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Health Law

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We welcome your suggestions for future articles. Please call Michael E. Reed (312) 609-7428 with suggested topics (or other questions or comments concerning materials in this newsletter).

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Spring 1998

ILLINOIS APPELLATE COURT HOLDS EMPLOYED ATTENDING PHYSICIANS MAY NOT UNIONIZE

As physicians around the nation continue their efforts to unionize for purposes of collective bargaining, a union organizing attempt by employed Attending Physicians at Cook County Hospital has been rebuffed by the Illinois Appellate Court. By a vote of 21, the Court affirmed a ruling of the Illinois Local Labor Relations Board that Cook County Hospital Attendings meet the definition of "supervisor" under the Illinois Public Labor Relations Act and so are exempt from the coverage of the Act. As a result, the Union seeking to represent them, the National Union of Hospital and Health Care Employees, an affiliate of the American Federation of State, County and Municipal Employees, could not petition the Board to hold a union representation election among the Attendings.

Cook County Hospital is a 918-bed acute care teaching hospital operated by Cook County and located on the near west side of the City of Chicago. Residents employed by the Hospital and participating in the Hospital's graduate medical education programs provide most of the Hospital's direct patient care. The approximately 200 Attending Physicians employed by the Hospital provide very little direct patient care, although they are ultimately responsible for the care provided all patients of the Hospital. Roughly 80% of their time is spent in teaching the Hospital's roughly 530 Residents, monitoring and directing the care they provide and guiding their professional development.

After extensive evidentiary hearings, an Administrative Law Judge of the Board held that the direction the Attendings provided Residents was not supervisory in character because the Attendings were not acting out of their concern for the Hospital's interests as an employer or their standing as an employer representative but based on their superior skills and technical expertise. The Board reversed the ALJ by a 21 vote, and the Union appealed to the Appellate Court.

The Appellate Court ruled that Attendings met the test for supervisory status under the Illinois law, a test which is more demanding than that contained in the National Labor

Relations Act, which applies to private employers. The Court — noting that "virtually all supervisors have authority over their portion of an operation because of their Employer's conclusion that they have greater skill and experience" — rejected the Union's theory that Attendings, in fulfilling their responsibilities toward Residents, were not acting out of the Hospital's interest. The Court held that the Union's theory did not acknowledge the Hospital's role as a teaching hospital or the importance of the graduate medical education programs in producing quality Residents and attracting new Residents to serve the Hospital's large patient population. The Court concluded that the Hospital had specifically assigned the teaching function to the Attendings and that, by the Attendings' direction of Residents as they provide patient care and in the Hospital's education programs, the Hospital was able to fulfill its mission of providing efficient and economical health care to the indigent. Thus, ruled the Court, the direction Attendings provide Residents is in the Employer's interest and makes them supervisory employees exempt from the coverage of the Act. The Union's election petition was therefore dismissed.

The *Cook County Hospital* decision, while decided under Illinois law, has potentially broader application. It recognizes that the supervisory position of physicians with respect to other personnel (potentially including employees such as nurses and techs) does not rest solely on their superior skill and experience but instead can derive from responsibilities given the physicians by their employers, even where in carrying out those responsibilities the physicians act based upon their superior skills and experience and not their sense of professional responsibility.

A cautionary note — while residents are employees under the Illinois law as the result of an express provision of the statute, they have been ruled to be students under the National Labor Relations Act (though recent efforts have been made to overturn that ruling). As a result, at a private hospital covered by the NLRA, physicians playing the same role Cook County Hospital Attendings play with respect to its Residents would not be preforming a statutory function because, at the private, NLRA-covered hospital, residents would be considered students, not employees.

Cook County Hospital was represented by Vedder Price attorneys Larry Casazza (312/609-7770) and Mike Cleveland (312/609-7860). Should you desire further information about the case or the subject of physician union organizing, please contact either of them.

National Union of Hospital and Health Care Employees, American Federation of State County and Municipal Employees (Doctors' Council of Cook County Hospital) v. County of Cook (Cook County Hospital) and Illinois Local Labor Relations Board, No. 1-96-2690 (March 20, 1998).

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HCFA OUTLINES APPLICATION PROCESS FOR MEDICARE+CHOICE PLANS

Background

Prior to the enactment of the Balanced Budget Act of 1997 (Pub. L. No. 105-33) ("BBA"), Medicare beneficiaries could choose to receive their Medicare benefits on a fee-for-service ("FFS") basis or by enrolling in a health maintenance organization ("HMO") under contract with the Medicare program. Section 4001 of the BBA modified these traditional options by creating a Medicare program called Medicare+Choice. Under Medicare+Choice, eligible individuals may elect to receive Medicare benefits through more varied types of health plan options than were previously available to them. Plans that may participate in Medicare+Choice include provider-sponsored organizations ("PSOs"), preferred provider organizations ("PPOs"), private FFS plans, medical savings accounts ("MSAs"), and, for those who qualify, religious fraternal benefit society plans.

Preliminary information regarding the application process and other requirements for entities planning to participate in the Medicare+Choice program for the contracting period beginning January 1, 1999 are set forth in a proposed rule and notice published on January 20, 1998 in the Federal Register (63 Fed. Reg. 2920-01). The BBA requires final regulations to be published by June 1, 1998.

Application Process

The Health Care Financing Administration ("HCFA") encourages organizations that wish to participate in the Medicare+Choice program to submit their applications as soon as possible, and, in any event, no later than August 1, 1998. An interim final rule is expected to be published in June 1998, after which applicants may submit a "supplemental" application. The application for Medicare+Choice plans is similar to the current Medicare risk contract application. Prospective Medicare+Choice plan applicants must provide the following information:

- General information, including a description of the plan, brief history, banking information, board of directors, management staff, geographic region, and other pertinent data for the Medicare product;
- Organization and contract information, including the type of legal entity, state authority to operate, organizational charts, and management contracts;
- Description of the health services delivery network, including a detailed description of the delivery system, Medicare subscriber agreements, evidence of coverage, membership information, and quality assurance systems;
- Financial information, including certified audits, financial projections, and all information necessary to demonstrate a fiscally sound operation; and
- Marketing information, including marketing plans, projections, and enrollment assumptions.

The application packages are available on HCFA's Internet web site at http://www.hcfa.gov. Additional information on the application process can be obtained by writing HCFA's Health Plan Purchasing and Administration Group ("HPPAG") at: HPPAG, Field Liaison Staff, Health Care Financing Administration, Center for Health Plans and Providers, Health Plan Purchasing and Administration Group, 7500 Security Blvd., 03-18-13 South Building, Baltimore, MD 21244-1850; or by calling 410-786-7623.

In general, only state-licensed organizations will be eligible to participate in the Medicare+Choice program. The only exception will be PSOs, which may apply for a waiver of state licensure requirements under the circumstances outlined below. HCFA will review each

application and, for those determined to be incomplete, will allow an additional sixty (60) days for the applicant to submit necessary information. Once an application is complete, HCFA will conduct an extensive review of the data, including a site visit for most plans. An organization approved as a Medicare+Choice plan must be ready to enroll and serve beneficiaries by January 1, 1999 or the first day the contract becomes effective.

PSO Waiver Requirements

Pursuant to the BBA, HCFA may grant a waiver of state licensure requirements for PSOs if the organization files an application for such waiver by not later than November 1, 2002 and HCFA determines, based on the application and other evidence presented, that:

- the state failed to complete action on the organization's license application within ninety (90) days of the state's receipt of a substantially complete licensure application;

- the state's denial of the organization's license application was based on discriminatory treatment as demonstrated by evidence showing that (i) the licensure standards (other than solvency requirements) or review processes imposed by the state as a condition of approval of the license are not generally applicable to other entities engaged in a substantially similar business or (ii) the state required the organization, as a condition of licensure, to offer any product or plan other than a Medicare+Choice plan;

- the state's denial of the licensure application was based the on the application of state solvency requirements; or

- with respect to waiver applications filed on or after the date of publication of federal PSO solvency standards, the state denied the licensing application (in whole or in part) because the organization failed to meet applicable solvency requirements and (i) the state solvency requirements are not the same as the federal PSO solvency standards; or (ii) the state has imposed, as a condition of approval of the license, documentation or information requirements relating to solvency or other material requirements,

procedures, or standards relating to solvency that are different from the organizational and financial requirements for Medicare+Choice organizations enacted by the BBA (*see* related article in this issue, "PSO Solvency Standards").

Once a prospective Medicare+Choice PSO submits documentation that one or more of the above conditions has been met, HCFA must grant or deny the waiver application within sixty (60) days. Form applications for PSOs seeking waiver from state licensure are available on HCFA's Internet web site or from HPPAG at the address and telephone number given above. The package includes the waiver forms as well as the contract application and all definitions.

Practical Application

The creation of Medicare+Choice represents one of the most significant health care reform measures since the initial enactment of the Medicare program. In addition to providing beneficiaries with expanded service delivery options, the Medicare+Choice program opens the door to Medicare participation and competition among a number of different types of health care entities, including HMOs, PPOs, MSAs, and PSOs.

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PSO SOLVENCY STANDARDS TO BE PUBLISHED IN MAY

On March 5, 1998, members of the federal Negotiated Rulemaking Panel submitted to the Health Care Financing Administration ("HCFA") a draft committee statement (the "Statement") outlining the panel's recommended solvency standards for provider-sponsored organizations ("PSOs") participating in the Medicare+Choice program. The 14-member panel represents providers, beneficiaries, and insurers.

Initial Net Worth Requirements

The Statement recommends that PSOs be required to have an initial net worth of at least $1.5 million. Of that total, at least $750,000 must be in cash or cash equivalents at start-

up. HCFA could lower the initial net worth requirement to $1 million if the PSO were able to demonstrate that start-up costs would be reduced due to access to an established administrative infrastructure. Under the Statement, 100% of the book value (GAAP depreciated value) of "health care delivery assets" could be applied toward the $1.5 million. A "health delivery asset" is defined in the Statement as "any tangible asset that is part of PSO operations, including: [h]ospitals, medical facilities, and their ancillary equipment and such property as may reasonably be required for the PSO's principal office or for such purposes as may be necessary in the transaction of the business of the PSO." If at least $1 million of the initial net worth requirement were met by cash or cash equivalents, then HCFA would allow up to 20% of the value of intangible assets to count toward the minimum net worth requirement. If less than $1 million of the initial minimum net worth requirement were met by cash or cash equivalents or if HCFA had, in its discretion, reduced the net worth requirement below $1.5 million, then only 10% of the value of intangible assets could be counted toward the minimum net worth requirement.

Ongoing Net Worth Requirements

Once approved, every PSO must maintain a minimum net worth equal to the greater of:

- One million dollars ($1,000,000); or
- Two percent (2%) of annual premium revenues as reported on the most recent annual financial statement filed with HCFA on the first $150,000,000 of premium and one percent (1%) of annual premium on the premium in excess of $150,000,000; or
- An amount equal to the sum of three months uncovered health care expenditures as reported on the most recent financial statement filed with HCFA; or
- An amount equal to the sum of: (1) eight percent (8%) of annual health care expenditures paid on a noncapitated basis to nonaffiliated providers as reported on the most recent financial statement filed with HCFA; (2) four percent (4%) of annual health care expenditures paid on a capitated basis to

nonaffiliated providers plus annual health care expenditures paid on a noncapitated basis to affiliated providers; and (3) zero percent (0%) of annual health care expenditures paid on a capitated basis to affiliated providers (regardless of downstream arrangements from the affiliated provider).

Financial Plan

PSO applicants must submit a financial plan covering the first 12 months of operation under the contract. This financial plan must include:

- a detailed marketing plan;
- statements of revenue and expense on an accrual basis;
- a cash flow statement;
- balance sheets;
- assumptions made in support of the financial plan; and
- if applicable, availability of financial resources to meet projected losses.

PSOs also must demonstrate sufficient cash or cash equivalent reserves to cover projected losses for the entire contract period to break even. In general, the resources of the PSO must be cash or cash equivalent assets. The following alternative sources of capital may, however, be utilized either individually or in combination, if approved by HCFA:

- Guarantees, if the following conditions are met:
  - In the first year, the guarantor provides the PSO with cash or cash equivalents:
    1. prior to the beginning of the first quarter, in the amount of the projected losses for the first two quarters;
    2. prior to the beginning of the second

quarter, so that the PSO has cash or cash equivalents sufficient to meet projected losses through the end of the third quarter; and

3. prior to the beginning of the third quarter, so that the PSO has cash or cash equivalents sufficient to meet the projected losses through the end of the fourth quarter.

- The guarantor generally demonstrates financial commitment to the PSO by providing the PSO with cash or cash equivalent disbursements in a timely manner. In the third quarter, the PSO will be required to notify HCFA if the PSO intends to reduce the period of funding of projected losses and HCFA must notify the PSO within 60 days of receiving the notice if the reduction is not acceptable; and

- The guarantor meets any other requirements that may be imposed by HCFA in future regulations.

- An irrevocable, clean, unconditional letter of credit may be used in place of cash or cash equivalents; and

- Lines of credit from regulated financial institutions, legally binding agreements for capital contributions, or other legally binding contracts of a similar level of reliability, subject to standards to be promulgated by HCFA.

In addition to demonstrating adequate capital reserves to cover projected losses, the PSO must maintain sufficient cash flow to meet its obligations as they become due. In determining whether a PSO meets this requirement, HCFA will consider the following:

- the timeliness of payment;

- the extent to which the current ratio is maintained at 1:1, or whether there is a change in the current ratio over a period of time; and

- the availability of outside financial resources.

In the event the PSO fails to pay obligations as they become due, HCFA will require the PSO to initiate corrective action to pay all overdue obligations. HCFA also may require the PSO to initiate corrective action if any of the following are evident:

- a significant decline of the current ratio; or
- a continued downward trend in the current ratio.

The corrective action may include a change in the distribution of assets, a reduction of liabilities, or alternative arrangements to secure additional funding requirements to restore the current ratio to 1:1. If there is a change in the availability of the outside resources, HCFA will require the PSO to obtain funding from alternative financial resources.

Practical Application

The federal PSO solvency standards are intended to ensure such plans will be financially secure when participating in the Medicare+Choice program. While most panel members apparently agreed on the $1.5 million net worth requirement, there was some disagreement over what portion of the net worth requirement would have to be in cash and hard assets.

Many providers agree that some minimum solvency standards are necessary; however, some providers, including small rural hospitals and physician groups, believe the proposed cash requirements under the Statement might prevent many otherwise qualified providers from participating in Medicare+Choice. These groups are advocating for allowing a higher percentage of intangible assets to be counted in determining initial net worth. To date, the panel has not determined how intangible assets such as physician management contracts, established networks, and goodwill will be valued. Insurers, not surprisingly, favor the more restrictive allowances for intangible assets and higher cash requirements. HCFA is expected to address these concerns in proposed rules that are scheduled to be published some time this spring.

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HCFA ANNOUNCES MEDICARE/MEDICAID PARTICIPATION REQUIREMENTS FOR HOME HEALTH AGENCIES AND DME SUPPLIERS

Introduction

Pursuant to provisions of the Balanced Budget Act of 1997 (Pub. L. No. 105-33) (the "BBA"), the Health Care Financing Administration ("HCFA") has promulgated final rules ("Final Rules") implementing new participation requirements for home health agencies ("HHAs") and proposed rules ("Proposed Rules") regarding new participation requirements for suppliers of durable medical equipment ("DME"), prosthetics, orthotics, and supplies (referred to collectively as "DMEPOS Suppliers"). The Final Rules require every HHA to obtain surety bonds of at least $50,000 in order to participate in the Medicare and Medicaid programs (a separate $50,000 bond is required for each program). New HHAs also must demonstrate that they have sufficient capital reserves before they may obtain Medicare provider numbers. Under the Proposed Rules, DMEPOS Suppliers also will be subject to the $50,000 surety bond requirement. In addition, DMEPOS Suppliers will be required to meet a number of new standards established by HCFA in order to obtain a billing number and receive payment from Medicare.

Home Health Surety Bond and Capitalization Requirements

The BBA requires that every HHA wishing to participate in Medicare must provide a surety bond to HCFA that equals the greater of $50,000 or 15% of the annual amount paid to the HHA by Medicare, as reflected in the HHA's most recently accepted Medicare cost report. The same requirement is imposed on HHAs that wish to participate in state Medicaid programs, except that Medicaid surety bonds must be submitted to the state Medicaid agency rather than the HCFA and must be in the form specified for Medicare participation and in an amount that is not less than $50,000 or some other comparable surety bond under state law. The surety bond requirement applies to all participating Medicare and Medicaid HHAs, regardless of the date their participation in the programs began. The BBA further specifies that the surety bond requirement must be incorporated into all new and existing Medicare

and Medicaid provider agreements.

The surety bond provisions were implemented in the Final Rules (with comment period) published in the Federal Register on January 5, 1998 (63 Fed. Reg. 292). HCFA has since announced proposed revisions to the Final Rules, in response to comments submitted following their publication. The proposed revisions were announced in two notices published March 4 (63 Fed. Reg. 10730 and 10732 (collectively, the "Notices")). The Notices extend the implementation date of the Final Rules and the deadline for submission of surety bonds, and also propose a number of technical changes designed to make it easier for smaller, reputable HHAs to meet the surety bond requirement. In order to better assess the extent and nature of the problems HHAs are encountering with respect to obtaining bonds, HCFA has requested that an HHA that is unable to secure a bond notify its Medicare fiscal intermediary and/or state Medicaid agency of this fact.

New Deadline

The surety bond requirement was technically effective as of January 1, 1998. The Final Rules imposed a deadline of February 27 for participating HHAs to submit a surety bond to HCFA and/or the state Medicaid agency, as applicable. Surety bonds were to be effective beginning January 1, 1998 through the end of the HHA's current fiscal year. Thereafter, participating HHAs must submit new surety bonds on an annual basis. The February 27 deadline has been deferred due to the inability of some HHAs to secure bonds by that date. HHAs now will need to submit a surety bond no later than sixty (60) days after the date of publication of amended Final Rules.

Waiver for Government-Operated HHAs

As detailed in the Final Rules, the Medicare surety bond requirement is waived for HHAs operated by federal, state, or local governments if, during the preceding five years, such an HHAs has not incurred long-term, unpaid debts based on unrecovered Medicare overpayments or on unpaid civil monetary penalties. Although the BBA permits HCFA also to waive the surety bond requirement for any agency or organization that provides a comparable surety bond under state law, HCFA has chosen not to implement the full scope of its waiver authority at this time. According to the Final Rules, HCFA is considering

what standards and criteria would be appropriate to implement such a waiver, and is seeking public comment on current state requirements as to surety bonds for HHAs.

Sanctions for Failure to Comply or for Payment by Surety

An HHA's failure to obtain and maintain a surety bond as required under the new regulations is deemed sufficient basis for HCFA to terminate the HHA's provider agreement or to refuse to enter such agreement. Additionally, the Final Rules specify that HCFA may, at any time, require an HHA to demonstrate that it is in compliance with the surety bond requirement.

In the event HCFA must seek payment from a surety on an HHA's bond, the payment from the surety shall constitute collection of the unpaid claim, unpaid civil monetary penalty, or assessment owed by the HHA. Such collection also shall be grounds for termination of the HHA's provider agreement.

Medicaid Provisions

Section 4724(b) of the BBA prohibits Federal Financial Participation ("FFP") payments to a state for home health services under Medicaid unless the participating HHA has provided the state with a surety bond that meets the requirements for surety bonds required under the Medicare program.

The Final Rules provide that, generally, the Medicare requirements for HHA surety bonds also apply to HHAs participating in Medicaid. An HHA must submit its surety bond to the state Medicaid agency. Additionally, the Final Rules provide that state Medicaid agencies can specify any other requirements for Medicaid-participating HHAs which are deemed necessary for surety bond compliance.

Capitalization Requirements

As noted above, the Final Rules provide that on or after January 1, 1998 all HHAs seeking for the first time to participate in the Medicare or Medicaid program, including HHAs that are seeking new provider numbers because of change in ownership, must have initial reserve funds sufficient to start and operate the HHA for its first three months. The purpose of the capitalization

requirement is to insure that HHAs entering the federally funded health care programs are financially stable. The requirement is viewed by HCFA as necessary in light of findings by the Office of the Inspector General ("OIG") that many HHAs entering the Medicare program are undercapitalized and that, as a result, these HHAs expose Medicare and Medicaid programs to unnecessary financial risk and adversely affect the quality of care provided to HHA patients.

Under this new provision, HCFA, through its intermediaries, will determine the amount of reserve funds that each HHA is required to have before becoming certified in the Medicare or Medicaid program. The required amount will be based on the average cost-per-visit of comparable new HHAs, using data from cost reports submitted by those HHAs for the first full year of operation. The initial capitalization requirement must be met in order for the HHA to be certified to participate in the Medicare or Medicaid program. After certification, however, HCFA expects that such reserves will be used by the HHA to provide patient care.

The HHA must show that at least 50% of the mandated initial reserve operating funds are nonborrowed, unencumbered, cash or cash equivalent funds. If an owner loans his or her own funds to the business, those funds, whether loaned or contributed, also will be considered part of the HHA's nonborrowed funds. The remaining initial reserve funds may be secured through a borrowing or line of credit from an "unrelated lender" which is defined in 42 CFR § 413.153(b)(3) as a lender not related through control or ownership, or personal relationship to the borrowing organization.

For HHAs that participate in Medicaid only, and not in Medicare, the state Medicaid agency is responsible for determining whether the capitalization requirements are met in the same manner that Medicare intermediaries make the determination for HHAs seeking to enter the Medicare program (or both the Medicare and Medicaid programs).

Durable Medical Equipment Suppliers

The BBA requires DMEPOS Suppliers to post a surety bond of at least $50,000 in order to participate in Medicare. In the Proposed Rules published in the Federal

Register January 20, 1998 (63 Fed. Reg. 2926), HCFA announced its plans to implement the $50,000 surety bond requirement for all DMEPOS Suppliers. In addition, the Proposed Rules would impose upon DMEPOS Suppliers a number of new standards, including a requirement that DMEPOS Suppliers maintain a physical facility and a listed business phone number, as well as a specific prohibition on telemarketing. The Proposed Rules confirm that a supplier number is not required for payment for medical equipment and supplies furnished "incident to" a physician's service.

Sliding Scale Surety Bond

In combination with the $50,000 minimum surety bond requirement, the Proposed Rules explain HCFA's plan to establish a sliding scale for the "penal amount" of the surety bond that relates to the volume of business a DMEPOS Supplier does with Medicare. The penal amount is the amount for which a surety bond would be liable to HCFA. Under the Proposed Rules, the sliding scale would be based on 15% of the amount paid to the DMEPOS Supplier by Medicare in the previous year, with a $50,000 minimum and a $3,000,000 maximum. Although the BBA authorizes HCFA to waive the surety bond requirement if a DMEPOS Supplier provides a comparable surety bond under state law, HCFA has not yet implemented the waiver authority. However, HCFA is soliciting comments on standards and criteria for implementing a waiver of the DMEPOS Supplier surety bond requirement.

Billing Number Certification Standards

In order to bill Medicare, DMEPOS Suppliers must apply for and receive billing numbers. Any items furnished by a DMEPOS Supplier prior to the date a supplier number is issued will not be reimbursed by Medicare. The Proposed Rule sets forth a number of new and revised standards with which DMEPOS Suppliers must comply in order to obtain a Medicare billing number:

- A DMEPOS Supplier must have a physical facility for its business operations. The facility must be a site where the supplier's delivery, maintenance and beneficiary communication records can be stored and to which mail can be delivered.

- A DMEPOS Supplier also must have a business

telephone which is located at the physical facility and listed under the name of the business.

- A DMEPOS Supplier who signs the application for a supplier number is responsible for confirming the accuracy of all statements in the application and must have the authority to bind the business entity.

- DMEPOS Suppliers must provide pertinent information and documentation sufficient for HCFA to make correct payment determinations. Upon request, a DMEPOS Supplier must provide a copy of any contract it has with another company to furnish items or supplies, as well as documentation showing that it has explained to all beneficiaries the warranty coverage for items supplied and the option to rent or purchase inexpensive or routinely purchased equipment. A DMEPOS Supplier must also, upon request, provide documentation demonstrating that it has delivered Medicare-covered items to beneficiaries.

- Consistent with the current OIG regulations on program integrity, DMEPOS Suppliers must agree not to contract with entities excluded from Medicare for the purchase of items necessary to fill their orders. Under the Proposed Rules, if a DMEPOS Supplier is subject to an exclusion, HCFA will automatically revoke its supplier number, effective upon the date of the exclusion.

- A DMEPOS Supplier must verify with manufacturers the extent of warranties for items they are supplying; the DMEPOS Supplier is prohibited from billing beneficiaries or the Medicare program for repairs, parts, or equipment covered by either an express warranty or an implied warranty.

- In addition to delivering Medicare-covered items to beneficiaries, DMEPOS Suppliers must provide beneficiaries, at the time of delivery, with information and instructions on how to use the items safely and effectively.

- Telemarketing by DMEPOS Suppliers is expressly prohibited.

- A DMEPOS Supplier is required to obtain a

comprehensive liability insurance policy that covers both the DMEPOS Supplier's place of business and any and all customers and employees of the supplier.

- Unless a DMEPOS Supplier meets applicable state licensing requirements, it may not bill Medicare for prescription drugs or oxygen used with DME or prosthetic devices.

- DMEPOS Suppliers are prohibited from conveying or reassigning a supplier number issued by HCFA.

Current regulations require a DMEPOS Supplier to renew its application for a billing number every three (3) years. When renewing such application, a DMEPOS Supplier must recertify that it meets all applicable standards. Under the Proposed Rules, DMEPOS Suppliers will not be required to submit new applications on the date the new regulations become effective. Rather, they will be required to submit new applications when their current supplier numbers expire. However, in certain circumstances, such as an investigation regarding compliance with standards, a DMEPOS Supplier may be required to demonstrate that it is in compliance with all standards prior to expiration of its billing number.

Practical Application

HCFA's decision to delay the HHA surety bond deadline and reexamine other controversial provisions in the Final Rules provide some good news for those agencies that have had trouble securing the bonds. However, the minimum required surety bond amount still stands at $50,000, and many in the industry have expressed continued concern that the current surety bond amount requirement may drive small, reputable agencies out of the market.

In addition, state Medicaid officials fear that the surety bond requirement may have the greatest adverse impact on Medicaid beneficiaries. The BBA requires agencies that deal with both Medicare and Medicaid to carry separate $50,000 bonds for each program. Most HHAs have few Medicaid patients, however, and often lose money on the Medicaid program. Thus, there may be little incentive for these HHAs to spend the money for the required Medicaid surety bonds. Small agencies may instead opt to drop their

Medicaid business altogether in order to avoid the requirement. The end result, of course, would be less availability of home health services for Medicaid beneficiaries.

Opponents of the surety bond requirement argue the requirement might have a similar impact on DMEPOS Suppliers that may not generate sufficient profit on the Medicare program to justify spending the money to obtain the surety bonds. HCFA claims that the requirement enables the Medicare program to mitigate its losses should a supplier billing number be revoked or should a company discontinue its Medicare business.

HCFA's new and proposed regulations for HHAs and DMEPOS Suppliers represent another step in the federal government's ongoing effort to combat health care fraud and abuse in the Medicare and Medicaid programs. The HHA and DME industries have been targeted as being particularly vulnerable to fraud and abuse, due to undercapitalization of many agencies as well as a perceived proliferation of disreputable operations. Still, industry groups are concerned that the surety bond, capitalization, and other new requirements may be difficult for many smaller, reputable agencies to meet.

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OIG CLARIFIES ADVISORY OPINION ON AMBULANCE RESTOCKING

Clarifying a formal advisory opinion issued in October, the Office of the Inspector General ("OIG") of the Department of Health and Human Services said recently that a hospital which restocks ambulances with supplies or medications used in transporting patients to that hospital may not be in violation of the Medicare/Medicaid Anti-Kickback Statute (the "Anti-Kickback Statute") (42 U.S.C. § 1320a-7b), as long as the hospital receives adequate payment for the restocked items.

In Advisory Opinion No. 97-6, issued October 8, 1997, the OIG stated that hospitals that restock ambulances, free of charge, with items used in transporting patients to them may be violating the Anti-Kickback Statute because restocking could be considered an inducement to the

ambulance service to bring patients to a particular hospital, or a trade-off for future referrals. The Anti-Kickback Statute prohibits remuneration (defined in the statute to include anything of value, "directly or indirectly, overtly or covertly, in cash or in kind") in exchange for Medicare or Medicaid patient referrals, and it imposes civil monetary or criminal penalties for violations. 42 U.S.C. § 1320a-7b.

The American Ambulance Association requested a clarification of the opinion. In addition, several members of the House of Representatives wrote to the OIG expressing concern over the enforcement of the Anti-Kickback Statute with regard to ambulance restocking arrangements.

The OIG responded to each inquiry with similar letters, in which it said the Anti-Kickback Statute would not be violated if the hospital receives adequate compensation for the restocked items, whether at the time of restocking or at a later date. In its clarification letters, the OIG indicated that the advisory opinion was not intended to prevent an ambulance from leaving a hospital adequately stocked with necessary medications and supplies.

Whether a restocking arrangement violates the Anti-Kickback Statute will be determined on a case-by-case basis, according to the OIG. It spelled out several criteria to be considered in determining whether the statute has been violated, including (1) the number of referrals subject to control by the ambulance provider; (2) any state or local laws that may require hospitals providing emergency services to restock ambulances; (3) any special arrangements with respect to supplies or medications that are subject to control by physicians at the receiving hospital; (4) whether restocked items are provided by the hospital to the ambulance company at cost; and (5) the reimbursement methodology used by the parties.

As required by the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-91) ("HIPAA"), the OIG issues formal advisory opinions as to whether a specific business activity or financial arrangement violates the Anti-Kickback Statute or other fraud and abuse laws. While the opinions serve as guidance for the industry, only the requestor of a particular opinion can rely on that opinion. To date, six advisory opinions have been issued. The opinions, with the parties'

names redacted, are available to the public at OIG headquarters and on the HHS/OIG web site at http://www.sba.gov/ignet/internal/hhs/hhs.html.

In response to OIG's advisory opinion and clarification on ambulance restocking, a bill (H.B. 3247) has been introduced in Congress which would expressly provide a "safe harbor" for hospitals' restocking of ambulances with certain drugs and supplies. Safe harbor provisions specify various payment and business practices which are considered to be legal under the Anti-Kickback Statute.

The bill, introduced on February 24, 1998 by House Rep. Bill Ney (R-Ohio), would allow a hospital to restock ambulances, without charge, if the following requirements are met: (1) the ambulance service is owned or operated by a state or local government agency or tax-exempt organization; (2) the replenishment is for drugs or supplies, or both, which are used by the ambulance during the transport of a patient to that hospital; and (3) the restocking agreement is not intended to induce referrals or business otherwise generated between the parties for the purpose of Medicare or Medicaid reimbursement.

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"PRACTICE OF MEDICINE," IN CONTEXT OF COVENANT NOT TO COMPETE, CANNOT INCLUDE A PHYSICIAN'S COMMUNICATION WITH PATIENTS OR ADMINISTRATIVE SERVICES

In a dispute arising out of a non-compete clause in an employment agreement, an Illinois appellate court held recently that a physician who engages in certain administrative and managerial activities such as billing, scheduling and updating patient charts or responds to patient telephone inquires from an office located in his home does not violate an agreed court order that the physician "not be involved in the business of providing urological medicine services" within a certain geographical area. *Bloomington Urological Associates, S.C. v. Scaglia* , 292 Ill. App. 3d 793 (October 21, 1997).

Factual Background

In May, 1994, Bennett Scaglia, M.D., entered into an employment agreement with Peoria Urological Associates, S.C., which agreement was assigned to Bloomington Urological Associates, S.C. ("Bloomington Urological") in June 1996. The agreement contained a covenant not to compete which provided that, upon termination of his employment, Scaglia would not "engage in the… provision of medical services" from any office located within a fifty (50) mile radius of any Bloomington Urological office for a twelve (12) month period.

Scaglia subsequently resigned from Bloomington Urological. In August 1996, Bloomington Urological filed a complaint for declaratory and injunctive relief against Scaglia, on the grounds that Scaglia was violating the covenant not to compete. The trial court granted a temporary restraining order ("TRO"), after which the parties reached an agreement. On September 6, 1996, the court entered an agreed order which provided, in relevant part, that Scaglia "shall not be involved in the business of providing urological medicine services within a fifty (50) mile radius of Bloomington, Illinois, from this date until June 30, 1997." *Bloomington Urological Assoc., S.C.,* 292 Ill. App. 3d at 795.

The following month Bloomington Urological filed a motion alleging that Scaglia was in violation of the agreed order, based on Scaglia's operation of a part-time office out of his home in Bloomington. During hearings in October and December, 1996, Scaglia testified that his medical office is located in Ottawa, Illinois. However, two days a week at least one nurse works out of Scaglia's home in Bloomington performing such tasks as organizing and preparing patient charts, checking on patients' status and laboratory work, scheduling surgery and outpatient procedures, billing, mailing, faxing, and other clerical duties. Scaglia's home office has two telephone lines and one fax line listed under the name of "Bennet Scaglia, M.D."

Scaglia testified that he is rarely at his home office, although he occasionally receives telephone calls at home from patients who have treatment-related questions, and he sometimes calls in prescriptions from his home. He further stated that he does not have an examination room in his home office and has never consulted with or treated a patient there.

At the conclusion of the hearings, the trial court found that Scaglia was in violation of the agreed order. The court entered an order finding Scaglia in indirect civil contempt and ordering that he not be involved in the business of providing urological medicine within the restricted area through June 30, 1997. Specifically, the court ordered that Scaglia: (1) keep no files relating to patients within fifty (50) miles of Bloomington; (2) have no in-person or telephone contact with any patient when he is physically within fifty (50) miles of Bloomington; (3) maintain no medical practice and employ no staff within fifty (50) miles of Bloomington; and (4) not have an office in Bloomington, and have no office telephone, fax, or address within fifty (50) miles of Bloomington.

Scaglia appealed the order, arguing "that the trial court erred in finding him in indirect civil contempt because the agreed order upon which the contempt finding was based was ambiguous and did not clearly establish what acts were prohibited." *Bloomington Urological Assoc., S.C.*, 292 Ill. App. 3d at 798. The Fourth District appellate court agreed with Scaglia that the relevant language in the agreed order prohibiting Scaglia from being "involved in the business of providing urological medicine services" was ambiguous in its scope and, therefore, that the trial court erred in finding Scaglia in contempt. *Id.*

The Court's Analysis

Looking to the employment agreement from which the agreed order was developed, the court noted that the noncompete clause provided that, upon termination, Scaglia would not engage in "the provision of medical services" from any office located within a 50-mile radius of any Bloomington Urological office for a 12-month period. Additionally, the court found that, at the October 1996 hearings, Bloomington Urological had discussed what "the parties thought it meant not to be in the business of providing urological medicine" and had suggested that it involved "treating" patients. Thus, the court concluded that the agreed order prohibited Scaglia from being involved in the "practice of medicine." *Id.* at 793.

The court agreed with Scaglia that the practice of medicine, as defined in Illinois, "does not include administrative or managerial aspects of a medical practice such as billing, scheduling and updating patients' charts" *Id.* at 799 (*see also* 225 ILL. STAT. ANN. 60/49 (describing

the "practice of medicine" as the diagnosis and treatment of ailments or conditions)). Although the court declined to decide precisely what "the practice of medicine" means in the context of restrictive covenants, it concluded that said practice could not "include telephone inquiries from existing patients to a physician (or his employees acting as conduits of information) or responses to those patients — either in the form of recommending treatment or prescribing medication." *Bloomington Urological Assoc., S.C.,* 292 Ill. App. 3d at 799. The court reasoned that "where telephones and beepers travel with an individual and telephone calls can be automatically forwarded to another line — it simply makes no sense to place significance upon where a physician happens to take phone calls." *Id.*

To hold that telephone inquiries from existing patients constitutes the practice of medicine in the context of a noncompete clause "would effectively force a physician to neglect or abandon his patients whenever they telephone or page him with medical-related questions, concerns or emergencies at a time when he happens to be in the restricted geographical area." *Id*. at 800. The court noted that physicians licensed in Illinois are prohibited by statute from abandoning their patients. *See* 225 ILL. COMP. STAT. §60/22(a)(16).

The agreed order permitted Scaglia to examine, diagnose and treat patients in his Ottawa office. Thus, because it was undisputed that he never personally examined a patient in his home office, and there was no evidence that he ever solicited patients from his home office, the court concluded that Scaglia did not violate the agreed order.

Practical Application

Under the holding of *Bloomington Urological Associates*, noncompete covenants in physician contracts may no longer impose restrictions on a physician's telephone contact with established patients when the physician is within the restricted geographical area.

However, it should be noted that the court in this case was construing language in a specific contract and in an agreed order which prohibited Scaglia from being "involved in the business of providing urological medicine services." The appellate court found that "under the circumstances of this case," Scaglia did not violate the agreed order by

engaging in certain conduct within the restricted geographical area. As pointed out by the dissenting opinion, however, Illinois public policy strongly favors freedom of contract, and courts will not declare a contract against public policy unless it clearly contravenes a law or public policy of the state. The dissent noted that the Illinois Supreme Court, in upholding the validity of a contract provision restricting the right to practice medicine, found that no public policy is violated by such contract because the doctor could practice elsewhere and other doctors would move their practice to the area to alleviate any shortage. *(See Canfield v. Spear*, 44 Ill. 2d 49, 52 (1969)).

Thus, to the extent that parties are free to draft contract provisions as they see fit, the *Bloomington Urological* opinion does not appear to prevent parties from drafting restrictive covenants in the future to prevent conduct similar to that engaged in by Dr. Scaglia.

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RESTRICTIVE COVENANT ENFORCEABLE AS PART OF AT-WILL EMPLOYMENT ARRANGEMENT

Generally, in Illinois a covenant not to compete must be ancillary to either a transaction or a valid relationship in order to be enforceable. In *Woodfield Group, Inc. v. Donna DeLisle*, No. 1-97-1737, 1997 (Ill. App. Ct., March 31, 1998), the Illinois Appellate Court held that a restrictive covenant agreement may be considered ancillary to an employment relationship even where the employment was at will. Although the restrictive covenant agreement in *Woodfield Group* expressly stated that it was not an employment contract, the Appellate Court found it significant that the preamble to the agreement stated that continued employment was conditional upon the employee's signing the restrictive covenant agreement. In reversing the lower court, the Appellate Court remanded additional issues of enforceability including consideration and reasonableness while noting that "Illinois law provides that substantial continued employment may constitute sufficient consideration to support a restrictive agreement." *Woodfield Group*, at 12. *Woodfield Group* demonstrates that restrictive covenants can be analyzed in

the context of an at-will employment arrangement.

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LEGISLATURE CONSIDERS HMO LIABILITY BILL

Introduction

Historically, the preemptive provisions of the Employee Retirement Income Security Act of 1974 ("ERISA") have shielded Health Maintenance Organizations ("HMOs") and other managed care organizations ("MCOs") from medical liability claims. MCOs have successfully used ERISA as a means to transfer most state malpractice lawsuits to federal court where damages are limited to those available under ERISA. Alternatively, in cases where ERISA preemption is less certain, MCOs have found protection in state statutes dealing with medical malpractice or negligence, which generally premise liability on the provision of medical treatment or decision-making regarding medical treatment. Since MCOs have historically been regarded as health insurers rather than treatment providers or decision-makers, these statutes, coupled with exculpatory language in provider contracts, have made it difficult if not impossible to hold MCOs liable for malpractice or negligent treatment.

As managed care continues to grow, however, state legislatures, courts, and medical boards increasingly are taking steps to hold MCOs accountable when coverage or "medical necessity" determinations, payment denials, or utilization review decisions are part of a patient's allegation of injury. A number of states have passed laws tightening oversight of MCOs by requiring such measures as external grievance and appeals, certain information disclosure to enrollees, and the ban of "gag clauses." Last year, Texas became the first state to pass legislation specifically imposing liability in connection with an MCO's treatment coverage determinations. The Texas statute, which was enacted without the Governor's signature, is being challenged in a pending federal lawsuit filed by major insurers. (*Corporate Health Insurance v. Texas Dept. of Insurance*, No. H-97202 (S.D. Tex., filed June 16, 1997)). Other states are considering similar legislation, including California, Ohio, and Illinois.

Managed care reform has been a key issue before the Illinois legislature in recent years. A comprehensive Managed Care Reform Act (H.B. 626), introduced during the state's 1997 General Assembly, would have imposed a number of similar requirements on MCOs, including extensive disclosure of information to consumers, a ban on physician "gag clauses," and formal grievance and appeals processes for consumers who are denied medical treatment coverage. The proposed act, which passed the Illinois House of Representatives, failed to advance from the Senate by the end of the 1998 legislative session. Now, new managed care legislation has been introduced in the 1998 General Assembly, including a bill which would impose tort liability on MCOs for negligent treatment coverage determinations.

Proposed Illinois Legislation: Health Care Entity Liability Act

The Health Care Entity Liability Act (H.B. 2621) would require health plans to exercise ordinary care when making health care treatment decisions, and would impose liability for damages to an insured or enrollee proximately caused by the failure to use ordinary care. "Ordinary care" is defined in the bill to mean the degree of care that a health care provider or entity of "ordinary prudence would use under the same or similar circumstances."

Introduced by Rep. Lou Lang (D-Skokie), the bill provides that a plan is accountable not only for its own treatment determinations, but also for damages for harm caused by health care treatment decisions made by its employees, agents, ostensible agents, or representatives. Further, it expressly prohibits plans from including indemnification or hold harmless clauses in their provider contracts which would require the provider to indemnify the plan for its actions or conduct. The bill also provides that the state's corporate practice of medicine doctrine, which prohibits insurance carriers and MCOs from practicing medicine or being licensed to practice medicine, may not be asserted as a defense by such entity in a negligence or malpractice action against it.

Medical necessity determinations must be made by a physician under the proposed bill, and, if the physician determines that a procedure or treatment is medically necessary, the plan must cover the treatment or procedure. The bill specifies, however, that there is no obligation for

an insurer to pay for treatment that is not covered by the terms of the plan. In addition, the bill provides that a plan may not terminate or refuse to renew a provider's contract for the provider's advocating on behalf of an enrollee for appropriate and medically necessary health care.

Unlike last year's Managed Care Reform Act, which was largely a consumer-driven bill, H.B. 2621 does not specifically address the rights of enrollees or insureds. For example, it does not include provisions requiring information disclosure or grievance and appeals procedures. However, by expressly imposing a duty of care on MCOs and authorizing a private right of action for damages caused by a plan's treatment coverage determinations, the bill is intended to achieve the same overall objective: protection of the rights of patients and providers by expansion of tort liability of MCOs.

Practical Application

The Illinois legislature's continued effort to mandate tighter regulation and oversight of the managed care industry reflects a nationwide trend. Not surprisingly, while the Health Care Entity Liability Act has the support of physicians and consumer rights advocates, the insurance and managed care industries strongly oppose the bill. The Illinois Association of HMOs ("IAHMO") takes the position that with some specific exceptions, health plans do not make medical treatment decisions and in fact are prohibited from doing so by Illinois' corporate practice of medicine doctrine. In addition to urging its members and industry partners to lobby heavily against H.B. 2621, IAHMO has crafted its own proposal for managed care reform. The Managed Care Reform Act of 1998 (H.B. 3445), introduced in the Illinois House on February 17, is a revised version of a similar bill introduced by IAHMO last year (H.B. 1042). This new bill sets forth a number of "patient rights" and reform measures, including a ban on gag clauses, the establishment of grievance procedures and information disclosure requirements.

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MEDICAID WILL REIMBURSE TELEMEDICINE SERVICES

managed care initiatives.

Associated Health Practices:

Corporate: Michael G. Beemer, Douglas M. Hambleton, Robert J. Moran, John R. Obiala, Dalius F. Vasys, Dana S. Armagno, Lane R. Moyer

Labor: Bruce R. Alper, George P. Blake, Lawrence J. Casazza, Michael G. Cleveland, John P. Jacoby, Richard H. Schnadig, Nina G. Stillman

Antitrust: Douglas J. Polk, Gregory G. Wrobel, Andrew M. Gardner

Finance: Michael A. Nemeroff

OSHA: Nina G. Stillman

Tax: Timothy W. O'Donnell, Daniel T. Sherlock, William F. Walsh

Litigation: David E. Bennett, Diane M. Kehl, Allan E. Lapidus, Randall M. Lending, Gregory G. Wrobel,

Insurance: Margaret A. Arnold, Thomas A. Baker, Randall M. Lending

ERISA: Thomas P. Desmond, John J. Jacobsen, Jr., Phillip L. Mowery, Paul F. Russell,

Intellectual Property: Richard A. Zachar

Securities: Jennifer R. Evans, Steven J. Gray

Real Estate and Housing Development: Norman B. Julius, Pearl A. Zager

Insolvency and Workout: Douglas J. Lipke

New York: Alan M. Koral, Dan L. Goldwasser

Vedder, Price, Kaufman & Kammholz
A Partnership including Vedder, Price, Kaufman & Kammholz, P.C.

Chicago

The Illinois Department of Public Aid ("IDPA") will now reimburse health care providers for selected telemedicine services used to treat eligible Illinois Medical Assistance recipients, making Illinois one of a small but growing number of states that provide Medicaid reimbursement for telemedicine.

Medicaid coverage of telemedicine services is effective for services provided on or after January 1998. The new policy, including requirements and procedures for providers and covered services, is outlined in an informational notice from IDPA to participating physicians, hospitals and managed care entities. IDPA Information Notice, February 9, 1998 ("IDPA Notice").

The IDPA Notice defines telemedicine as the "[t]wo-way transfer of medical data and information between places of lesser and greater medical capacity and expertise, for the purposes of patient evaluation and treatment." Telemedicine data may be exchanged in the form of text, graphics, still images, audio, and video, and the exchange or transfer may occur in real time through interactive video or multimedia formats or in near-real time through what is known as "store and forward" applications.

Consultation Requirements

To receive Medicaid reimbursement, the telemedicine services must be provided in a hospital outpatient or emergency room setting where the telemedicine consultant is located (the "Hub Site"). There is no specific requirement by IDPA that telemedicine services be furnished within the state of Illinois, or that telemedicine consultants be Illinois-licensed physicians. The IDPA Notice states, however, that "the consulting physician must meets the requirements of Illinois law covering consultations." (IDPA Notice ¶2). It should be noted that Illinois' Medical Practice Act was recently amended to require physicians in other states engaging in the practice of telemedicine within Illinois to obtain an Illinois medical license before consulting directly with patients in this state. *See* 225 ILL. COMP. STAT. ANN. § 60/49.5 (West 1998) (the "Act"). The amendment to the Act provides an exception, however, for "periodic consultations" between a licensed Illinois physician and an out-of-state physician, although it does not define the term "periodic consultations." The Act also exempts second opinions provided to physicians licensed in Illinois, and follow-up

diagnosis or treatment of an Illinois patient after treatment in another state where the provider is licensed to practice medicine.

Except in cases of emergencies, the telemedicine consultation must be requested by the patient's attending physician (located at the "Spoke Site") in order to be covered by Medicaid, and all requests, as well as the consultant's findings and recommendations, must be documented in the patient's medical record.

Video teleconsultations must, at a minimum, be capable of transmitting clearly audible heart tones and lung sounds as well as clear video images of the patient and any diagnostic tools such as radiographs. The IDPA Notice also requires that "appropriate steps" be taken by both the Hub and Spoke Site staffs to assure confidentiality of patients' records and medical information, although it does not define or establish specific confidentiality requirements. Illinois law provides generally that patients' medical records must be kept confidential and may not be released or disclosed without the patients' consent.

Billing and Reimbursement Provisions

IDPA will reimburse one provider at the Spoke Site, where the patient is located, and one or more providers at the Hub Site, where the telemedicine consultant is located.

New "W" codes have been designated for use in billing telemedicine services. These codes correspond to the existing Evaluation and Management codes in IDPA's Medicaid coding system but are to be used exclusively for telemedicine services. Covered Spoke Site services include outpatient visits for the evaluation and management of a new patient, and emergency department visits. Hub Site telemedicine services covered by Medicaid include "confirmatory consultations" for a new or established patient. These services are treated like all other consultation visits/services as defined in IDPA's current Physician and Hospital Handbooks. A detailed list of covered services with corresponding billing codes is included in the IDPA Notice.

No additional registration or certification is required for participating providers to receive reimbursement for covered telemedicine services. According to IDPA, providers simply bill those services, using the appropriate

222 North LaSalle Street
Chicago, Illinois 60601
312/609-7500
Facsimile: 312/609-5005

New York
805 Third Avenue
New York, New York 10022
212/407-7700
Facsimile: 212/407-7799

New Jersey
354 Eisenhower Parkway
Plaza II
Livingston, New Jersey 07039
973/597-1100
Facsimile: 973/597-9607

W code, along with their other services to Medicaid beneficiaries.

Practical Application

Coverage of telemedicine services under Medicaid is intended to enhance the delivery of medical care to the state's Medicaid population. In many cases, the use of telemedicine services eliminates the need for extensive and often costly transportation of patients to obtain specialty care from providers which may not be available in the patient's immediate area. In developing its telemedicine reimbursement policy, IDPA worked with and received input from a number of groups statewide, including physicians, advanced practice clinicians, hospital administrators, and the Illinois Hospital and HealthSystems Association ("IHHA"), which organized a Telemedicine Task Force to address various clinical and administrative issues, as well as legal issues such as state licensure requirements and confidentiality. IDPA did not engage in formal regulatory or rulemaking actions in implementing the new policy.

Individuals with questions or who wish to receive a copy of informational notice outlining the new policy may contact Christopher Surrell or Steven Perlin at the IHHA at 630-505-7777 or e-mail: csurrell@ihha.org or sperlin@ihha.org. To contact the IDPA, write to: Illinois Department of Public Aid, Prescott E. Bloom Bldg., 201 South Grand Ave. East, Springfield, IL 62763-0001, Attention: George A. Hovanec, Administrator, Division of Medical Programs.

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LEGISLATURE ADDRESSES ADVANCED PRACTICE REGISTERED NURSE ISSUE

Background and Introduction

The term "APRN" generally encompasses four groups of registered nurses with advanced education and specialized training: certified nurse-practitioners; registered nurse-anesthetists; certified nurse-midwives; and clinical nurse specialists.

While the Illinois Nursing Act (the "Act") recognizes the expanded duties and functions of these nursing specialities, it does not expressly grant greater authority or a broader scope of practice than that of a general registered nurse. ILL. COMP. STAT. § 65/1-49 (West 1998). Under Illinois law, all registered nurses — whether advanced or not — must practice within the limits of "professional nursing" as defined in the Act. This definition does not provide nurses with diagnostic or prescriptive authority. While recent developments in the law recognize the use of professional knowledge, diagnostic skills, and supervisory authority by registered nurses and advanced nurse specialists (*see, e.g.,* 225 ILL. COMP. STAT. § 65/3(1) (West 1998) (expanding definition of registered nursing profession)), the Illinois legislature has declined to provide statutory recognition, licensure, or expanded authority for APRNs.

Proposed Legislation

These issues are once again before the Illinois legislature and the health care community. A bill recently introduced in the state Senate would amend the Illinois Nursing Act to include a statutory definition of, along with professional licensure requirements for, APRNs ("S.B. 1253"). S.B. 1253 also would give APRNs the authority to issue prescriptions for certain classes of drugs. In order to be licensed as an APRN under S.B. 1253, an individual must successfully complete a master's degree program as a clinical nurse specialist, certified nurse midwife, certified registered nurse anesthetist, or certified nurse practitioner, as well as gain national certification and at least ten years' experience in one of the above mentioned nursing specialties.

The proposed measure includes a requirement that licensed APRNs and the physicians with whom they work enter into "written practice agreements" defining the collaborative working relationship and authorizing the categories of care, treatment, or procedures to be performed by the APRN. The bill calls for the establishment of an advisory committee to review matters relating to the collaborative practice between APRNs and licensed physicians and to make recommendations regarding such matters to the Board of Nursing and the Illinois State Medical Disciplinary Board regarding such matters.

S.B. 1253 represents a substantially revised and more detailed version of measures introduced during the 1997 General Assembly which did not advance from their originating committees. Although other 1997 bills (S.B. 606, H.B. 1078) included a similar statutory definition of APRNs, they did not propose formal licensure requirements. While the 1997 bills would have expanded the scope of APRN authority to include, generally, "prescribing, dispensing, and administering drugs," there were no provisions indicating what types of drugs or if there would be limitations on this prescriptive authority. The new bill would amend the Pharmacy Practice Act (225 ILL. COMP. STAT. § 85/3 (West 1998)) and the Illinois Controlled Substances Act (720 ILL. COMP. STAT. § 570/102 (West 1998)) to allow APRNs to issue prescriptions for "Schedule II, III, IV or V" classes of controlled substances "as delegated by a physician" pursuant to a written practice agreement between the physician and the APRN. *Id.*

Proponents of the new legislation contend that a significant number of states have statutes recognizing APRNs, and that Illinois is one the few states that does not grant APRNs at least some limited prescriptive authority. In states that do provide such authority, the scope of an APRN's prescriptive authority ranges from being "completely attendant" *(e.g.*, little independent discretion to prescribe medication) to being "completely delegated" (*e.g*., substantial authority to prescribe certain classes of drugs). Illinois' proposed measure would provide limited delegated authority.

The Illinois State Medical Society ("ISMS"), which has opposed past APRN measures, recently published a position paper in which it generally supports the recognition and licensure of APRNs. The ISMS paper advocates the need for close working relationships between APRNs and physicians under the terms of written agreements defining the collaborative arrangement. And while ISMS apparently supports some delegated prescriptive authority for APRNs, it specifically opposes granting APRNs the authority to prescribe Schedule II drugs, which include substances such as opium and morphine.

Practical Application

While nearly all would agree that APRNs play a vital role

in health care delivery, there has been some lack of consensus in Illinois on the exact nature of that role. Some believe that APRNs should function under close physician supervision, while others argue that APRNs should have a more independent scope of practice. Although the licensure of APRNs offers potential savings to payors and may increase access to care, due to the ethical issues involved, APRN legislation likely will remain a much debated issue in the health care community and the Illinois legislature.

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ILLINOIS HME AND SERVICE PROVIDER ACT REQUIRES LICENSURE AND INSPECTIONS

The Illinois legislature, overriding a veto by Governor Jim Edgar, enacted legislation to require state licensure and regulation of home medical equipment and services providers on November 14, 1997. The Home Medical Equipment and Services Provider License Act ("the Act") directs the Department of Professional Regulation ("the Department") to establish standards and criteria for licensure, and to begin issuing licenses to qualified providers by November 14, 1999. 225 ILL. COMP. STAT. § 51/1-180 (West 1998). The Act also provides that the Department shall conduct periodic mandatory inspections of licensed providers, and it sets forth civil and criminal penalties for violations.

"Home medical equipment and services" as defined in the Act includes the delivery, installation, maintenance, replacement, or instruction in the use of medical equipment used by a sick or disabled individual in the individual's residence. A provider of such services and equipment is defined in the Act as a "legal entity" engaged in the business of providing home medical equipment and services, whether directly or through a contractual arrangement.

Key Provisions

Exemptions

The Act specifically exempts a number of entities and individuals. Exempted individuals include those already

licensed or registered by any other Illinois law who are engaging in the profession or occupation for which they are licensed or registered, as well as health care practitioners who lawfully prescribe, order, or use home medical equipment and services to treat their patients, and home medical service providers accredited under home care standards by a recognized accrediting body. Home health agencies that do not have a Part B Medicare supplier number or that do not provide home medical equipment and services are not subject to the new requirements, nor are home medical service providers which are accredited by a recognized accrediting body. Also exempt are manufacturers and wholesale distributors who do not sell directly to a patient, and other entities that do not sell, rent or otherwise provide home medical equipment and services, including hospitals (but not hospital-owned or hospital-related providers of home medical equipment and services), pharmacies, hospice programs, nursing homes, veterinarians, dentists, and emergency medical service providers.

Licensure Requirements

To qualify for licensure as a home medical equipment and services provider, the Act requires that a provider maintain a physical facility and medical equipment inventory, and make life-sustaining home medical equipment and services available to patients twenty-four (24) hours a day, seven (7) days a week. Additionally, providers must carry commercial liability insurance and comply with all applicable federal and state licensure and regulatory requirements. The Act further requires that providers furnish the Department with records of annual continuing education of its personnel, maintain records on all patients, and comply with any additional qualifications for licensure to be established by the Department.

Penalties for Violations

Providers who fail to comply with or violate the regulations are subject to a number of disciplinary actions, including monetary penalties. The Act provides that the Department may refuse to issue, renew, or restore a license, or may revoke, suspend, or reprimand a provider for a number of violations, including making a material misrepresentation to obtain licensure, negligent or intentional disregard of the Act or its rules, conviction of a crime involving dishonesty or a crime directly related to

the provision of home medical equipment and services, engaging in dishonorable, unethical or unprofessional conduct, or failing to provide information in response to a written request by the Department within sixty (60) days of the issuance of such request.

In addition, an entity which practices, attempts to practice, or holds itself out as practicing as a home medical equipment and services provider without a license is subject to a civil monetary penalty of up to $5,000 for each offense. The Act also provides that violators may be subject to court orders enforcing compliance with or enjoining further violation of the law. Such court action may be in the form of a temporary restraining order or preliminary and permanent injunctions. If the entity's violation of the injunction is established, the court may impose penalties for contempt.

Mandatory Inspections

The Act calls for mandatory inspection of a licensed provider within three (3) years after the date of initial licensure and at least once every three (3) years thereafter, unless the licensee can demonstrate proof of renewal of accreditation with a recognized national accrediting body. The Act also requires the Department to conduct random inspections of a provider upon renewal of a license as necessary "to ensure the integrity and effectiveness of the licensing process."

Practical Application

The passage of this legislation reflects the Illinois legislature's ongoing effort to improve the delivery and quality of medical care to home-bound patients, as well as to enhance public confidence in providers of home medical equipment and supplies. By exempting certain professions, occupations and entities which are already licensed in the state, and that do not provide home medical equipment and services through a separate entity, the Act is intended to reach those providers which have previously operated virtually, if not completely, outside the scope of government oversight and to ensure that only qualified entities may act and hold themselves out to the public as home medical equipment and services providers.

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