CMS Issues Final Provider-Based Rules: And Why Is This So Important Again?
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For those following the development of the provider-based rules since the issuance of Program Memorandum A-96-7 back in August of 1996, one can only be reminded of that catchy tune by former LA Lakers’ cheerleader turned pop star Paula Abdul, “Opposites Attract”—two steps forward, two steps back. Every turn and twist in the development of the provider-based rules have been characterized by one move forward by the Centers for Medicare & Medicaid Services (CMS) and subsequent retraction in the face of industry criticism, scholarly commentary, and congressional mandates. It should therefore come as no surprise that the latest “final” revisions in the provider-based rules issued on August 1, 2002 represent some movement forward, but do not amount to a complete reversal of the agency’s long-standing efforts to “reign in” entities or facilities asserting provider-based status.

Because the final provider-based rules (Final Provider-Based Rules) assume a basic understanding of these provisions, this summary only addresses the final revisions, including any important clarifications between the proposed and final rules.

I. Scope of Provider Based Rules

Since publication of the provider-based rules in April 2000 (Provider-Based Rules), CMS continues to field questions regarding which types of entities would be subject to the rules’ provisions. The Final Provider-Based Rules restate the general rule that provider-based status will not be made where the determination would have no impact on Medicare payment, the scope of benefits, or beneficiary liability.

Consistent with its prior comments, CMS adds a technical amendment to make clear that provider-based criteria do not apply to independent diagnostic testing facilities, clinical diagnostic laboratories, and ambulance services operated by providers. With regard to physical, occupational, or speech therapy furnished to ambulatory patients, the general rule remains that CMS will not make provider-based determinations with respect to facilities or entities providing such services so long as the $1,500 annual cap for such services remains in effect (as set forth in § 1833(g)(2) of the Social Security Act). However, CMS notes that a payment difference for such services does exist when such services are provided by critical access hospitals (CAH) and, therefore, provider-based determinations will be made for CAH’s furnishing these types of services. Lastly, CMS deletes the requirement that provider-based entities may not be licensed in their own right if state law requires separate licensing of facilities or organizations that would otherwise meet the provider-based criteria.

CMS considered and rejected special exemptions for neonatal intensive care units (NICUs) operating by children’s hospitals and consolidated hospitals operating on separate campuses under a single provider number. With regard to the “consolidated hospital” issue, the Final Provider-Based Rules provide that, when two or more hospital facilities are dispersed among two or more geographically separate campuses, it will be necessary for one of the campuses to be designated by the hospital as the “main campus” and one as the “remote location” and that the agency will generally defer to the provider’s self-determination unless “the campus selected by the provider clearly does not actually function as the main campus.” Providers attempting to consolidate Medicare provider agreements in a merger/acquisition situation should carefully consider the implications of the provider-based criteria.

II. Delay in Effective Date of Provider-Based Rules

As in the proposed revisions, CMS grants an additional extension for facilities that were treated as provider-based in relation...
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to a hospital or CAH on October 1, 2000 until the start of the hospital’s first cost reporting period beginning on or after July 1, 2003. For purposes of this extension, a facility would be considered as having been provider-based on October 1, 2000 if on that date it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital or CAH. This extended “grandfathering” provision applies to the requirements at § 413.65(d), (e), (f), (h), and (i). CMS considered and rejected requests to create a permanent “grandfathering” extension.

III. Revision of Application Requirements

As in the proposed revisions, CMS now finalizes its replacement of the mandatory “application” process with a “voluntary” attestation process with varying requirements based upon whether the entity seeking provider-based status is located on or off-campus. Provider-based facilities located on the main campus of the main provider must submit an attestation stating that its facility meets the criteria in § 413.65(d) and, if it is a hospital, also attest that its facility will fulfill the obligations of hospital outpatient departments and hospital-based entities, as set forth in § 413.65(g). If the facility or entity is not located on the provider’s main campus, the potential main provider would be required to meet the requirements for on-campus attestations and supply additional documentation of the basis for its attestation to CMS at the time it submits its attestation. Under this now final provision, there is no longer an explicit requirement that a provider-based approval be obtained before the facility may bill for such services as “provider-based.” CMS indicates that the “attestation” must be submitted on a “uniform request or attestation form” that the agency intends to develop. Until this form is developed, the provider should:

- include the identity of the main provider and the facility or organization for which provider-based status is being sought and supporting documentation for purposes of applying the provider-based status criteria in effect at the time the request or attestation is submitted. The provider must also enumerate each facility and state its exact location (that is, its street address and whether it is on campus or off campus) and the date on which the facility became provider-based to the main provider.

In response to long-standing provider concerns regarding the timeliness of CMS application processing (an all too familiar experience for those filing CMS-855 enrollment applications), the Final Provider-Based Rules require that, upon receipt of a voluntary attestation, CMS will send the provider written acknowledgement of receipt of the attestation, review the attestation for completeness, consistency with the provider-based criteria in § 413.65, and consistency with information in the possession of CMS at the time the attestation is received, and then make a determination as to whether the facility is provider-based. For off-campus facilities or organizations, the rule separately adds that the contractors will review the “submitted documentation” for consistency with the application. However, as with the general Medicare enrollment process, CMS has refused to require that its Regional Offices process attestations within a set time frame.

While the BPA-grandfathered facilities receive an extension until cost reporting periods beginning on or after July 1, 2003 to come into compliance, the final rules do not provide an express exception to the attestation process after that date. Therefore, grandfathered providers are not required to submit attestations; however, providers who do not submit a voluntary attestation after July 1, 2003 could be subject to recovery of overpayments for all cost reporting periods beginning after this date.

One problem created by the new voluntary attestation process is due, in part, to the fact that CMS’ ability to recoup payments from the provider relates back to the date CMS receives a “complete application.” Specifically, the general rule is that CMS will only recover the “difference” in Medicare payment amounts (as opposed to the entire amount) back to the date that a “complete application” was received. Herein lies a catch-22. While CMS indicates that they will be issuing guidance as to what information should be included in a “complete” attestation, historically CMS has given its Regional Offices and contractors broad discretion in determining application “completeness.” If the application is not “complete” until sixty days into the review process (after supplemental documentation is furnished), then the overpayment protection only commences at that point. Of course, recoupment is limited to the “difference” between the amounts that should have been paid and the amounts that were received by the entity or facility claiming provider-based status.

IV. Requirements Applicable to All Facilities or Organizations & Off-Campus Specific Criteria

As in the proposed revisions to the Provider-Based Rules issued in May 2002, the provider-based criteria are dependent upon whether the facility or organization will be located on or off-campus. The Final Provider-Based Rules separately break out these sections in the regulations under the headings “Requirements applicable to all facilities or organizations” and “Additional requirements applicable to off-campus facilities or organizations.” In short, the Final Provider-Based Rules provide that the common licensure, clinical services integration, financial integration, and public awareness criteria apply to all facilities or organizations and “Additional requirements applicable to off-campus facilities or organizations.”
of a provider-based entity other than a hospital department must be reported in the appropriate cost center or cost centers of the main provider.\textsuperscript{18} Second, with regard to the common licensure criteria, CMS revises the rules to provide that the provider-based entity must be operated under the same license as the main provider, except in areas of the country where state law requires separate licensure or state law does not permit operation under a single license.\textsuperscript{19}

Off-campus facilities or organizations asserting or seeking provider-based status also must meet the ownership and control, administration and supervision, and geographic location criteria, which, other than re-organization within the regulations so as to make clear that these criteria only apply to off-campus facilities or organizations, remain unaltered.

\textbf{V. Joint Ventures}

As in the proposed revisions issued in May 2002, joint ventures only will qualify for provider-based status if they are located on the campus of one of the potential main-providers. CMS revises the criteria to state that, in order for a facility or organization operated as a joint venture to be considered provider-based, it must (1) be partially owned by at least one provider; (2) be located on the campus of a provider who is a partial owner; (3) be provider-based to that one provider whose campus on which the facility or organization is located; and (4) meet all of the requirements applicable to all provider-based facilities and organizations in the provider-based rules.\textsuperscript{20} CMS rejected commenter's requests to provide an exemption to the joint venture criteria for rural areas.

\textbf{VI. Management Contracts}

The favorable news from a provider perspective is the fact that the management contracts criteria only will apply to off-campus facilities or organizations seeking provider-based status. This means that most common on-campus management contract arrangements (including lithotripsy and radiology management arrangements) should not fail provider-based status solely on this criteria. That being said, the Final Provider-Based Rules continue to require that a facility or organization operated under a management contract only may be considered provider-based if the main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule.\textsuperscript{21}

This provision does not preclude the management company from employing other support staff, such as maintenance or security personnel, and others who are not directly involved in providing patient care.

The Final Provider-Based Rules revise the regulations to clarify that “leased employees” (that is personnel who are actually employed by the management company but provide services for the provider under a staff leasing arrangement) are not considered to be employees of the provider for purposes of meeting this provision. Importantly, the revisions clarify that a management company may employ clinical staff paid on a fee schedule (such as physicians, physician assistants, and nurse practitioners) and they may “lease” such employees to the main provider to provide services in the provider-based facility or organization. Thus, clinical personnel such as nurses, medical technicians, and other clinical personnel who cannot separately bill for such services must be directly employed by the main provider. CMS rejected commenters’ suggestions that the regulations allow at least some of the staff to be provided by the management company.\textsuperscript{22}

\textbf{VII. Clarification of Obligations of Hospital Outpatient Departments and Hospital-Based Entities}

With regard to the specific obligations for hospital outpatient departments and hospital-based entities (e.g., the compliance obligations for the facilities meeting the provider-based criteria), CMS clarifies that the Emergency Medical Treatment and Active Labor Act (EMTALA) applies only to those departments on the hospital's main campus that are provider-based. Accordingly, EMTALA does not apply to provider-based entities (such as rural health clinics) that are either on or off the hospital campus.\textsuperscript{23} Note, however, although CMS issued this one EMTALA clarification, the Final 2003 Inpatient Prospective Payment System rules do not include the balance of the EMTALA provisions proposed in the May 2002 proposed rule. CMS states that they are planning to finalize the EMTALA provisions “shortly.”\textsuperscript{24}

Second, CMS revises the reference to site-of-service “indicators” with minor editorial changes to more accurately describe how payments are made under the physician fee schedule. Importantly, CMS clarifies that the written notice requirements (the requirements to provide the beneficiary with a notification of the amount of any coinsurance liability attributable to an outpatient visit) do not apply if the beneficiary is examined or treated for a medical condition in compliance with the EMTALA anti-dumping rules set forth in 42 C.F.R. § 489.24.

Rather, notice must be given as soon as possible after “the existence of an emergency has been ruled out or the emergency condition has been stabilized.”\textsuperscript{25}

\textbf{VIII. Inappropriate Treatment Ramifications for Provider-Based Entities}

The Final Provider-Based Rules adopt a policy of recoupment and continuation of payment that closely parallels the overall structure of the regulations. Recoupment and continuation of payment depends upon a number of factors, including (1) whether the provider submitted a complete attestation; (2) whether the provider submitted a complete attestation but failed to notify CMS of “material changes”; and (3) whether the “good faith” and grandfathering provisions will nevertheless

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“save” the provider in certain situations for certain time periods. In general, if CMS learns that a provider has treated a facility or organization as provider-based and the provider failed to submit an attestation of provider-based status, and CMS determines that the facility or organization did not meet the requirements for provider-based status, CMS would take several actions. First, CMS issues notice to the provider and automatically adjusts future payments to the provider. Second, unless an exception applies, CMS would recover the difference between the amount of payments that actually was made and the amount that should have been made for all cost reporting periods subject to reopening.26

Recovery for past payments would be limited in certain circumstances. If a provider did not request a provider-based determination for a facility by October 1, 2002, but is included in the grandfathering provisions, recoupment only would begin with cost reporting periods after July 1, 2003.27 Second, even if the grandfathering provisions would not apply, the provider may still be entitled to the “good faith” effort protection that would limit recoupment to periods on or after January 10, 2001 (the effective date of the Provider-Based Rules) if during all that period (1) the licensure and public awareness criteria were met; (2) all facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and (3) all professional services of physicians and other practitioners were billed with the correct site-of-service. If a facility or organization is found by CMS to have been inappropriately treated as provider-based for any period on or after October 1, 2002 (or, in the case of facilities or organizations qualifying for grandfathering extension until cost reporting periods starting on or after July 1, 2003), CMS will not restore full payment until it “has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status . . . .”28

IX. Temporary Treatment As Provider-Based

CMS substantially adopted the voluntary attestation process which allows providers to bill at the provider-based payment rates without awaiting a determination. The Final Provider-Based Rules provide that if CMS determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that was made since the date the “complete request” was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based criteria.

Second, if CMS determines that a facility or organization that previously received the provider-based determination no longer qualifies for provider-based status due to a “material change,” the agency’s ability to recoup and the amount of recoupment will depend upon whether the provider reported the “material change” to CMS. If the provider reported the “material change,” treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status;29 however, CMS would not recoup any funds from the provider prior to that date. If, however, the facility failed to report the “material change” to CMS, the agency would treat the provider in the same fashion “as if they had never obtained an advance determination” and recoupment of any overpayments could go back to all cost reporting subject to reopening, as modified by the grandfathering (July 1, 2003) and “good faith” (January 10, 2001) exceptions, to the extent applicable.30

CMS refused to develop a definition of “material change,” noting that a change of ownership, adoption of a new management contract for an off-campus department of a provider or a provider-based entity, change to an off-campus location, a change in licensure status, and formation of a separate medical staff would be considered “material changes.”31 Because CMS’ ability to recoup is tied back to whether and when a provider reports “material change” events to the agency, counsel would be wise in taking a conservative posture in reporting events that affect the operations of a provider-based entity. When in doubt, it may be wise to report.

X. Conclusion

In the end, the Provider-Based Rules remain in tact with welcome clarification. Whether the new “voluntary attestation” process will greatly simplify the current “application” process remains to be seen. Indeed, in an era of second guessing CEO certifications of financial statements in a post-Enron and WorldCom environment, providers seeking definitive comfort may elect to submit an attestation and await a formal determination before billing for provider-based services. If this occurs, then the attestation will simply become a surrogate for the now defunct “application” process.

Endnotes

2. Revisions to the Provider-Based Rules were proposed in the Medicare Program’s Changes to the Hospital Inpatient Prospective Payment Systems regulations for FY 2003. See 67 Fed. Reg. 31404, 31480 (May 9, 2002).
3. In this summary, “Provider-Based Rules” refers to the rules as originally published on April 17, 2000 (65 Fed. Reg. 18434), whereas “Final Provider-Based Rules” refers to the final rules issued on August 1, 2002.
4. 67 Fed. Reg. 49981, 50081 (to be codified at 42 C.F.R. § 413.65(a)(1)(K)).
5. 67 Fed. Reg. 50081 (to be codified at 42 C.F.R. § 413.65(a)(1)(H)).
6. Id. at 50081.
7. Id. at 50083.
8. Id. (to be codified at 42 C.F.R. § 413.65(b)(2)).
9. Id.
10. Id. at 50084.
There are no modifications to the definition of “campus” which continues to be defined as “the physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider’s campus.” 42 C.F.R. § 413.65(a)(2). (Emphasis Added).

67 Fed. Reg. 49981, 50084 (to be codified at 42 C.F.R. § 413.65(b)(3)(i)).

Id. at 50085 (to be codified at 42 C.F.R. § 413.65(b)(3)(ii)).

Id. at 50086 (to be codified at 42 C.F.R. § 413.65(b)(3)(iii), (iv)).

Id.

Id.

Id.

Id.

Id. at 50089 (to be codified at 42 C.F.R. § 413.65(d)(3)).

Id. (to be codified at 42 C.F.R. § 413.65(d)(1)).

67 Fed. Reg. 49981, 50090 (to be codified at 42 C.F.R. § 413.65(f)).

Id. at 50091 (to be codified at 42 C.F.R. § 413.65(h)(1)).

Id.

Id.

Id. at 50091 (to be codified at 42 C.F.R. § 413.65(g)(1)).

Id. at 50090.

Id. (to be codified at 42 C.F.R. § 413.65(g)(7)(v)).

Id. at 50093 (to be codified at 42 C.F.R. § 413.65(j)(1)).

Id.

Id. (to be codified at 42 C.F.R. § 413.65(j)(1)).

Id.

Id.
Tripped Up on Lithotripsy

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On July 12, 2002, the Honorable Henry H. Kennedy, Jr. of the U.S. District Court for the District of Columbia, issued an opinion in the case of American Lithotripsy Society and Urology Society of America v. Thompson, which will likely add further confusion regarding interpretation and application of the Stark Law to lithotripsy services arrangements with hospitals.

Lithotripsy is a non-invasive urological procedure that is used to dissipate kidney stones. Because lithotripsy is generally not a high-volume service, and because lithotriptors (the equipment required to perform the procedure) are expensive, many hospitals and urology practices do not own a lithotriptor to provide lithotripsy services. Nonetheless, because of the effectiveness of lithotripsy in dissipating kidney stones that cannot be passed, and which would otherwise require surgery, hospitals and urologists desire to have access to this equipment. As a result, a number of private lithotripsy companies and partnerships have been established across the country. The companies that own lithotriptors have forged successful business models based on the fact that lithotriptors can be housed in vans or mobile units that can be moved from facility to facility as patient demand requires. The companies typically enter into contracts with hospitals to either (1) lease a lithotriptor to the facilities on an as-needed basis, or (2) provide lithotripsy services for patients of the facilities. In the former case, the hospital generally uses its own technicians and personnel to provide the lithotripsy services; accordingly, the hospital bills the appropriate payor, including Medicare, for such services. In the latter case, for non-Medicare patients, the lithotripsy company may bill the appropriate payor for the services it provides. However, for Medicare patients, the lithotripsy services are bundled into the hospital inpatient prospective payment system or the hospital outpatient ambulatory procedure code; therefore, the hospital purchases the entire service “under arrangement” from the lithotripsy company and includes the service in its facility charge.

Because the need for lithotripsy services is driven by urologists who order and supervise these procedures and are most familiar with the procedure and the technology involved, many of the lithotripsy companies are owned in whole or in part by urologists. Controversy arose when it became apparent in the proposed Stark II regulations that the Stark Law could apply to urologists who order lithotripsy for hospital patients, if the lithotripsy services would ultimately be provided by the urologist-owned company. Part of this controversy resulted from CMS’ decision in the proposed Stark II regulations to include services that are purchased by a hospital “under arrangement” from a third-party supplier, but which are furnished to inpatients or outpatients of the hospital, within the definition of inpatient and outpatient hospital services that are “designated health services” under the Stark Law. This decision, which was confirmed by CMS in the initial phase of the final Stark II regulations, meant that, absent complying with an exception to the Stark Law, urologist owners of lithotripsy companies would be prohibited from ordering lithotripsy services for hospital patients if the lithotripsy services would be provided by a company in which the urologist has an ownership interest.

As a result of this outcome, the American Lithotripsy Society and the Urology Society of America brought an action against CMS contending, in part, that CMS violated the Administrative Procedure Act and the Regulatory Flexibility Act by classifying lithotripsy services furnished by a lithotripsy company as inpatient or outpatient hospital services and, therefore, as Stark Law “designated health services.” The plaintiffs argued that lithotripsy services purchased by a hospital should not be included in the definition of “inpatient or outpatient hospital services” under the Stark Law because, in purchasing services from a lithotripsy company “under arrangement” for Medicare and Medicaid patients, a “hospital does little more than bill Medicare” for the service. The court agreed with the plaintiffs, in spite of the fact that hospitals are: (1) required to provide oversight of the services, (2) required to ensure that the quality of the services is in accordance with the standards required of the hospital under the Medicare conditions of participation, and (3) liable to the Medicare program and the patient for any improper care or false claims associated with the service. Accordingly, the court held that lithotripsy services are not “designated health services” under the Stark Law.

In spite of the apparent victory for the lithotripsy industry, the limited scope of this opinion will not measurably diminish the regulatory risks faced by urologists and hospitals under these arrangements. The fact that lithotripsy services are not “designated health services” according to the court does not provide any significant protections to hospitals that enter into services arrangements with lithotripsy companies that have physician investors because (1) the scope of the Stark Law prohibition reaches beyond the prohibition against urologists ordering lithotripsy services, and (2) the ruling does not address the fact that these arrangements may implicate, and some even may be found to violate, the federal Anti-Kickback Statute.

The Stark Law prohibits physicians from making referrals to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception is met. Because a “financial relationship” under the Stark Law can be indirect, physician owners of lithotripsy companies may have a financial relationship for purposes of the Stark Law with hospitals that contract for lithotripsy services. Thus, absent structuring the lithotripsy services agreement to meet a Stark Law exception, the physician owners of
the lithotripsy company may be prohibited from ordering any designated health services from that contracting hospital. Even though the court determined that the lithotripsy services are not designated health services, the urologists likely will still order many other services that are provided directly by the hospital and, therefore, would be “inpatient and outpatient hospital services” that are designated health services. Accordingly, this ruling does not appear to significantly reduce the risk of Stark Law violations.

Perhaps more importantly, the controversy over the application of the Stark Law to lithotripsy services has drawn the industry’s focus away from the fact that these lithotripsy arrangements must also be structured to comply with the Anti-Kickback Statute and similar state laws. Many lithotripsy services arrangements involve compensation on a per procedure basis. CMS states in the preamble to the final Stark II regulations that unit-of-service-based payments that are consistent with fair market value for the services provided will be viewed as relating to the “volume or value” of referrals made by a referring physician, even if the physician receives direct or indirect payments as a result of the arrangement each time he/she makes a referral for a designated health service. Accordingly, arrangements involving unit-of-service-based payments may be structured to comply with the Stark Law. Nonetheless, the Department of Health and Human Services Office of Inspector General (OIG), not CMS, is responsible for enforcement and administration of the Anti-Kickback Statute. CMS acknowledges in the final Stark II regulations that many unit-of-service-based payment arrangements that comply with the Stark Law could implicate the Anti-Kickback Statute, which applies a different definition of being “related to the volume or value of services.” There is no safe harbor in the Anti-Kickback Statute that would protect unit-of-service-based payment arrangements. Therefore, parties to such lithotripsy services arrangements must carefully evaluate whether the arrangement could serve as an inducement to the urologist owner(s) to admit patients to, or order lithotripsy services through, those hospitals that contract with the urologist’s company, as opposed to other facilities that may have their own lithotriptor or that may contract with other lithotripsy services suppliers.

Accordingly, the courtroom victory for lithotripsy companies and urologists may be little more than a false panacea masking the true risks raised by arrangements between hospitals and urologist-owned lithotripsy suppliers. Although many such arrangements apparently have been structured to comply with the Stark Law and the Anti-Kickback Statute, the risks involved remain significant, and have not been dramatically reduced as a result of this new decision. Therefore, healthcare providers and their counsel should be sure to carefully review the regulatory implications of any lithotripsy services arrangement.

Endnotes
8 The court’s holding, although only applicable to lithotripsy services, arguably would apply to all other hospital services that are provided “under arrangement” to the hospital by outside service providers and suppliers, including most notably many types of radiology services that are often purchased “under arrangement.”
9 42 U.S.C. § 1320a-7b(b).
12 Id at 877.
13 See 42 C.F.R. § 1001.952.

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HMOs Get Hit

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Health maintenance organizations (HMOs) across the country were dealt a decisive blow with the U.S. Supreme Court decision on June 20, 2002 in *Rush Prudential HMO, Inc. v. Moran*, 122 S.Ct. 2151, in which the Court found that an Illinois state statute mandating the use of an independent panel to review decisions of HMOs was not pre-empted by the Employee Retirement Income Security Act of 1974 (ERISA). Presently, thirty-eight states and the District of Columbia have similar statutes; therefore, this decision has the potential to have far-reaching effects nationwide. Under federal law, ERISA pre-empts state laws that “relate to any employment benefit plan,” unless such laws also “regulate insurance.” (This is known as the insurance “saving clause.”) ERISA pre-emption was designed to reduce the amount of regulation governing employer-sponsored plans, allowing employers to maintain a single structure for a plan that is effective in numerous states and, ideally, reducing costs to both employers and employees. Throughout years of ERISA litigation, things such as plan coverage, plan administration, and plan policies have been found to relate to employment benefit plans and, by applying a very narrow interpretation of the insurance saving clause, were determined to be pre-empted by ERISA.

The significance of this decision relates not only to the large number of people in the United States who are insured through employer-sponsored health plans, but to anyone insured under an HMO. Prior to the Supreme Court’s ruling in *Rush Prudential*, there was a question as to whether an HMO was a medical provider or an insurer. Now that the Supreme Court has clarified the matter by stating that HMOs are insurers, the question arises as to how their newly-defined status will affect their standing under ERISA.

*Rush Prudential* originated with a suit brought by a beneficiary of an employer-sponsored benefit plan that contracted with Rush Prudential HMO, Inc. (Rush) for medical services. Debra C. Moran, a resident of Illinois, suffered from pain and numbness in her right shoulder. When an unaffiliated Virginia surgeon recommended that she undergo a particular surgical procedure, Rush insisted instead that Moran consult in-network specialists. Moran then sued Rush, insisting that an independent review panel, which is called for under § 4-10 of the Illinois HMO Act, 214 ILL. COMP. STAT., ch. 125, § 4-10 et seq., review the case. Section 4-10 mandates that an HMO follow the recommendations of the review panel, but Rush refused to allow a panel to review the medical records. Moran sued to compel compliance with the state statute and won. The medical records were submitted for review and the reviewing physician determined that the surgery was medically necessary. Nevertheless, Rush continued to deny her request.

Moran went forward with the surgery anyway and amended the complaint to seek reimbursement for the cost of the procedure, which amounted to over $90,000. Following this amendment, Rush removed the case to federal court on the basis that the amended complaint was no longer a state claim but rather a federal claim because it now fell under ERISA. The district court agreed, analyzed the case as if it were an ERISA claim, and granted summary judgment for Rush on the basis that § 4-10 was pre-empted by ERISA.

Moran appealed to the Seventh Circuit, which found that § 4-10 falls within the saving clause and was not pre-empted by ERISA, even though it relates to an employment benefit plan. In order to determine whether or not the state statute regulates insurance, the court considered two particular questions. The first is whether, from a common sense point-of-view, the statute regulates insurance, and the second is whether the statute meets any of the three factors specified in the McCarran-Ferguson Act, 15 U.S.C. § 1011 et seq. The McCarran-Ferguson factors determine whether or not a statute governs entities in the “business of insurance.” The Seventh Circuit determined that § 4-10 not only regulates insurance from a common sense point-of-view, but also meets two of the three factors specified by the McCarran-Ferguson Act and, therefore, ruled that § 4-10 was not pre-empted by ERISA.

Rush asserted that the case was very similar to a Texas case (*Corporate Health Ins., Inc. v. Texas Dept’ of Ins.*, 215 F.3d 526 (2000)) in which the Fifth Circuit decided in favor of the HMO. Texas has a statute similar to § 4-10 of the Illinois HMO Act. It is commonly understood that, if a state statute conflicts with a substantive provision of ERISA, then that statute may be pre-empted even if it falls within the saving clause. The Fifth Circuit concluded that the statute could be pre-empted even though it regulated insurance within the meaning of the saving clause because the statute’s provisions were contrary to a substantive portion of ERISA, § 502(a)(1)(B) of the civil enforcement scheme. This ERISA provision offers relief similar to that allowed under the Texas statute, and the Fifth Circuit argued that it would give the plan members alternative mechanisms through which to seek redress. The Seventh Circuit did not agree that this created an alternative remedy. They determined that § 4-10 of the Illinois HMO Act did not conflict with § 502(a)(1)(B) of the civil enforcement scheme, but actually established an additional internal mechanism for making decisions that enforced Moran’s rights under the plan.

Based on the conflicted decisions of the Seventh and the Fifth Circuits, the Supreme Court granted certiorari. The Supreme Court agreed with the Seventh Circuit and decided in favor of Moran. Justice David H. Souter wrote the majority opinion, asserting that Congress had in the past demonstrated its determination that HMOs were in fact risk-bearing organizations and, therefore, were subject to state insurance regulation. Likewise, Souter maintained that “HMOs have taken over much business formerly performed by traditional indemnity insurers, and they are almost universally regulated as insurers under state law.” Rush had argued that the
independent review procedure was just another form of arbitration, specifically a “form of binding arbitration that allows an ERISA beneficiary to submit claims to a new decision-maker to examine Rush’s determination de novo, supplanting judicial review.” Justice Souter disagreed, stating that the independent review procedure “provides no new cause of action under state law and authorizes no new form of ultimate relief.” Rather, it provides the same relief that would be authorized under ERISA.

The dissent stated that Congress’ intention in enacting ERISA was to have the federal government regulate employee benefit plans. The purpose of implementing federal regulation was to “ensure that plan and plan sponsors would be subject to a uniform body of benefits law,” minimizing costs associated with the administrative and financial burden of complying with multiple and/or conflicting state regulations. The dissent maintained that the Supreme Court had consistently upheld that ERISA plans are regulated under a “uniform national system.” Additionally, the dissent argued that there was presently a scheme in place under ERISA by which Moran could have obtained relief. That she chose to go outside of ERISA and utilize the scheme set up under § 4-10 of the Illinois HMO Act was her choice. In the dissenting opinion, appeal to § 4-10 was nothing but an alternative remedy for Moran and, accordingly, state law should not pre-empt ERISA.

The dissent did express its sympathy with Moran, arguing that, while we may all sympathize with individuals in situations similar to hers and want them to have every opportunity to gain relief from sickness or injury, this cannot be accomplished without increasing healthcare costs for everyone. The dissent pointed out that, presently, employers are not mandated to provide health insurance and, if the costs of coverage rise above a level that employers feel they can afford, they will be far less likely to provide it. The dissent stated that this is an issue that should have been left up to Congress rather than to the courts.

So far, however, Congress has failed to address the question adequately. Some believe that pressure needs to be put on Congress to implement a national standard of settling such disputes between HMOs and individuals, perhaps by enacting a federal external review requirement. Measures have been attempted in the past. The House and the Senate have considered different versions of the Patients’ Bill of Rights, both of which included a federal review process. However, each has stalled. If the Rush Prudential decision stands, the effect on employers’ healthcare costs could be more than employers are willing to bear.
Ethical and Regulatory Implications of Payments for the Referral of Research Participants
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With the ever-increasing number of clinical research activities occurring at any one time, researchers often find themselves in a quandary—how to recruit the necessary number of human subjects. Fortunately for investigators, what used to require seemingly endless efforts to identify appropriate candidates can now be as easy as contacting hospitals and physician groups for referrals.

Now more than ever, hospitals and physicians seek to facilitate and support clinical research activities and to foster relationships with researchers. One important way this is accomplished is through the referral of eligible candidates for clinical trial participation. While such referrals are permissible when made in accordance with applicable legal requirements, including patient confidentiality rules and regulations such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and related regulations, the way in which hospitals and physicians are reimbursed for such referrals may implicate certain ethical and legal guidelines. This discussion examines whether the simple and direct approach of payment per identified research candidate is advisable from a legal and ethical perspective.

I. Impact of Applicable Rules and Regulations

Much of the clinical research conducted today is subject to Food and Drug Administration (FDA) rules and regulations governing research on drugs for human use and the Federal Policy for the Protection of Human Subjects under Title 45 C.F.R. Part 46 (the Common Rule). Additionally, depending on the funding sources for a particular clinical research protocol, the rules of the National Institutes of Health (NIH) may also be implicated.

A. Current State of the Common Rule and FDA and NIH Rules and Regulations

To date, the Common Rule and FDA and NIH rules and regulations do not specifically prohibit payment for patients referred for participation in clinical research trials. However, over the past several years, a number of federal agencies and national healthcare organizations have expressed a concern that payment for referral of research participants is inappropriate. Fortunately for investigators, what used to require seemingly endless efforts to identify appropriate candidates can now be as easy as contacting hospitals and physician groups for referrals.

Now more than ever, hospitals and physicians seek to facilitate and support clinical research activities and to foster relationships with researchers. One important way this is accomplished is through the referral of eligible candidates for clinical trial participation. While such referrals are permissible when made in accordance with applicable legal requirements, including patient confidentiality rules and regulations such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and related regulations, the way in which hospitals and physicians are reimbursed for such referrals may implicate certain ethical and legal guidelines. This discussion examines whether the simple and direct approach of payment per identified research candidate is advisable from a legal and ethical perspective.

Beyond the potential conflict of interest that referral incentives may create, other reported concerns include that such incentives may (i) prompt investigators to distort information provided to potential subjects during the consent process, (ii) pressure potential subjects to enroll, (iii) encourage researchers to mishandle confidential patient information, or (iv) cause investigators to stretch eligibility criteria to enroll a potential subject. While much of the concern stems from the dual investigator-physician role—where referral incentives implicate conflict of interest, patient trust, and related issues in a doctor-patient relationship—one or more of these issues could also arise in the context of a hospital/physician-patient relationship given a hospital or physician group’s relationship with its patients.

Based on information provided in the Reports and other documents assessing the appropriateness of payment for referrals, it is evident that federal rules or regulations will likely be developed over the next several years to curb or at least limit such activity. While current Common Rule and FDA and NIH rules and regulations do not prohibit payment for referrals at this time, any organization contemplating such practice should consider the industry concerns reflected in the Reports and whether the practice would contradict the organization’s own code of ethics. Moreover, in the event that a hospital or physician group chooses to accept recruitment incentives, it should also track legislative changes that may prohibit or otherwise limit such activity in the future so as to remain compliant with applicable law.

B. Implications of the Anti-Kickback Statute

Beyond concerns that the proposed referral incentives could have ethical implications that may lead to their legal prohibition in the near future, such incentives may also implicate the Anti-Kickback Statute. Because the Anti-Kickback Statute prohibits payment for referral of patients for services that may be reimbursed under
Medicare and Medicaid, providers should avoid any payment for referrals that could implicate these federal programs.\textsuperscript{10}

With respect to Medicare patients, per patient referral incentives are inadvisable regardless of the status of the Common Rule and FDA and NIH rules and regulations. Although Medicare currently does not reimburse directly for clinical research, it does cover usual patient care services needed while participating in clinical trials or needed as a result of such participation.\textsuperscript{11} Accordingly, given the nexus between patients who may be referred by a hospital or physician group for clinical research trial participation and Medicare billing by a hospital or physician group in the event any such patient requires healthcare services during, or as a result of, participation (e.g., a patient suffers an adverse outcome and requires inpatient or outpatient services through a hospital or physician group that would be billed to Medicare), the Anti-Kickback Statute may be implicated by payment for referral of Medicare patients to clinical research trials through a hospital or physician group.

While a hospital or physician group could take the approach that the referral payments are strictly for referrals to clinical trials, and any ensuing Medicare or Medicaid services related to participation in the trials are an unanticipated byproduct, given how direct the payment is to the referral and how the potential exists for related Medicare and Medicaid services, this may not be prudent under the Anti-Kickback Statute.

\section*{II. Potential Alternatives}

Although hospitals and physician groups should exercise caution when entering into agreements whereby payments are received for patients (especially Medicare/Medicaid patients) referred to a researcher for clinical trial participation, and such referrals should be made in accordance with applicable laws (e.g., patient confidentiality laws), they should not be discouraged from continuing to support clinical research and working with researchers or others to develop appropriate relationships to foster clinical research. Neither the Reports, the industry comments referenced in the Reports, the Common Rule, FDA and NIH rules and regulations, nor the Anti-Kickback Statute prohibit or criticize working to identify appropriate candidates for clinical trials. In fact, part of the concern in further legislating in this area is that it will impede research efforts.

Therefore, parties should carefully consider alternate ways of fairly compensating a hospital or physician group for the time and effort required to identify appropriate clinical trial candidates, while avoiding mechanisms that could encourage inappropriate referrals or provide a nexus between such referrals and the Anti-Kickback Statute. A simple approach would be for the researcher to reimburse a hospital or physician group certain salary and benefits, on a pro rata basis, for employee time dedicated to working through patient health information, consent, and related matters in order to facilitate clinical trial participation through researcher-coordinated activity. Or, to the extent a hospital or physician group’s efforts in recruiting subjects for clinical trials facilitates a researcher’s ability to meet its responsibilities to sponsors for which it receives sponsor funds, part of the sponsor funds could be allocated to a hospital or physician group.

\textsuperscript{1} This discussion focuses on federal law. Before entering into any payment arrangement for the referral of research participants, hospitals and physician groups are encouraged to consult applicable state laws.


\textsuperscript{3} Report 196 at 9.

\textsuperscript{4} Id.

\textsuperscript{5} Id.

\textsuperscript{6} Id. at 89.

\textsuperscript{7} Id. at 15; Report 195 at 33.

\textsuperscript{8} Report 195 at 20-26; Report 196 at 8.

\textsuperscript{9} For example, currently pending House Resolution 4697 (107th Cong. § 2 (2002)) includes provisions regarding the disclosure of investigator conflict of interest, including financial interests, and obtaining the proper informed consent of research subjects. Also significant in the legislation are provisions regarding “harmonization” of existing rules and regulations addressing clinical research within three years of the passage of the law.

\textsuperscript{10} The Anti-Kickback Statute provides that whoever knowingly and willfully solicits or receives any remuneration (including a kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which the payment may be made in whole or in part under a federal or state health program (including Medicare and Medicaid), or in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under such programs, shall be guilty of a felony. 42 U.S.C. § 1320a-7b(b)(1).

\textsuperscript{11} See 42 C.F.R. § 413.90 (2001) for a discussion of allowable research costs, and general Medicare/Medicaid payment provisions for a discussion of reimbursement to hospitals and physicians for medically reasonable and necessary care.

Endnotes
Regulatory Trends for Ambulance Suppliers

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The ambulance industry has been the focus of recent fraud and abuse enforcement efforts. In June, the largest ambulance company in the country agreed to pay $20 million to settle allegations brought by a qui tam relator that it billed Medicare for non-emergency trips that were not medically necessary or lacked supporting documentation. American Medical Response settled charges that it had falsely billed Medicare for routine transports of scheduled non-emergency patients and had misrepresented patients’ bed confinement status and medical conditions to support medical necessity.

On the criminal front, the owner of an ambulance company pled guilty to healthcare fraud charges involving the padding of mileage records, billing for wheelchair vans as ambulance transportation, and medically unnecessary trips. In United States v. Shpirt, the government charged the owners and operators of a California ambulance company for criminal healthcare fraud and money laundering offenses. The owners and a supervisor allegedly submitted Medicare claims that falsely stated patients were bed-confined when they were not and billed for individual transports when transporting patients simultaneously.

With this focus on enforcement, ambulance suppliers and their counsel should be aware of new and existing regulatory requirements specific to entities that bill Medicare for ambulance services. The Department of Health and Human Services (DHHS) has issued rules and guidance for ambulance suppliers on billing, the anti-kickback and beneficiary inducement laws, and compliance that should help with this task.

I. New Medicare Payment Rule

Medicare pays for ambulance services only if other transportation methods are contraindicated by the patient’s condition as defined by DHHS rules. Generally, ambulance suppliers must have a physician certification statement (PCS) of medical necessity or demonstrate that they could not obtain one prior to billing Medicare.

The Balanced Budget Act of 1997 mandated that the DHHS Centers for Medicare & Medicaid Services (CMS) establish a national fee schedule to replace the reasonable charge reimbursement system through negotiated rulemaking by January 1, 2000. Subsequent to the rulemaking negotiations, CMS promulgated a final rule on Medicare billing for ambulance services, implementing several major changes effective April 1, 2002:

- A five-year phase-in of a national fee schedule based on the relative value assigned to each service under five categories of ground ambulance and two categories of air ambulance services ranging from basic life support to specialty care support. These fees are adjusted to reflect geographical wage differences, rural area pickups, and mileage.
- Uniform definitions of Advanced Life Support (ALS), Basic Life Support (BLS) services, and bed confinement.
- Higher payments authorized for emergency (911) response.
- Loosening the medical necessity requirements to allow certain professionals employed by the attending physician to complete a PCS for unscheduled non-emergency transports and requiring a PCS in advance only for repetitive scheduled non-emergency transports.
- Mandatory patient assignment of benefits preventing ambulance providers from balance billing patients for the difference between the new fee schedule and their usual customary charges.

The implementation of the new payment system is still evolving. In a recent federal district court case, a Tennessee ambulance supplier overcame the jurisdictional and administrative exhaustion hurdles to successfully argue that DHHS’ delay in implementing the national fee schedule exceeded its statutory discretion. Further, CMS intends to work with the industry to establish a uniform set of covered medical condition codes for medical necessity determinations that all suppliers must use. Ambulance suppliers should review these developments and develop a working knowledge of the new definitions and the documentation that should be maintained.

II. Anti-Kickback and Beneficiary Inducement Issues

The DHHS Office of Inspector General (OIG) recently issued safe harbors and advisory opinions under the federal Anti-Kickback Statute and the beneficiary inducement provisions of the Civil Monetary Penalty Statute. In 1997, the OIG issued an unfavorable advisory opinion on an arrangement whereby a hospital would have replenished drugs and supplies used by ambulance suppliers in connection with transports, finding that the risk of improper steering and unfair competition would likely constitute prohibited remuneration. After several more favorable opinions, the OIG promulgated a final ambulance restocking safe harbor under the Anti-Kickback Statute in December 2001.

Three types of restocking arrangements are protected: general replenishing on an equal basis in an open and public manner, fair market value replenishment arrangements, and a government mandated replenishing safe harbor. Much like other safe harbors, the conditions include a prohibition on conditioning the restocking on referrals or otherwise accounting for the volume or value of referrals or business generated between the parties.

The OIG also issued several advisory opinions dealing with the legality of routine waivers of Medicare copayments and deductibles by governmental ambulance suppliers. The OIG interprets the routine waiver of Medicare copays and deductibles without an individu-
analyzed assessment of financial hardship to violate these laws under the theory that such waivers induce patients to obtain future services and are something of value in return for arranging for federal healthcare program services to be provided. In three favorable advisory opinions, the OIG determined that it would not impose sanctions against ambulance suppliers owned and operated by a political subdivision of a state that waived copays and deductibles if the waiver was limited to bona fide residents. The legal basis for allowing waivers is the statutory prohibition against Medicare payments for services paid for directly or indirectly by a governmental entity and CMS manual instructions regarding services provided by suppliers that are owned and operated by a state or a political subdivision of a state, such as a municipality or a fire district.

Key to the favorable opinions was the direct governmental status of the ambulance supplier, the funding through local tax revenues, and the residency requirement. In contrast, the OIG stated in a fourth opinion that waivers by a private ambulance company contracted exclusively by a city could subject the parties to administrative sanctions where the waiver of copays was a condition of receiving an exclusive contract. Recently, the OIG opined that states and political subdivisions of states may however fund the uncollected patient copays for residents and pay a private company either through lump sum or periodic payments so long as the aggregate payments reasonably approximate the amount of uncollected copayments.

III. Compliance Plans

On June 6, 2002, the OIG issued draft compliance program guidance for ambulance suppliers. Like the models it has issued for other types of providers, the OIG provides guidance on the seven building blocks for an effective compliance program and addresses the specific fraud and abuse risk areas unique to ambulance suppliers.

Some of the risk areas addressed in the guidance include:

- Medical necessity issues, in particular the documentation required, non-emergency transports to and from hospitals, and upcoding BLS to ALS services.
- Documentation regarding dispatch instructions, contraindications of other modes of transportation, reasons for the level of service, transport origins and destinations, bed-confined status of the patient, and services provided to support the claim submitted.
- Illegal remuneration issues under the Anti-Kickback Statute that may be considered suspect, including arrangements with responders, hospitals, nursing facilities, and contracts between municipalities or EMS sponsors and municipalities.
- Routine waivers of Medicare copayments and deductibles.

Spokeswoman for the OIG anticipates that the final ambulance compliance guidance will be out by the end of the year. Implementation of the new rules presents opportunities for ambulance suppliers to ensure that appropriate compliance documentation is maintained. With the improved clarity and uniformity under the new Medicare payment system, now is a good time for counsel to ambulance suppliers to review the guidance to better understand the government’s view of these risk areas.

Endnotes

1 See Ambulance Firm Pays $20 Million to Settle Allegations of Fraudulent Medicare Billings, 6 BNA Health Care Fraud Report, 489 (June 12, 2002).
2 Owner of Main Ambulance Company Jailed, Fined for Medicare, Medicaid Fraud, 6 BNA Health Care Fraud Report, 644 (Aug. 7, 2002).
3 See Owners of California Ambulance Service Arrested, Charged with Defrauding Medicare, 6 BNA Health Care Fraud Report, 495 (June 12, 2002).
4 Technically, the ambulance industry includes both ambulance suppliers and institutional providers such as hospitals, but the term supplier will be used in this article to refer to all entities that bill Medicare directly for ambulance services.
7 Quality Care Ambulance Serv., Inc. v. United States, 204 F. Supp. 2d 1096 (W.D. Tenn May 21, 2002).
9 42 U.S.C. § 1320a-7(b).
10 42 U.S.C. § 1320a-7(a)(5).
11 See OIG Advisory Opinion No. 97-6 (Oct. 8, 1997).
12 OIG Advisory Opinions Nos. 98-7 (June 11, 1998); 98-13 (Sept. 23, 1998); 98-14 (Oct. 28, 1998); and 00-09 (Dec. 8, 2000).
14 42 C.F.R. § 1001.952(v)(3).
15 OIG Advisory Opinions Nos. 01-11 (July 20, 2001); 01-10 (July 20, 2001); and 02-08 (June 19, 2002).
17 CMS Carrier Manual § 2309.4.
18 OIG Advisory Opinion No. 01-12 (July 20, 2001).
19 See 67 Red. Reg. 30024, n. 27, See also OIG Advisory Opinion 01-18 (Nov. 7, 2001).
Year-In-Review

I. Case Law Summary
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Court Decisions

U.S. Court In Nebraska Finds CMS failed to Properly Apply Its Own Regulations And Prevents It from Recoding An Orthotic Device
Dewall Enterprises, Inc. (Dewall) sued the Secretary of the Department of Health and Human (DHHS) Services (Secretary) because the Centers for Medicare & Medicaid Services (CMS) failed to consistently interpret its own regulations by subjecting Dewall to repeated administrative hearings regarding the proper coding of an orthotic device. The code for the device in question was established by CMS. Nonetheless, CMS, through its durable medical equipment regional carrier, repeatedly assessed overpayments against Dewall for billing the incorrect code. In each of those cases, when Dewall appealed those overpayment assessments to an Administrative Law Judge, the overpayment was overturned. Finally, CMS informed Dewall that it was going to initiate a coding verification re-review regarding the code to be used for the orthotic device, which prompted this civil action seeking declaratory and injunctive relief. The court found that it had jurisdiction to hear the case and then determined that CMS had repeatedly failed to uniformly interpret its own regulations and repeatedly disregarded Dewall’s constitutional due process rights. Consequently, it granted Dewall’s motion for preliminary injunction against the Secretary, preventing CMS from conducting its coding review pending a full trial on the merits. Dewall Enters., Inc. v. Thompson, No. 8:02CV69 (D. Neb. June 26, 2002).

U.S. Bankruptcy Court In New York Stops A Physician Exclusion

The U.S. Bankruptcy Court for the Southern District of New York recently ruled that the New York State Department of Health could not exclude a physician from participating in the New York Medicaid Program for failing to repay an overpayment of Medicaid funds. The physician had previously entered into a Reinstatement Agreement in which he had agreed to repay the overpayment over a ten-year period if the state of New York reinstated his Medicaid privileges. However, the physician declared bankruptcy several years later and the state then terminated the physician’s participation for failing to repay the debt. The court ruled that the state’s effort to exclude the physician from participating in the Medicaid program conflicted with § 525(a) of the Bankruptcy Code, which prohibits governmental units from taking action that discriminates against debtors for failure to pay debts. The court found that the state’s exclusion of the physician would have prevented him from making a fresh start, thereby undermining the purpose of the Bankruptcy Code. In re Berkelhammer, No. ML. 01-14772 (AJG) (S.D.N.Y. June 13, 2002).

Ninth Circuit Rules EMTALA Does Not Apply Once Patient Is Admitted For In-Patient Care

The Ninth Circuit recently reviewed a case against a hospital under the Emergency Medical Treatment and Active Labor Act (EMTALA) in which plaintiffs alleged that the hospital’s medical staff failed to detect an emergency medical condition and failed to treat the patient appropriately after the patient was admitted for in-patient care. Plaintiffs argued that the hospital could be liable if its medical staff negligently failed to detect an emergency condition, but conceded that the hospital screened the patient. The court held that EMTALA was not enacted to establish a federal medical malpractice cause of action or to establish a national standard of care. Plaintiffs also argued that the hospital should be liable under EMTALA for failing to stabilize the condition once the patient was admitted. The court held, however, that EMTALA’s stabilization requirement ends when a patient is admitted for in-patient care. Bryant v. Adventists Health Assistance/West, No. 00-16399 (9th Cir. May 20, 2002).

U.S. Court In D.C. Rules That Lithotripsy Is Not A Designated Health Service Under Stark II

The U.S. District Court for the District of Columbia recently held that the CMS rule applying the self-referral ban under Stark II to lithotripsy services is invalid because it was inconsistent with congressional intent. CMS found that lithotripsy would be included within the definition of "in-patient and out-patient hospital services." But the court disagreed, concluding Congress did not intend for lithotripsy to be included in this definition. CMS also questioned the court's jurisdiction over the case, given that CMS had not intended to enforce the regulation against any physician or hospital. The court determined, however, that the severity of sanctions that can be imposed for violating the self-referral prohibition and the difficulties that physicians would encounter in accessing the administrative review process allowed it to have jurisdiction. American Lithotripsy Soc'y v. Thompson, No. 01-01812 (HHK) (D.D.C. July 12, 2002).

PRRB Decision

PRRB Disallows Legal Fees

The Provider Reimbursement Review Board (PRRB) recently determined that a fiscal intermediary had properly disallowed legal fees that a home health agency (Agency) claimed related to patient care. The attorneys' fees were spent on litigation with several former employees for breach of contract and non-solicitation provisions. The Agency maintained that the expenses were the result of protecting the interest of its patients and their ability to receive uninterrupted patient care services. The fiscal intermediary contended, and the PRRB agreed, that the legal fees were not incurred in the ordinary course of business and did not reflect a common practice in the industry. Further, the PRRB found that there was
not sufficient documentation to show a relationship between patient care and the litigation, but that there was documentation to indicate that the litigation was instituted to protect the Agency's market share. *HomeAid, Inc. of Cumberland Plate v. Blue Cross Blue Shield Ass'n*, Palmetto Gov't Benefits Adm'n, PRRB Hearing Dec. No. 2002-D21, Case No. 96-1820 (P.R.R.B. May 29, 2002).

**DAB Departmental Appeals Board, Civil Remedies Division**

**DAB Reverses Civil Money Penalty**

The DAB Departmental Appeals Board, Civil Remedies Division, (DAB) recently ruled that CMS improperly imposed a civil money penalty on a long term care facility. The facility, located in Alabama, had been the subject of a finding of non-compliance and a recommendation to impose a civil money penalty by the Alabama Department of Public Health, which later rescinded its findings. Although CMS had the authority to independently determine that this facility was not in compliance and impose sanctions, it did not do so in this case. Instead, CMS imposed penalties based solely on the initial recommendation of the state agency. The DAB found that, because the state agency had rescinded its findings, there was no basis for the imposition of the penalty. *NHC Health Care*, Moulton, Dec. No. CR#89 (Dep't of Health & Human Servs., Dep'tal App. Bd. Civ. Remedies Div. May 7, 2002).

**DAB Sanctions CMS for Failing to Comply with Court Orders**

A long term care facility in Colorado was the subject of the imposition of civil remedies because CMS determined that it had failed to substantially comply with applicable regulations. An Administrative Law Judge (ALJ) issued initial orders to the parties. Although counsel for CMS filed a notice of appearance, it did not respond to the ALJ's orders. Consequently, the ALJ imposed sanctions on CMS under applicable law and determined that the only appropriate disposition was to find in favor of the facility and essentially enter a default judgment against CMS. *Alpine Living Ctr.*, Dec. No. CRA97 (Dep't of Health & Human Servs., Dep'tal App. Bd. Civ. Remedies Div. May 7, 2002).

**II. JCAHO**

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**JCAHO Announces 2003 National Patient Safety Goals**

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) adopted six National Patient Safety Goals for improving the safety of patient care in healthcare organizations, which are: (1) Improve the accuracy of patient identification by using at least two patient identifiers whenever taking blood samples or administering medications or blood products, and conducting a final verification process prior to the start of any surgical or invasive procedure to confirm the correct patient, procedure, and site, using active communication techniques; (2) Improve the effectiveness of communication among caregivers, including the implementation of a process for taking verbal or telephone orders that requires a verification “read-back” of the complete order by the person receiving the order and standardization of the abbreviations, acronyms, and symbols used throughout the organization, including a list of abbreviations, acronyms, and symbols not to use; (3) Improve the safety of using high-alert medications, including removing concentrated electrolytes from patient care units and standardizing and limiting the number of drug concentrations available in the organization; (4) Eliminate wrong-site, wrong-patient, wrong-procedure surgery by creating and using a preoperative verification process, such as a checklist, to confirm that appropriate documents (e.g., medical records, imaging studies) are available and implementing a process to mark the surgical site and involve the patient in the marking process; (5) Improve the safety of using infusion pumps by ensuring free-flow protection on all general- use and PCA (patient controlled analgesia) intravenous infusion pumps used in the organization; and (6) Improve the effectiveness of clinical alarm systems, including implementing regular preventive maintenance and testing of alarm systems and assuring that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit. The Standards become effective January 1, 2003.

**JCAHO Supports Proposed Legislation for Patient Safety**

The "Patient Safety Improvement Act of 2002," introduced in the House in June by House Ways and Means Subcommittee on Health Chairman Nancy Johnson (R-CT), would afford confidentiality protections to reports of serious adverse events and the analyses of their underlying causes. JCAHO supports this legislation to encourage the voluntary reporting of healthcare errors. In addition, the "Patient Safety and Quality Improvement Act," introduced in the Senate in June by Senators Jim Jeffords (I-VT), Bill Frist (R-TN), John Breaux (D-LA), and Judd Gregg (R-NH), affords similar protections. Both bills create an opportunity for healthcare organizations to share their experience with others. Currently, information about errors is not considered confidential. Thus, many errors are not reported.

**III. Regulatory Update**

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**CMS Issues Final Rule to Give Strong Protection for Medicaid Managed Care Beneficiaries**

On June 14, 2002, the Centers for Medicare & Medicaid Services (CMS) issued a final rule to provide Medicaid managed care beneficiaries similar types of protections to those that participants in private plans would enjoy under patient rights' legislation being
considered in Congress. Some of the new protections established by the rule are better access to emergency room care, a right to request a second opinion when needed, and a timely right to appeal adverse coverage decisions. According to Department of Health and Human Services Secretary Tommy G. Thompson, the new rule "ensures Medicaid beneficiaries get the rights and protections enjoyed by other Americans enrolled in managed care plans."
The new rule allows significant flexibility in how the states implement beneficiary protections and use managed care in their Medicaid programs.

**CMS Issues Proposed Rule Updating Physician Payment Rates**
On June 28, 2002, CMS published a proposed rule updating the physician fee schedule for fiscal year 2003 and revising certain Medicare Part B payment policies affecting physicians. Medicare payment under the physician fee schedule is expected to increase by $43 million in 2003. Significantly, under the proposed rule, CMS will modify the methodology used to calculate the Medicare Economic Index (MEI), a measure of inflation in providing physicians' services and one element of a formula used to update the physician fee schedule. CMS has proposed to raise the 2003 MEI update from 2.3% to 3.0%. Further, the proposed rule significantly increases the Medicare payment for some vaccine immunizations. Some of the other policy changes proposed include pricing of the technical component for positron emission tomography (PET) scans, Medicare qualifications for clinical nurse specialists, and a process to add or delete services to the definition of telehealth.

**CMS Announces Increase in Skilled Nursing Home Payments Under the SNF Prospective Payment System**
On July 31, 2002, CMS issued a notice updating payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year 2003. CMS announced that payments will be increased by 2.6%, which will result in nearly $400 million more in payments for SNFs in 2003. The increase will be offset, however, by the expiration of two temporary add-on payments to SNFs as required by Congress. The effect is a net decrease of $1 billion in payments to SNFs in fiscal year 2003.

**CMS Announces Increase in Hospital Inpatient Payments**
On August 1, 2002, CMS published a final rule announcing a 2.95% rate increase for payments to acute care hospitals under the inpatient PPS. The increase is higher than the 2.75% proposed in May. The final rule establishes reimbursement for new technologies, drug eluting stents. To make payment available for drug eluting stents, CMS created two new diagnosis related groups (DRGs)-the payment becomes effective April 1, 2003. Other changes to hospital payment policies include: payments to hospitals for the direct and indirect costs of graduate medical education; pass-through payments for the services of nonphysician anesthetists in some rural hospitals; clinical requirements for swing-bed services in critical access hospitals; and requirements and responsibilities related to provider-based entities. The final rule, however, does not expand the post acute transfer policy to cover all DRGs. CMS reasoned it needs more time to study the impact of such a change. The final rule also does not include the proposed amendments to the Emergency Medical Treatment and Active Labor Act. CMS stated a separate final rule on the proposed amendments will be issued at a later date.
PROGRAM REGISTRATION FORM

FALL 2002–SPRING 2003

To register: Remit payment and completed registration form by mail to the American Health Lawyers Association, PO Box 79340, Baltimore, MD 21279-0340, by fax with credit card information to (202) 833-1105, or by phone at (202) 833-0766. To avoid duplicate charges, please do not mail this form if you have already faxed it to us.

Name:_________________________________________ Member ID #:_________________________________________

First Name on badge (if different than above):__________________________Title:_________________________________

Organization:____________________________________________________________________________________________

Address:_________________________________________________________________________________________________

City:_____________________________________________ State:___________________ ZIP:___________________________

Telephone: (_____)(______)_________Fax: (_____)(______)_________E-mail:___________________________________

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For registration fee information, see calendar on inside back cover.

*If you are not a member of Health Lawyers but join when you register for the program, you will be eligible for the member registration fee!

PAYMENT INFORMATION

Please fill in applicable amount

(Sorry! Registrations cannot be processed unless accompanied by payment.)

Registration Fee(s): $________________

Membership Dues (see box below): $________________

Practice Group Lunch Fee: $________________

Total Enclosed: $________________

☐ Check enclosed

(Make check payable to Health Lawyers, U.S. dollars)

Bill my credit card: ☐ ☐ ☐

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Exp. Date: _______________________________

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Signature of Cardholder: ______________________

ZIP Code of Cardholder’s
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□ Attorney ☐ In-House Counsel

Date of Admission to the Bar:
Admitted to Bar less than four years ago ..........$150
Admitted to Bar four to eight years ago ..........$275
Admitted to Bar more than eight years ago ........$315
Academician (full-time faculty) .................$150
Government Attorneys .............................$150
Health Professional/Other .........................$315
Student .............................................$20
Call for Authors!
The RAP Sheet

If you would like to be considered as an author for the upcoming RAP Sheet newsletter, please complete this form. If you would like to submit an article, please fill out sections I and II. Please submit this form and article to:

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600 13th Street NW, 12th Floor
Washington, DC 20005-3005
Phone: (202) 756-8148  Fax: (202) 756-8087
E-mail: ezimmerman@mwe.com

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The Practice Corner......

The Regulation, Accreditation, and Payment Practice Group Leadership is pleased to announce the roll-out of its latest membership benefit- The Practice Corner. RAP members can now access The Practice Corner on the RAP Practice Group web page at www.healthlawyers.org/pg/rap/

The Practice Corner contains documents from the Centers for Medicare and Medicaid Services, CMS regional offices, fiscal intermediaries, and carriers. These documents consist of interpretations of statutes, regulations, and other regulatory materials, which have been provided to law firms, providers, and other regulatory authorities. Unpublished regulatory opinions will also be available. The Practice Corner will continue to post new documents upon their receipt.

The RAP Practice Group Leadership will rely largely on the RAP Practice Group members for new documents to be added to this web page. Please send all submissions to:

American Health Lawyers Association
RAP: The Practice Corner
1025 Connecticut Ave NW, Ste 600
Washington, DC 20036-5405
or email to lgarvey@healthlawyers.org

Attribution to the sender will be included in the posting unless requested to withhold the sender's identity.

We look forward to providing the membership with this benefit, and we hope that all of our members will give thought to how they can participate to make this service truly useful!