PRACTICAL*HEALTH*LAW

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Building a solid foundation

Construction contract issues for health care facilities

Are you thinking about renovating or building a health care facility? Three types of construction projects are typical in the health care industry: 1) new facility construction, 2) additions to existing facilities and 3) renovations to existing facilities. While some projects may have a larger price tag or involve more parties, the contractual relationships formed during any construction project are similar.

TYPES OF CONTRACTS

Understanding your construction contracts and how they relate to each other is key. Health care facilities and physician practices will usually enter into three major contracts:

1. Architect/engineering contract. An architect or engineer will help you conceptualize your project. The construction industry oftentimes uses standard contracts known as AIA (American Institute of Architects) contracts.

2. Program manager/consultant contract. Oftentimes a health care facility will hire a program manager or consultant to oversee and manage the project and the owner's relationship with the architect/engineer and the general contractor or construction manager. This manager/consultant is typically an entity or individual with construction industry experience that will ensure your interests are protected and the project is completed as desired.

3. General contractor or construction manager contract. A general contractor or construction manager is the entity that actually completes the construction. Your architect/engineer will draft or provide an AIA contract for the general contractor or construction manager to execute.

Whether you use an AIA or other contract, have your construction attorney review your contracts to ensure your interests are protected, the contracts are compatible and the contracts don't conflict with your state's specific laws.

Certificate of need: Shield or sword?

If your health care facility or physician practice is interested in expanding, examine your state-specific requirements to see if your state is a certificate of need (CON) state. Currently, 36 states plus the District of Columbia and Puerto Rico have CON regulations in place. In an effort to reduce medical costs, states look to CON rules to help guide the implementation of new health care services or facilities.

While advocates believe the limitation on available services encourages competition and keeps consumer prices lower, opponents argue CON regulations are actually a restraint on trade and that CON programs don't help maintain lower prices. State health planners may also use CON programs to limit Medicaid beds during times of state Medicaid funding shortfalls.

States vary widely in the types of regulated facilities and services. Not surprisingly, the most commonly regulated facilities are long term care and rehabilitation facilities. Both are high on Medicaid expense lists. Acute hospital beds are also commonly regulated, which means that a facility can expand in space but not add any beds to its CON-permitted amount.

Other commonly regulated services include ambulatory surgical centers, home health and hospice providers, intermediate care facilities, long term acute care facilities, MRI scanner facilities, psychiatric services, radiation therapy and substance and drug abuse facilities.

The following states currently have CON laws in place: Alabama, Alaska, Arkansas, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, Washington, West Virginia and Wisconsin.

ELEMENTS OF CONTRACTS

Important provisions in construction contracts may be overlooked without an experienced eye. These include, but aren't limited to:

- The scope of the work,
- Compensation and payment schedules,
- Acceptable reasons for cancellation and the notification process,
- Indemnification,
- The ramifications of delay,
- Bonding, and
- Dispute resolution.

For example, make sure you handle all disputes using the same dispute resolution procedure, whether it be litigation, arbitration or mediation. If you're not careful, you may end up with multiple contracts, each with different dispute resolution clauses.

The contracts should require that all necessary parties be joined into any dispute resolution. Otherwise, you may spend extra time and money wading through numerous dispute resolution clauses. Your construction law attorney will be able to discuss the benefits and pitfalls of each of the above provisions and tailor the contract to your particular project.

> *State or local governments often require special permitting for health care facilities.*

AREAS OF CONCERN

You'll need to be aware of several other topics and understand them before entering into a construction project. Although not an exhaustive list, some include:

Certificate of need (CON). States with CON statutes may limit the number of certain health care facilities. If your state is a CON state, the last thing you want to do is spend a large amount of money planning — or even building — a new facility and then be told you aren't going to be granted a CON. (For more on CONs and to see if your state has a statute, see "Certificate of need: Shield or sword?" on page 2.)

Specialized permitting. State or local governments often require special permitting for health care facilities. Be sure you have all the required permits for your facility before beginning construction.

Tax zones. Special tax zones have become popular in recent years to stimulate development and growth in

certain areas of a state or even within a community. Consider whether you should build your facility in a certain area to take advantage of potential tax breaks and possible reimbursements to help pay for your facility.

Americans with Disabilities Act (ADA) compliance. Be sure your new facility meets ADA requirements. Your architect and legal counsel can help you ensure your strict compliance.

Special requirements. Don't forget about particular safety and functional needs that affect the design of your health care facility. Make sure your architect and general contractor are aware of any special needs. For example, you may need to strengthen the building's foundation and supports for heavy medical equipment or build walls as protection barriers to harmful materials or waves.

THE BOTTOM LINE

If you're considering a construction project, contact an experienced construction law attorney to assist you in contract negotiations and administration. By doing so, you'll protect yourself, prevent disputes and help ensure your project's success.

Prescription monitoring programs

Combating drug diversion while helping patients

More than 11 million people over the age of 12 have used a prescription pain reliever for nonmedical reasons annually, according to the 2006 National Survey on Drug Use and Health by the Department of Health and Human Services (HHS). And advocates contend that more than $1 billion is lost annually to Medicaid fraud for prescription drugs.

Faced with increasing prescription drug abuse and fraud, states have been implementing regulations to track narcotic prescriptions filled by in-state pharmacies. These prescription monitoring programs (PMPs) have been passed into law or proposed in almost all 50 states.

WHERE ARE PMPs NOW?

Kentucky became one of the first states to initiate an electronic data collection program. It requires pharmacies and other licensed pharmaceutical drug dispensers to report specific information for all dispensed Schedule II through V drugs. As of December 2007, 35 states had PMP laws. An additional 14 states are drafting or at least considering PMP legislation for 2008, with Wisconsin being the sole holdout.

After the enactment of the Kentucky law, the U.S. Department of Justice (DOJ) created a grant program to develop and monitor PMPs. A multiagency effort, the program helps establish new PMPs and make existing programs more effective. PMPs enhance collaboration between law enforcement, treatment professionals, the medical community, prosecutors and pharmacies. To streamline collaboration among states, the National Association of State Controlled Substances Authorities (NASCSA) has drafted the Prescription Monitoring Program Model Act. The act spells out essential elements for any PMP, including electronic submission of information by the pharmacy, minimum data elements and privacy and confidentiality standards in line with HIPAA requirements.

NASCSA is now focusing on synchronizing PMP information between states. Last year, a test exchange of information between the Nevada and California PMP systems was successfully executed. Further pilot exchanges between other border states are scheduled for 2008.

The National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER), though slow to get off the ground, is an additional grant program for states to create prescription drug monitoring databases and enhance existing ones. NASPER requires states to collect specific data for all Schedule II, III and IV prescriptions, as well as develop the capability to share the data

Tamper-resistant prescription pads

2007 amendments to the Social Security Act require that payment not be made for covered outpatient drugs for which the prescription was executed in written form unless it's executed on a tamper-resistant pad. The purpose, similar to that of prescription monitoring programs (PMPs), is to reduce Medicaid fraud and to make it more difficult for patients to illegally obtain controlled drugs.

The regulation became effective on April 1, 2008. Although CMS has left the actual regulations to the states, it has issued guidelines on the three types of forms that would meet the requirement:

1. Those that prevent unauthorized copying of a completed or blank prescription form,
2. Those that prevent the erasure or modification of information written on the prescription by the prescriber, or
3. Those that are resistant to being counterfeited.

The guidelines are an either/or choice for forms in use as of April 1, 2008. But by Oct. 1, 2008, states must require all three characteristics to be met for prescription pads to be considered tamper-resistant.

The new requirements don't apply to electronic, verbal or faxed prescriptions. And tamper-resistant forms aren't required for prescriptions paid for by a managed-care entity or drugs provided by institutional or clinical facilities.

across state lines. Therefore, even Wisconsin will be required under the program to create a PMP.

WHO CAN ACCESS THE PMP?

Although access varies by state, most programs allow several parties access to PMP information. For example, law enforcement officials can access PMPs for bona fide drug-related investigations. Prescribers can request reports for patients they are treating to aid in treatment decisions. Dispensers may access the system to review pharmaceutical treatment of a current patient. Licensing boards can gain access during the investigation of a licensee after complaints by patients or co-workers. Information also may be accessed under a court order or grand jury subpoena.

Due to Medicaid fraud issues, many states are considering granting access to state Medicaid officials for prescription overuse or misuse indicating fraud. Currently, only Kentucky allows Medicaid officials PMP access.

Information legally accessed may be shared in only two instances: with another health care provider treating the patient or with law enforcement. Most states allow sharing the information with the patient but prohibit giving a copy of the report to the patient.

WHAT INFORMATION IS AVAILABLE?

Depending on the state, PMP information may include the patient's name and date of birth, the doctor's name, and the quantity, days supplied, drug name and strength for the prescription filled. Other state variations include the length of wait between requesting the report and actually receiving it (minutes to days) and how often the data is collected (daily to monthly).

One snag in information sharing between states is medication scheduling. Different states may schedule medications differently. Therefore, if State A has designated a particular drug as a Schedule IV and State B has designated the same drug as a Schedule II, the information is more difficult to translate. This is especially true if either state only collects data for Schedule II drugs.

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WHAT CAN IT DO FOR YOUR PRACTICE?

A state PMP is an important resource for any provider. PMPs can deter and identify many types of illegal activity, including prescription forgery, and can notify physicians if a patient is seeing multiple prescribers for the same drugs. PMPs help health care professionals enhance patient care by allowing them to intervene on the patient's behalf and assist them in obtaining appropriate treatment. To learn more about your state's PMP program, contact your health care attorney.

Are you ready?

2008 IRS guidance plan for nonprofit organizations

During fiscal year 2004, nonprofit health-care-related entities accounted for roughly 20% of the total Form 990s submitted to the IRS. That 20% accounted for 39% of the assets and 57% of revenue reported. With such high numbers, nonprofit health care facilities don't want to lose their tax-exempt status. The IRS fiscal year 2008 exempt organizations (EO) implementing guidelines target 2008 compliance issues.

ISSUES EXPAND IN 2008

Many of the 2007 compliance targets are expanded in 2008 to encompass a wider range of organizations and issues. This includes the Pension Protection Act of 2006 (PPA). Some health care organizations have already felt the impact of the PPA from provisions affecting supporting organizations, such as new excise taxes on certain distributions from a donor that provide more than an incidental benefit to the donor or related persons.

IRS Form 990 and the supporting schedules underwent numerous changes, with the latest version released in December 2007. Schedule H — specifically for hospital returns — collects data including the percentage of indigent care, revenues from Medicare and Medicaid patients, unreimbursed costs and subsidized health services.

As political elections heat up in 2008, so will IRS surveys of exempt entity donations to candidates.

POLITICAL INVOLVEMENT

In response to increased allegations of political intervention by nonprofit organizations, the IRS launched the Political Activities Compliance Initiative (PACI) in 2004. PACI examines reports filed by political candidates and organizations to identify campaign contributions made by nonprofit organizations.

As political elections heat up in 2008, so will IRS surveys of exempt entity donations to candidates. The IRS has published two examples in a Revenue Ruling involving hospitals and political candidates, one dealing with an endorsement by a hospital's chief executive officer and the other dealing with the appearance of a political candidate at a hospital sponsored function.

EXECUTIVE COMPENSATION

The IRS will also focus on the high salaries and generous benefits given to some nonprofit executives. In 2007, the IRS assessed $21 million in excise taxes for excess benefits or self-dealing. The agency will continue to examine nonprofit compensation, including surveying hospital executive compensation in 2008.

Form 990 requires disclosure of reportable compensation for current officers, directors, trustees and key employees. Schedule J requires detailed compensation information for the above persons, including base salary and bonus amounts as well as the methodology used to determine compensation. Currently the IRS is taking a closer look at loans to officers and board members which hospitals must report on Form 990 Schedule L.

JOINT BUSINESS VENTURES

A new area of concern is a growing interest in joint business ventures between nonprofit and for-profit organizations. Nonprofit health care entities are teaming up with for-profit organizations, such as physician groups and real estate investment groups, to provide specialized services. The IRS has concerns with the purposes of these ventures.

During 2008, the IRS will examine nonprofit/for-profit ventures to determine if "the venture is part of the organization's overall mission" or is "an unrelated trade or business." The compliance effort will work in tandem with the new Schedule R to Form 990. The schedule

intends to capture the complex organizational structures of tax-exempt organizations.

NEW FOR 2008

In addition to the expanded compliance issues rolled over from 2007, the guidelines cover new areas of compliance. These include:

Universities. The IRS will be looking at how health care facilities falling under a university's umbrella report income and expenses, calculate losses and set executive compensation.

Donor control and contribution valuation. If a donor maintains any control over a donation given to a hospital, or expects to receive some type of benefit as a result, the donor may be subject to additional taxes.

Further guidance is expected later this year on the targeted compliance issues as well as new PPA requirements and Form 990 revisions.

KEEP YOUR NONPROFIT STATUS

It's clear the IRS will remain focused on nonprofit health care organizations to ensure public benefit requirements are met, executive pay remains in line and organizations aren't simply shells for a for-profit organization. Form 990's increased transparency will elicit the public's assistance in ensuring nonprofits remain true to their stated mission.

WASTE NOT, WANT NOT: THE EPA AND YOU

Health care facilities and physician practices have come to expect numerous agencies to audit, inspect and investigate every aspect of providing health care to the public. But don't overlook Environmental Protection Agency (EPA) requirements. While the EPA's primary health care facility concern is medical waste, the agency is increasingly concerned with all health care waste streams.

Many basic health care items require disposal as hazardous waste. For example, thermometers and flow meters that contain mercury are considered hazardous waste. If you haven't progressed to digital photography, you may have X-rays processed with silver and "fixers" such as glutaraldehyde, hydroquinone and potassium hydroxide — all of which are hazardous waste under EPA regulations.

Pharmaceuticals of all forms provide particular challenges for disposal. Particularly hazardous are chemotherapy and antineoplastic drugs, nine of which are on the EPA's list of regulated hazardous materials.

The classification of the drug — either "P" or "U" — dictates how to handle it. P-listed pharmaceuticals (such as arsenic trioxide, epinephrine and nitroglycerin) require hazardous-waste-regulated disposal of any amounts. This includes vials, bags, tubing and even empty containers.

You must dispose of U-listed wastes (such as chlorambucil, chloral hydrate and diethylstilbestrol) similarly to P-listed hazardous waste, except empty containers aren't treated as hazardous. Because anesthetic gases can be both flammable and toxic, they require special disposal.

Laboratories and pathology and histology departments also contribute to the hazardous waste stream. Assess testing reagents, alcohols, fixatives, solvents and cleaning solutions for hazardous listing and disposal requirements. Some labs require EPA air permits for any fume hoods that release material into the air.

Don't overlook routine items used in your facility. Housekeeping and maintenance use cleaning solutions, paints and paint strippers, pesticides and fertilizers. The EPA regulates waste oils and fuels from storage tanks, equipment and generators. All of these require special disposal.

Remember, even when you hire an independent contractor to remove hazardous waste from your facility, you're still responsible for proper handling during transportation and disposal (including landfills and incineration). "Cradle to grave" is the length of time a hazardous waste producer is on the hook for the resulting exposures. Research anyone handling, transporting or disposing of facility-generated waste and ensure every step follows EPA regulations.

A message to our clients and friends:

Hall Render is pleased to provide you with this issue of ***Practical Health Law***. This newsletter will be sent to you bi-monthly compliments of our health law attorneys; each issue will also be housed in the **Articles and Newsletters** section of **www.HallRender.com**.

We understand the value of good information when making sound business decisions. ***Practical Health Law*** is written by Hall Render's health law attorneys, each with extensive experience handling the legal issues of health care providers. We trust the information in each issue will be a valuable resource. Our attorneys stand ready to respond promptly to your questions and needs; please contact us if there are specific topics you'd like to see addressed.

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- Antitrust
- Certificate of Need
- Charity Care/Billing & Collection Audit
- Clinical Ethics
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