IN-HOUSE COUNSEL BRIEFING

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Remain Independent or Align?

Considerations for Choosing the Best Future for Your Hospital

Many hospitals are facing increasing financial pressures. The federal government's threatened cutbacks for reimbursement under the Medicare and Medicaid programs, the need to upgrade aging facilities, the significant costs to keep pace with IT operational needs and the uncertainties of future health care reform are all factors that bear on a hospital's decision whether to remain completely independent or to align with another hospital or hospital system.

In deciding whether to remain independent, the fundamental question that a nonprofit hospital's Board needs to answer is: "Which future course will ensure that our hospital is best positioned to continue to fulfill its mission of service to the community?" In satisfying his or her fiduciary duty, each officer and director of the hospital needs to answer this question.

If the hospital determines that giving up its independence is the best choice, it needs to determine what it should seek from an affiliation partner in return. A hospital may want to seek some or all of the following items: i) capital to construct new buildings or upgrade old ones; ii) capital to upgrade the hospital's IT capabilities; iii) a promise by the acquiring or other affiliate partner to maintain the hospital as a general acute care hospital for a specified number of years; iv) a commitment to assist in the recruiting of specified numbers of additional primary care or specialty physicians; and v) one or more seats on the Board of the partner organization.

In determining whether to align, a hospital's Board should follow a sound process so as to evaluate its options fully and carefully. That process might include: i) identifying all health systems present and competitive in their market; ii) identifying key factors by which to evaluate potential partners; iii) developing and distributing a formal partnership RFP to each potential hospital or health system partner; iv) establishing an explicit schedule and following it closely to avoid a protracted, ongoing effort to reach a decision; v) evaluating the responses to the RFP based upon the key decision criteria initially identified; vi) selecting a respondent that seems to best fit the decision criteria; vii) developing a Term Sheet and then agreeing upon and executing a non-binding Letter of Intent; viii) conducting a due diligence review of such potential partner; ix) if the due diligence review is satisfactory, negotiating and executing definitive agreements; and x) obtaining any required governmental and private third-party approvals and then closing.

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A critical element to the success of any affiliation arrangement is cultural compatibility between the hospital and its affiliation partner. Are the managements, medical staffs and philosophies of care of the two organizations culturally similar? If not, the long-term success of the affiliation may be at risk.

In sum, in the current climate of financial uncertainty, hospitals should consider carefully whether they should affiliate with other hospitals or systems to best accomplish their missions. ■

Stark Law Technical Violations: A Solution on the Horizon

Each year, hospitals and health systems across the country dedicate significant resources and thousands of dollars to avoid unintentional violations of the Stark Law. These "paperwork-type violations," which typically come in the form of a missing signature or expired contract, could result in a hospital paying millions of dollars in Stark Law penalties, even if there has been no overutilization of health care services, harm to the Medicare program or violation of any other federal law.

In response to this discrepancy, Rep. Charles Boustany, M.D., (R-LA) and Rep. Ron Kind (D-WI) introduced H.R. 3776, the Stark Administrative Simplification Act, late last year. This bipartisan bill would limit the excessive and disproportionate penalties that hospitals can incur by creating alternative sanctions for "technical noncompliance" with the Stark Law, which is defined as any:

- arrangement not signed by one or more parties;
- verbal agreement not put into writing; or
- expired arrangement where the parties continued to provide services as if the arrangement was still in effect.

Any self-disclosure of "technical noncompliance" made to CMS within one year would be subject to a $5,000 penalty. If disclosed more than one year from the date of technical noncompliance, the penalty doubles to $10,000.

In addition, CMS would have 90 days to determine whether a disclosure of "technical noncompliance" qualifies for a lower penalty using criteria set forth in the legislation. If CMS fails to act within 90 days, the disclosure would be deemed to be accepted. In order to clear the current backlog of disclosures waiting for review, which now totals well over 300, the measure would retroactively apply to any eligible disclosure that is pending before CMS at the time the bill is signed into law.

The fixed penalty structure and simplified self-disclosure process in H.R. 3776 would give hospitals and health systems more certainty and predictability regarding the outcome of a technical noncompliance disclosure while freeing CMS resources to pursue more egregious violations of the Stark Law. Furthermore, industry analysis of the bill shows it could generate as much a $1.03 billion in new revenue over 10 years.

H.R. 3776 has been formally endorsed by the American Hospital Association, Federation of American Hospitals, National Rural Health Association and the Healthcare Financial Management Association. It has been referred to the House Ways and Means and Energy and Commerce committees, and introduction of companion legislation in the Senate is imminent. The bill's authors hope to attach the measure to other health care-related legislation that is expected to be passed by Congress later this year. ■

Physician Practice Acquisitions Causing Antitrust Concerns

We all know the drill—health care reform requires providers to coordinate care, manage population health and bend the cost curve. In order to meet these lofty goals, many hospitals are looking to align with physicians through acquisition and employment. But be careful; the federal antitrust enforcers—the Federal Trade Commission ("FTC") and Department of Justice ("DOJ")—do not agree with the premise that health care reform requires consolidation. And, they are increasingly sensitive to and aggressive in challenging hospital acquisitions of physician practices, especially those that involve converting office-based ancillaries to provider-based ancillaries.

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With the FTC riding a wave of recent victories in the health care arena, the likelihood of antitrust scrutiny of a physician practice acquisition increases substantially if the acquiring hospital will employ 30% or more of the physicians of that specialty located in the acquired practice's primary service area (not the "market" for physician services generally), especially if the acquiring hospital cannot prove that the only way to achieve the desired consumer benefits is through an acquisition.

A traditional antitrust analysis typically focuses on "horizontal" issues—increased prices for physician services post-acquisition due to market power. But as the health care industry is transformed and more economic evidence is published suggesting anticompetitive effects from physician practice acquisitions, the FTC is likely to start focusing on "vertical" issues as well—competitors of the acquiring hospital being foreclosed from referral streams and increased costs due to provider-based reimbursement.

Substantial thought and planning should be given at the very outset of any discussion concerning a physician practice acquisition to determine the purpose of the transaction and whether it will garner antitrust scrutiny. ■

Employed Providers: Using the Medical Staff and Human Resources Processes to Get the Best Results

Recent data confirms that hospitals are continuing to employ a growing number of licensed providers. This ongoing trend underscores the need for legal counsel to consider the interplay between human resources ("HR") and medical staff processes when addressing quality concerns involving these employed providers. There are advantages and disadvantages associated with each of these processes.

On the HR side of the equation, employed providers are typically subject to an employment contract. This agreement, as well as particular HR policies, will routinely address implications for poor quality, including concerns with both professional competency and conduct. The employment contract will contain termination provisions, often including an option for terminating without cause. The contract may also link medical staff membership and clinical privileges to ongoing employment. These provisions, as well as other aspects of the employer/employee relationship, often permit a hospital to more nimbly address quality issues (as compared to the traditional, multi-tiered medical staff process) and at less immediate cost.

On the medical staff side of the equation, the employed provider will almost certainly be subject to the hospital's medical staff bylaws as well as multiple other medical staff policies addressing quality of care. These bylaws, and potentially these policies, will outline a process for investigating quality concerns and potentially taking corrective action. While the medical staff's multi-tiered review process is typically less nimble than HR, peer review confidentiality is formidable and can be critically important where there is significant concern regarding third-party litigation. Similarly, peer review immunity, as afforded by both state and federal law, often provides a strong incentive to engage the medical staff process.

While it is not always possible to engage one process over another, counsel should consider the relative advantages/disadvantages of each. Counsel should also consider whether both processes should be utilized, and if so, whether efficiency can be maximized by one process incorporating the findings of the other. Related considerations include: the extent to which HR and the medical staff can share peer review protected information, the hospital's anticipated future relationship with the subject provider, the complexity of the quality concern and anticipated review, whether use of attorney-client privilege and work product doctrine can mitigate risk, the likelihood of litigation with the provider and the likelihood of litigation with third parties.

Considering these issues at the outset of a quality review avoids confusion, increases efficiency and decreases risk. Proactively ensuring that relevant bylaws, policies and contracts contemplate the interplay between HR and medical staff processes avoids conflicting language and is equally advantageous. ■

HIPAA Breach Mitigation: Important Steps for General Counsel to Consider

Health information breaches are in the news every day, it seems. These breaches are becoming much more common and, in many cases, much more sophisticated. In some cases, they involve simple human errors that result in a patient taking home another patient's discharge papers. In other cases, thieves and overseas hackers are specifically targeting health care provider personnel and websites due to the value that health-related information can bring on the black market. Current estimates are that a social security number or credit card number is worth just a few dollars on the black market, while a single patient's medical record is worth approximately $50.00. As a result, hackers and criminal enterprises are specifically targeting health care providers. When coupled with the fact that state and federal agencies have dramatically increased their enforcement activities, often requiring resolution payments in excess of $1 million, and plaintiff attorneys are finding more success in individual suits and class actions for data breaches, breach prevention and response should be a top compliance priority for every health care provider.

While preventing breaches through a comprehensive HIPAA compliance program is very important, breaches can still occur. Once a breach is suspected, the steps the provider takes to assess and respond to the breach are critical. Key considerations in handling a suspected breach include:

Investigation. A thorough and comprehensive investigation is a key step to assessing a potential breach. The determination of whether a breach occurred should be made in collaboration with experienced legal counsel, as it often will turn on highly technical provisions of HIPAA or state breach laws. Depending on the nature of the potential breach, it may also be necessary to engage other third parties to aid in the investigation such as IT forensics firms. Such engagements should be made through legal counsel so that the investigation and findings will be protected by the attorney-client privilege.

Insurance. As soon as a provider identifies a potential breach, it should promptly notify its liability insurer in order to obtain the full benefits of any insurance coverage that may be in place. It is becoming more common for health care providers to obtain cyber liability and other data-related insurance policies that cover legal fees, mailing service fees, forensic examination fees and other breach-related costs. Most insurers have a panel of pre-approved third parties that the provider must use in order to obtain the full amount of available coverage.

Risk Assessment. Once a provider determines that a breach of HIPAA or a similar state law occurred, it must then determine if notification to the affected individuals and government agencies is required. In some instances, even though a breach occurred, if there is a low risk that the information involved in the breach has been compromised, notification to individuals and government agencies will not be required. This is an extremely important and fact-sensitive determination based on specific statutory and regulatory criteria that should be made in collaboration with experienced legal counsel.

Notification. When notification is required, a health care provider must carefully navigate the complexities of who must be notified, the deadline for such notification(s) and what the notification(s) should say. Mistakes in this step of the process could result in additional breaches, angry or confused patients and increased penalties.

Reducing Litigation Risk. Plaintiff attorneys have started finding success with individual and class action lawsuits arising from data breaches, including in situations where there is no proof that an individual's information was ever actually used in an illicit manner. How a provider responds, and particularly what a provider says in breach-related communications, must always be reviewed with a mind toward how it could be used against the provider by plaintiff attorneys. Protecting communications within the attorney-client privilege can help to mitigate risk in this area.

Reducing Other Risks. Health care providers who are not careful in handling breaches could inadvertently cause other significant impacts to occur. For example, statements made in public, in notification letters or as part of a government

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investigation could cause the government to question a provider's compliance with meaningful use requirements, resulting in a potential refund of monies received under that program. Such statements could provide the impetus for the federal government to initiate a HIPAA or meaningful use audit of the health care provider and could also draw the attention of the FTC, which has recently been exerting itself against health care providers in breach matters, at great cost and risk to the providers.

Every one of these considerations, if not addressed in an organized and thoughtful manner, could result in severe and unnecessary consequences that could consume the time and resources of general counsel and others within health care provider organizations for several years. ■

Acute/Post-Acute Alignment and Integration

As reimbursement for medical care faces increasing scrutiny, acute care and post-acute care providers will continue to investigate methods to cut costs while increasing the quality of care provided to patients. A shift to a bundled payment system would further intensify the need for acute and post-acute care providers to seek out integration or affiliation models that allow for care of the patient throughout the continuum of care. Acute care providers are wise to look to post-acute care providers, including skilled nursing facilities, home health care providers and hospice providers, to determine whether those provider types fit within the hospital system's mission and goals.

Spending on post-acute care continues to increase as the nation's population ages, rising towards $100 billion per year. The largest challenge facing acute care providers will be whether they enter the post-acute care realm via acquisition and affiliations or create their own service line. Acute care providers will need to understand the complexities of long-term care reimbursement methodologies, ancillary services and limitations on ownership and integration for purposes of post-acute care reimbursement as well as other provider types within the post-acute care setting. Home health agencies, hospices, home and community based care and programs of all-inclusive care for the elderly are just a few additional programs that all providers should be aware of when entering the post-acute care realm. In addition, an appreciation of the differences between the short-stay mentality of acute care and the continuing care mentality of post-acute care with an emphasis on maintaining the individual in their current setting is critical. The penalties for increased readmission rates mandate that the provider master the entire continuum of care or partner with successful and reliable partners. A thorough understanding of the post-acute care industry in considering integration or expansion opportunities to avoid poor business decisions and maintain the quality of care will be essential to thrive in the evolving health care environment. ■

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