42 C.F.R. §411.351.

¹⁴ *Id.* at 93.

¹⁵ *Id.* at 97.

¹⁶ 42 U.S.C. § 1395nn(e)(3)(A).

¹⁷ 554 F.3d at 96.

¹⁸ *Id.* at 97.

¹⁹ There is no need to have a site of service differential for services that only can be furnished in a facility because the facility would never have been included in the physician's payment in the first instance.

²⁰ 42 U.S.C. § 1395cc(a)(1)(H)(i).

²¹ *Id.* at 97-98.

²² *Id.* at 97 (emphasis added). It is remarkable that the court would render a decision with the breadth of this decision without concluding with certainty that the agreement was exclusive.

²³ See, e.g., Supplemental Hospital Compliance Program Guidance, 70 FR 4858, 4867 (Jan. 31, 2005).

²⁴ 42 C.F.R. § 413.65(g).

²⁵ Usually this is an issue only for evaluation and management (E&M) visit services. Nongovernmental payers usually will honor hospital charges for tests or procedures furnished in conjunction with a physician encounter in a hospital outpatient clinic.

²⁶ Depending on the facts, it may be difficult to determine whether the lump-sum payment to the physician includes payment for services furnished by the hospital. If the physician bills the nongovernmental payer with a hospital outpatient department site of service, the payer's claims processing system may reduce payment to the physician even though the payer will not honor a claim from the hospital for the technical component of the services. In that instance, neither the physician nor the hospital is receiving payment for the portion of the visit services furnished by the hospital.

Employment

Patient stopped from bringing service animal into hospital

A patient was enjoined from bringing any service animal into a hospital, and her Americans with Disabilities Act (ADA) public accommodation claim was dismissed because of the hospital's legitimate concerns regarding the animal.

The patient used a service animal to assist her, and kept the dog in her room when admitted to the hospital, despite the nurses being able to perform all assistance the dog provided. The dog suffered from infections, caused allergy problems, and interfered with staff duties. The hospital's requests that the patient's door be kept closed and that a high efficiency particulate air (HEPA) filter be used were refused by the patient and her husband.

While the patient and her dog were never denied admittance to the hospital, the patient claimed that the treatment she received from the hospital amounted to a violation of the public accommodation requirement of the ADA. However, since no other service animal caused these types of problems, and no other service animal owners claim to be harassed for using a service animal, no violation of the public accommodation requirement existed. Rather, the hospital, by requesting the patient to address the hospital's legitimate concerns regarding the animal, was attempting to accommodate patients, visitors and staff by keeping them safe. The hospital moreover proved its affirmative defense that the service dog posed a direct threat to the health and safety of others.

An injunction enjoining the patient from bringing any service animal into the hospital system's facilities was granted. Without a service animal, the patient will create no further challenges for the staff than those presented by other difficult patients. ■

Roe v. Providence Health System-Oregon, Aug. 31, 2009, Health Care Compliance Reporter, ¶800,722

In the News

Pfizer to pay \$2.3 billion for fraudulent marketing

Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. have agreed to pay \$2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products. Pfizer agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding a drug with the intent to defraud or mislead, and agreed to a \$1.3 billion criminal fine and a \$1 billion civil settlement. The company illegally promoted four drugs which caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs. As part of the settlement, the company also has agreed to enter into an expansive corporate integrity agreement with the HHS' Office of Inspector General. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to this matter.

CCH Chicago Bureau, Sept. 2, 2009

HIV screening for Medicare beneficiaries proposed

HHS Secretary Kathleen Sebelius has announced a CMS proposal that would cover human immunodeficiency virus (HIV) infection screening for Medicare beneficiaries who are at increased risk for the infection, including women who are pregnant and beneficiaries of any age who voluntarily request the service. This action marks the first time that CMS has proposed to expand its list of covered preventive services under a new authority established by Congress. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) gave CMS the ability to consider whether Medicare should cover "additional preventive services," if certain requirements are met. Under MIPPA, CMS can consider whether Medicare should cover preventive services that Congress has not already deemed as covered or non-covered by law, as long as they have been "strongly recommended" or "recommended" by the U.S. Preventive Services Task Force. The Task Force has graded HIV screening as "strongly recommended." CMS will accept public comments on the proposed decision through October 9, 2009, and will issue a final coverage decision by December 8, 2009. The proposed decision is available at <https://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=229>.

HHS News Release, Sept. 9, 2009

Funding for Medicaid HIT planning begins

State Medicaid agencies will be able to obtain 90 percent federal financial participation (FFP) for their administrative activities in preparing for the program for incentive payments to practitioners who adopt and use health information technology (HIT), including electronic health records (EHR). The incentive program, which was authorized by the American Recovery and Reinvestment Act (ARRA) (PubLNo 111-3) will reimburse states for 100 percent of their payments to providers who make "meaningful use" of EHRs. State payments to providers must be limited to the 85 percent of the "net average allowable cost," as determined by CMS, of certified EHR technology. To receive FFP for planning for the incentive program, states must submit a HIT Planning Advance Planning Document for CMS approval. Reimbursable planning activities may include administering the incentive payments to providers, and participating in statewide efforts to promote interoperability and meaningful use of EHRs.

CMS Letter, No. SMDL-09-006, Sept. 1, 2009