

## Medical Records Copying Continues to Pose a Dilemma for Providers

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The Pennsylvania Supreme Court recently examined the Pennsylvania Medical Records Act, or Act 26 of 1998, in affirming a lower court's decision that a company that provides copying services for medical records was liable to a class of medical records requestors for overcharges. (*Liss & Marion, P.C. v. Recordex Acquisition Corp.*, 983 A.2d 652 (Pa. 2009)). In light of the ongoing national discussion about electronic medical records, the Court's interpretation of Pennsylvania law's limits on copy charges is timely.

As described in the November 2009 Court opinion, the company, Recordex Acquisition Corp., and its parent company, Sourcecorp, Inc., have contracts with numerous Philadelphia-area hospitals to provide copying and retrieval services in response to requests for medical records. The hospitals generally stored records in one of a variety of media, including paper, microfilm and electronic (either as original computer-generated records or scanned paper records). One issue in the case was that the hospitals were charged for copies of both electronic and microfilm records at the higher microfilm rate (as opposed to the lower rate for paper). In 2003, a class action lawsuit was filed alleging the overcharges for the copies of electronic records.

### ACT 26 OF 1998

Pennsylvania Act 26 of 1998 amended the Pennsylvania Rules of Evidence on topics including: subpoenas for medical records, limits on charges for producing medical records and providing patients rights. Act 26 addresses obligations of health care pro-

THE APPROPRIATE AND LEGALLY COMPLIANT FEE TO CHARGE FOR COPIES OF MEDICAL RECORDS IMPLICATES A VARIETY OF LAWS DEPENDING ON THE PARTIES INVOLVED.

viders in responding to subpoenas for medical records, and the Act specifies that patients and their designees (including their attorney) have the right of access to medical charts and records. Act 26 also established limits on the charges for copies for medical records as well as for search and retrieval costs. Two per-page rates were included in Act 26: one rate for paper pages and a separate, higher rate for microfilm pages. Limits on charges for search and retrieval services, charges to district attorneys and exceptions for state agencies also are included in the act. The Act does not apply to X-ray film or other portions of a record that are not "susceptible to photostatic reproduction."

Under Act 26, the Pennsylvania Department of Health annually adjusts the amounts a health care facility or provider may charge for reproducing medical records. Effective January 1, 2010, the following charges may be made by a health care provider or facility for the reproduction of medical records or charts:

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- \$1.32 per page for first 20 pages, 98 cents per page for pages 21-60, and 33 cents for pages 61 and more
- \$1.95 per page for copies from microfilm
- actual cost of postage, shipping or delivery
- \$19.68 for search and retrieval
- charges to the district attorney may not exceed \$19.68 for search and retrieval plus the cost of postage, shipping or delivery, *unless* otherwise agreed to
- a flat fee for producing records to support a claim or appeal under the Social Security Act or claims under other federal or state financial needs based programs may not exceed \$24.94.

### PENNSYLVANIA SUPREME COURT OPINION

The Pennsylvania Supreme Court found, in part, that Act 26 does not include a statutory remedy for recovering overcharges for copies of medical records and found that the providers in the case did not have another avenue to obtain relief (for example, no administrative process was created by the statute). The Supreme Court also found that the parties' conduct supported the conclusion that the parties were using Act 26 to set the prices under their contracts. And, the court affirmed the lower court's conclusion that the providers had stated a breach of contract claim, after rejecting the argument that the providers' voluntary payment of the charges waived their right to recovery.

After establishing that the providers properly stated a contract claim, the Supreme Court's opinion turned to the question of whether that contract was then breached by the use of the higher microfilm rate (rate M) rather than the lower paper rate (rate D) for copies made from electronic records. In its examination of the statutory language, the Supreme Court concluded that the higher rate for microfilm only may be used for copies from microfilm and may not be used for any other medium:

The language of the MRA is clear: when providing paper copies from any medium, Appellants are entitled to receive rate D per page. The only exception is when the copies are made from microfilm; then, Appellants can charge the higher rate M. Here, Appellants made paper copies from electronic records and not from microfilm so the rate "for paper copies," rate D, applies. We affirm the lower courts' holdings that the MRA created a higher price rate for copies from microfilm, rate M, and a default rate, rate D, for copies from all other media.

983 A.2d 652, 662 (footnotes omitted). With the growing shift in use of electronic records, this ruling provides necessary clarification of the maximum copy charges in Pennsylvania for copies made from electronic records.

### HIPAA PRIVACY RULE

In addition to complying with state law (such as Act 26 in Pennsylvania), health care providers and other entities covered under HIPAA, when responding to records requests, must also comply with HIPAA's limits on copy charges. Copies of medical records are routinely requested by patients changing providers, by providers in connection with providing treatment to patients, and by attorneys as part of legal disputes. The HIPAA Privacy Rule requires covered entities (i.e., health plans, clearinghouses, and providers who transmit health information in electronic form in connection with a HIPAA-covered transaction) to inform individuals of their right of access to inspect and obtain a copy of their protected health information (PHI) in the individual's designated record set maintained by or for a covered entity. Generally, a designated record set consists of those records that contain health information, including billing information, about the individual.

The Privacy Rule permits covered entities to charge "reasonable, cost-based fees" for providing copies of PHI to individuals or their personal representatives. According to the Privacy Rule, fees for copies of medical records can only include the costs for: (1) copying, including the cost for supplies for and labor of copying, (2) postage if the individual has requested that the information be mailed, and (3) preparing an explanation or summary of the PHI, only if agreed to by the individual as required if the individual requested a summary or explanation instead of records.

In guidance on the Privacy Rule, the U.S. Department of Health and Human Services (HHS) has clarified that copying fees are to be reasonable and based upon the costs of making the copies, such as labor and supply costs. However, covered entities may not charge any fees for retrieving or handling the information, or for processing the request for copies. The Privacy Rule does not limit the fees beyond the reasonable cost-based standard; it does not set specific fee limitations. HHS also has clarified that fees for copying and postage costs provided under state law are presumed to be "reasonable," however per-page costs that include costs excluded under the Privacy Rule (e.g., processing, retrieving and handling) are not acceptable.

As a result, state-mandated fees for copying charges (such as Act 26) may be preempted by HIPAA and the Privacy Rule. For example, a HIPAA-covered entity would not be able to charge an individual requesting a copy of their record the \$19.68 search and retrieval fee permitted under Act 26 for 2010. While this search and retrieval fee is permitted under state law, it is not permitted under HIPAA. Additionally, state-mandated copying fee limits may be higher than the costs involved in copying the information and therefore these fees may be preempted by the lower “reasonable” cost standard. In connection with providing copies to individuals or their personal representatives, HIPAA-covered entities will need to carefully review the state-mandated fees and determine what fees they can charge while complying both with HIPAA’s “reasonableness standard” and state law.

It is important to note the scope of the fee limitations under the Privacy Rule. Based on the language in the applicable section of the Privacy Rule, the HIPAA copying fee requirements apply to requests made by individuals or their personal representatives and not to other requests or permissible disclosures under HIPAA. Additionally, in the Preamble to the Privacy Rule, HHS clarified that its own intent was to enable individuals’ access to their PHI: “We do not intend to affect the fees that covered entities charge for providing protected health information to anyone other than the individual.” 65 Fed. Reg. 82462, 82557 (Dec. 28, 2000), see also 67 Fed. Reg. 53182, 53254 (Aug. 14, 2002). As a result, requests in the form of subpoenas or from third parties and their attorneys appear to fall outside of the HIPAA-imposed fee limitations but remain subject to applicable state laws (such as Act 26).

### HITECH ACT

The Health Information Technology for Economic and Clinical Health Act (the HITECH Act), which was adopted as part of the American Recovery and Reinvestment Act of 2009, included a provision addressing copies of records in an electronic health record (EHR). Section 13405(e) of the HITECH Act requires that if a HIPAA-covered entity uses or maintains an EHR, the individuals have a right to a copy of the PHI in an electronic format, and any fee to be charged for the copy (or for the summary or explanation of the information), if the copy is in electronic form, cannot be greater than the entity’s “labor costs” in responding to the request. This HITECH Act requirement went into effect in February 2010, though Privacy Rule regulations have not (yet) been amended to incorporate this concept.

The recent Pennsylvania Supreme Court opinion has established that in Pennsylvania, the rate for making paper copies *from* any medium (including the electronic medium) would result in a maximum per-page fee at the default paper rate, or rate D. However, Act 26 does not set a maximum fee for copies of medical records provided in a medium other than paper. For HIPAA-covered entities providing copies in electronic format to individuals requesting their own information, the HITECH Act reasonableness standard will apply. Query what, if any, maximum fee would apply in responding to requests made by third parties for electronic formatted information.

### CONCLUSION

Determining the appropriate and legally compliant fee to charge for copies of medical records implicates a variety of laws depending on the parties involved – HIPAA, the HITECH Act, Act 26 (in Pennsylvania) or other applicable state laws, to list a few. The patchwork of regulations under various state laws governing requests by patients, subpoenas, workers compensation, insurance and medical claims, and other agency requests, combined with the federal law of HIPAA and the HITECH Act, can be confusing and can lead to litigation as in the case discussed above.

Please contact a member of Pepper’s Health Care Services practice group to assist you with questions regarding any of these developments.

# OIG Issues Troubling Report for Providers Concerning Never Events

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Over the past two years we have been keeping our clients and friends advised of the developments surrounding the Centers for Medicare & Medicaid Services (CMS)'s initiatives to stop payments for hospital adverse events and never events.<sup>1</sup> As predicted and as directed by Congress pursuant to the Tax Relief Act of 2006, the Office of Inspector General (OIG) of the Department of Health and Human Services has continued to pursue methodologies that will help track adverse events that affect Medicare patients.

## INTRODUCTION

In 2008, the OIG issued a preliminary report on its findings at two unidentified hospitals in order to determine the frequency of the adverse events occurring to Medicare patients in those hospitals. In that study, the OIG estimated that 15 percent of hospitalized Medicare patients experienced adverse events during their hospital stay. This percentage was based upon a random sample of 278 Medicare beneficiary hospitalizations. The adverse events were either on the National Quality Forum list of adverse events, were on Medicare's list of hospital-acquired conditions, or resulted in patient harm as determined by physician reviewers who studied the patient charts. In addition to the 15 percent of Medicare beneficiaries who were harmed, there were an additional 15 percent of Medicare hospital patients in those facilities who experienced less serious but temporary harm that required medical intervention to correct the harm according to the OIG.

## METHODOLOGY

On March 1, 2010, the OIG issued a follow-up report that provided guidance and recommendations to CMS from its experiences with the 2008 study. The 2008 study applied five methodologies to identify adverse events:

- nurse reviews
- analysis of present on admission (POA) indicators
- beneficiary interviews
- hospital incident reports
- analysis of patient safety indicators.

THESE STATISTICS DEMONSTRATE THE INABILITY TO IDENTIFY AND REPORT PATIENT SAFETY ISSUES, RESULTING IN POTENTIAL OVERPAYMENTS UNDER CMS RULES FOR ADVERSE AND NEVER EVENTS.

Any indication from any of these five reviews resulted in a flag being assigned to that patient. For example, if a hospital-acquired infection was picked up from a nurse review, the patient chart received one flag. If the same patient also experienced a fall, a second flag was added to the chart.

After the five types of reviews were performed, a second-stage review was performed by contracted physicians. The physicians were asked to review the flags as well as the entire patient chart. Only events that physicians confirmed as harmful were included in the final study results.

Two methods used by OIG investigators were identified as concerns to the future monitoring of adverse events by the Medicare program: (i) hospital billing data (and associated POA indicators) and (ii) incident reports. The OIG concluded that hospital-acquired conditions could not readily be determined by looking at the POA indicators in the charts at these two hospitals. This resulted in overpayments to those hospitals where the patients had actually experienced hospital-acquired conditions. The OIG study also found that when incident reports are not completed by hospitals and the information is not available to outside monitoring agencies, it makes it more difficult for CMS to detect such events, resulting in overpayments for such incidents. It throws into question the reliability of data for incident reports in hospitals, according to the OIG.

**TROUBLE AHEAD**

The OIG's conclusions and recommendations for future action is what is troubling for health care providers. First, the OIG concluded that the most effective way to determine whether an adverse event occurred is through a chart review by physicians and nurses. They acknowledge that such an approach is impractical and expensive. Less costly and time-consuming methods should be using billing reviews and incident report reviews. The OIG concluded that at these two hospitals there was under-reporting in both categories. As a result, the OIG made the following recommendations:

- CMS and AHRQ should explore opportunities to identify harmful adverse events when conducting record reviews for other purposes
- CMS should ensure that hospitals code claims accurately and completely to provide for identification of adverse events and hospital-acquired conditions, including POA indicators. OIG has indicated it is performing a national review of proper and accurate reporting of POA and adverse events for which payment is not appropriate
- CMS should provide interpretative guidelines for state survey agencies to assess compliance with the reporting of adverse events. The OIG is extremely concerned that even though providers under Medicare's conditions of participation are required to track medical errors and adverse events, few are completing incident reports. State surveyors should be educated on the types of events to be reported on incident reports
- AHRQ should inform PSOs that internal hospital reporting of incidents has been vastly underreported and PSOs need such information to gather statistics on overall patient safety.

**CONCLUSION**

While this OIG study was fairly small, it has provided the OIG and CMS with insights into the underreporting that apparently did occur at the two hospitals in the 2008 study. As per our prior advice, these statistics are troubling for providers since they demonstrate the inability to identify and report patient safety issues, resulting in potential overpayments under CMS rules for adverse and never events. There are potential liability issues associated with such adverse events and an overall strategy needs to be developed in each institution to deal with proper reporting

and billing procedures. State reporting requirements are also a concern. The OIG report is available on the OIG's Web site as document OEI-06-08-0021 (March 1, 2010): <http://oig.hhs.gov/oei/reports/oei-06-08-00221.pdf>.

**ENDNOTES**

- 1 See Pepper Hamilton LLP's February 27, 2009 *Health Care Law Update*, "The Refinement of Adverse and Never Events – Time for a Plan" and our October 30, 2009 *Update*, "Pressure Continues on HACs and Never Events: Recent Developments." Also see "Adverse and Never Events: A Dilemma for Compliance Officers," *HCCA Compliance Today*, Vol. 11, No. 10, October 2009, and a podcast on the topic of never events available on Pepper's Web site, <http://www.pepperlaw.com/>.

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## Negotiating an ASP/SaaS Agreement for Storage of Electronic Medical Records

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Hospitals and other health care providers are converting millions of paper records into digital form, and creating others in original digital form. All these records must be stored somewhere, and health care providers need ready access to them. There are at least two storage options. One is for a hospital to install and operate the necessary software and records database on its own servers; the other is to outsource that function to a host, which will install the software and database on its servers and give the hospital access to them, in an Application Service Provider (ASP) arrangement (also known as Software-as-a-Service or SaaS). The difference between these options is that in the first arrangement, the hospital licenses a product (software); in the second, it subscribes to a service (access to the software and database on the vendor's servers). The pros and cons of each arrangement are outside the scope of this article. But when a hospital elects an ASP/SaaS arrangement *for storage of its patients' medical records*, the implications are quite different from those presented by the use of an ASP/SaaS arrangement by a non-health care entity storing other types of records. This article offers a short summary of those implications, and suggests an approach to dealing with each.

***Access to Patient Records.*** The most significant difference lies in the importance to a health care provider of untrammelled access to its patients' medical records. In most ASP arrangements, there is a provision in the agreement to the effect that in the event of non-payment or other dispute, the vendor can suspend the customer's access to its records (no payment, no service, the argument goes). One can understand the vendor's point of view. But where a hospital is concerned, and lives depend on the information in those records, losing access to them – even temporarily, during the resolution of a dispute – would be untenable. *Suggestion: negotiate a provision to the effect that the vendor will not withhold or restrict access to patient records in its possession for any reason, under any circumstances; and where non-payment is concerned, provide that the vendor will not suspend or terminate access in the event of a good faith dispute between the parties of which the hospital gives the vendor notice in writing.*

WHEN CONSIDERING STORAGE UNDER AN ASP ARRANGEMENT, HEALTH CARE PROVIDERS NEED TO BE AWARE OF THE LIMITATIONS ON ACCESS TYPICALLY FOUND IN ASP AGREEMENTS – AND THAT THOSE LIMITATIONS CAN BE SUCCESSFULLY NEGOTIATED.

***Acceptable Use Policy.*** ASP arrangements often incorporate by reference an Acceptable Use Policy, or AUP, which provides that under certain circumstances, the vendor may block a health care provider's access to its system (and thus, its patients' records). This policy is designed to protect the vendor in the event that a user engages in any one of a variety of unacceptable behaviors that expose the vendor to risk. Those behaviors might include infringing on the intellectual property rights of third parties, engaging in illegal activities, transmitting information that is obscene or violates the privacy rights of third parties, promoting fraudulent financial schemes, interfering with the vendor's network, etc. A vendor has good reason to take steps to protect itself -- but those steps generally include blocking the hospital's access to the vendor's system. *Suggestion: negotiate a provision limiting the circumstances under which the vendor can block the health care provider's access to its system to one or more of the following: (i) blocking access by the particular user believed to have violated the AUP, (ii) blocking access when the parties agree that the conduct of the user constitutes criminal activity and the vendor could be found to be engaged in a crime by virtue of providing the hosted services, or (iii) blocking access immediately and with advance written notice to*

*the health care provider, following issuance of a court order permitting the vendor to do so.*

**Disaster Recovery Plan.** Consistent with the notion that it must preserve continuous access to its records, a hospital or health care provider should be sure its ASP vendor is contractually obligated to provide a copy of its disaster recovery plan, that the plan complies with appropriate guidelines for information technology disaster recovery plans and that the vendor provides the hospital or healthcare provider annually and at no charge with a statement from its auditors regarding the vendor's compliance with its disaster recovery plan.

**Sunsetting.** In the interest of avoiding disruption in its access to its patients' records, a hospital or health care provider may want to seek assurances that the ASP vendor will not cease to offer its services in the marketplace (known as "sunsetting") for some period of time. For example, the hospital may negotiate a provision to the effect that the vendor will provide twelve months' advance written notice prior to sunseting any component (or all) of its service, and will not give that notice for three years from the date the arrangement is entered into. The incentive for a vendor to honor a sunseting provision is a promise to refund to the hospital or health care provider a portion of the fees paid to the vendor in the event it ceases offering its services prematurely, such portion to decline with the passage of time.

**Transition Assistance.** All relationships come to an end, and a hospital's access to its patients' records can become an issue when its relationship with an ASP vendor ends, especially if the end is unexpected or the result of a dispute. Consistent with the notion that it must preserve continuous access to its records, the hospital should negotiate a provision to the effect that *upon termination for any reason*, the vendor will assist the hospital in the orderly transition to a new vendor. That assistance should take the form of access to the vendor's system and the vendor's support of that system for up to six (6) months following termination (or whatever period of time the hospital expects it would need to transition to a new vendor), for which services the hospital can be expected to pay the vendor at its then-current hourly rate.

**Indemnification.** Finally, there is another distinction between hospitals/health care providers and other companies (banks, for example) entering into ASP arrangements. Many hospitals and health care providers – and not just those associated with universities – are nonprofit organizations. For profit organizations are owned by shareholders or members who accept some level of

risk in exchange for the expectation of a return on their investments. One of those risks is that in the event the organization incurs liability in some form, it may be called upon to indemnify those to whom it is liable, resulting in a reduction in the investors' return. Nonprofit organizations have no shareholders who expect a return on investment. Indeed they are prohibited by law from directing earnings to the private benefit of those interested in their activities. The result is that the financial structure of a nonprofit organization is quite different from that of a for profit organization. *Suggestion: in cases in which the hospital or health care provider operates on a nonprofit basis, take the position that it is not in a position to defend, indemnify or hold harmless the ASP vendor from any damages of any kind.*

As health care providers accumulate patient records in digital form, the question of where to store them becomes critical, because the party that houses the records controls access to them. When considering storage under an ASP arrangement, health care providers need to be aware of the limitations on access typically found in ASP agreements – and that those limitations can be successfully negotiated.

## Are Accountable Care Organizations in Your Vocabulary?

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With new legislation on health care now in place, it is time to plan for the future of your provider organization. While challenges still remain, regulations will be drafted and funding for demonstration projects will start to flow; will you be ready for the new systems for payment and structure that will be required in this next stage of our health care system in the United States? One approach is to explore the establishment or involvement with an accountable care organization (ACO).

### INTRODUCTION

The new reform legislation is premised on the assumption that health care costs would be controlled, especially in the government's Medicare and Medicaid programs. Certainly the baby-boomer generation has recently swelled the ranks of Medicare. However, the loss of employment-based insurance in the deepest recession in recent memory has driven large numbers of adults and children into government-funded programs, a large portion of which is paid with federal dollars. Since health care reform legislation is focused on enrolling those without employer coverage at higher levels of income qualification, also paid for by the federal government, there are genuine concerns about whether financial savings can be realized from current programs.

One fear is that we will be adding millions of previously uninsured people to payment and patient care systems that are based on a fragmented fee for service model. This fee for service model is too expensive in its design and has had difficulty providing the quality of care that clinicians feel can be achieved with today's advancements in medical technology and electronic medical records. Under the fee for service model, it sometimes appears that the financial incentives are misplaced, encouraging behaviors that lead to overutilization. While many speak of best practices and evidence-based medicine, most providers structure their own individual treatment plans, which leads to disparities among the states, within a community and even within a particular hospital. Further, many medical staffs at acute care hospitals continue to be dominated by independent contractors. Certainly independent contractors are bound by credentialing committees and quality reviews at the hospitals where they practice, but the challenge is to align those physicians with the best practices and

FOR ACOs TO ACHIEVE THEIR ANTICIPATED GOALS A NUMBER OF LEGAL ISSUES NEED TO BE RESOLVED, RELEASING ACOs FROM MANY RESTRICTIONS AND CONSTRICTIONS THAT HAVE ARISEN IN A FEE FOR SERVICE ENVIRONMENT.

protocols that hospital medical directors feel are necessary to provide the best care for patients.

### BUNDLED PAYMENTS

Commentators who study health care systems and behavioral change feel that there are several approaches to the future of health care payment and organization that merit attention. One suggestion is to simply expand upon the DRG system of payment and pay both the acute care hospital and the physicians attending to the patients from the same "bundled payment." This bundled payment would encompass payment for all the hospital and physician services provided for the patient's care during the episode of treatment. It might also encompass post-discharge rehabilitation and home care. The payment would be severity-adjusted and would provide for pre-admission and post-discharge care. There would also be quality adjustments. In such an arrangement, the acute care hospital would receive the payment and contractually work out arrangements for payment to the physicians and other providers. There is some financial risk in accepting the bundled payment, but it would eliminate the fee for service and capitated payment now received by physicians. One concern of policy makers is whether the bundled payment system can work as designed, so long as there is a culture that does not value coordination of care of the patient. Without an internal control mechanism over the potential for unnecessary

or duplicative costs to be initiated by the physicians, the pundits feel that any savings hoped to be derived from a bundled payment approach will not be realized.

### ACCOUNTABLE CARE ORGANIZATIONS

One major variation of the bundled payment approach is to establish what are being called “accountable care organizations” (ACOs). ACOs already exist in various forms, primarily at academic medical institutions. They are funded by grants and demonstration project funds. Some believe that the benefit of ACOs is derived from how they engage physicians and hospital administrators on a different level, giving both groups the appropriate incentives to provide high quality care to patients while keeping an eye out for unnecessary cost and procedures. ACOs are a clinical and financial integration model. To some, ACOs look similar to the IPA and PHO organizations formed in the past when systems were attempting to consolidate for integration purposes and for negotiating with managed care organizations. The potential for ACOs is actually far beyond those limited goals. While there will certainly be the potential for increased integration of physicians and hospitals as a result of these changes; more importantly ACOs are intended to help physicians and hospitals focus on practicing the best medicine at the most effective cost.

### STRUCTURING THE ACO

So, with those lofty goals in mind, how does one structure an ACO? One significant structural matter for an ACO is that there would be a separate legal entity, with ownership and, more importantly, governance, shared by the hospital and the physicians. It is also expected that the ACO would have a robust information technology system to track patient health care, which would be accessible to all participants in the ACO.

More importantly, this separate legal ACO entity would provide primary and multi-specialty care for the patients assigned to it. The ACO would be the recipient of a bundled payment from Medicare or another payor. It is expected that the ACO would have an administrative staff separate from the hospital and the physicians, which would establish protocols and monitor and provide patient care both within and outside the hospital. The ACO function would be to integrate and align the interests of the hospital and the physicians. Furthermore, the ACO would absorb the financial risk of the care model and be designed as a profit center to distribute the excess of revenue over expenses

to be derived from providing for patient care and the costs of administration of the ACO.

### MEDICAL STAFF ISSUES

In the typical hospital, the administration needs to enlist members of the medical staff to chair clinical departments and provide oversight, provide coverage for the emergency department, and participate in quality of care committees. Physicians, whether independent or employed by a related physician foundation or practice group, typically controlled by the medical director of the hospital or the dean of the medical school, respond to the calls from the hospital for these necessary services as they feel best suits their personal profile and their available time. Under the ACO approach, the hospital would engage the ACO entity to be the provider of physicians for department leadership, coverage assignments and committee work, among other functions.

### SOME NECESSARY REQUIREMENTS FOR AN ACO

It is important to understand that the ACO would have patients assigned to it by payors, although some models will employ voluntary ACOs with a looser commitment among providers and patients. As envisioned by Congress and the Centers for Medicare & Medicaid Services (CMS), an ACO would have at least one hospital, a minimum of 50 physicians (primary care and specialists), commit to be in business for at least three to five years, and serve at least 5,000 patients. If the ACO met pre-established quality goals, it would receive an incentive payment. Penalties would be assessed if care did not meet the quality goals established. Incentive payments and penalties would be split between the members of the ACO. The providers in the ACO would follow best practices, be patient-centered and contribute to the development of best clinical practices to build standards of evidenced-based medicine. The danger of withholding care to achieve cost and quality goals would obviously have to be carefully monitored.

### LEGAL ISSUES TO CONSIDER

Obviously, organizations that are already employing integrated structures for physicians, with large numbers of physicians in foundations or academic departments in an employment setting, will have a head start in developing the ACO structure. Those in independent private practices will need to start investigating these new structures and determine how they can best relate to them legally. If the federal government is serious about promoting ACOs as a delivery model, for ACOs to achieve their anti-

pated goals a number of legal issues need to be resolved, releasing ACOs from many restrictions and constrictions that have arisen in a fee for service environment.

#### SOME OF THE LEGAL ISSUES

- *Stark Law* - Many of the services contemplated by ACOs will include “designated health services” under Stark, and the contemplated bundled payments will lead to new financial relationships for which the exceptions to the Stark law were not contemplated, especially in splitting incentive payments between a hospital and a physician group and allowing the structures necessary to meet the requirements of the ACO model.
- *Anti-Kickback Statute (AKS) and Civil Monetary Penalty (CMP) Law* - The key to ACO success—that the hospital and physician will negotiate and divide the savings realized from the bundled payment or provide payments to a home care or rehab provider—would probably violate most past interpretations of acceptable arrangements under the AKS and the CMP. For the ACO to be successful, the ACO might have to negotiate payments based on quality and volume incentives. While some gain sharing opinions do exist from the Office of Inspector General, they are not universal in application and currently only apply to the recipient.
- *Federal Antitrust Laws* - Recent pronouncements from the Federal Trade Commission (FTC) and the Department of Justice indicate that they are aware of changes taking place in the health care industry. Recently, the FTC approved an integrated structure contemplated by a health care system and a group of physicians in a small city to provide better quality of care for the residents. While it is unlikely that the antitrust enforcement agencies will provide blanket guidance, it is possible that they will increase their willingness to approve integration projects to promote more initiatives for efficiency and quality of care among doctors and hospitals.
- *Non-Profit Tax Issues* - If nonprofit hospitals decide to become involved in ACOs, one issue that may require examination is whether the arrangement with physicians, who are taxpaying entities, meets the nonprofit guidelines for private inurement and intermediate sanctions. Careful examination will be needed to be certain that the IRS does not assert a profit-making motive to the organization. While there may be structures that would meet these challenges, it will be

necessary to determine if the arrangements undermine the hospital’s nonprofit tax status.

#### CONCLUSION

We are certainly in a time of dramatic changes, with millions of individuals in the United States who were previously uninsured having some sort of coverage underwritten by the federal government. To assist in paying for such programs, cost savings in providing service to those currently insured by Medicare and Medicaid, through experimenting with new alignments among institutional and individual providers, are planned. While a number of legal issues need to be resolved, your organization should consider the ACO concept and how you plan to react to these challenges in the years ahead. Our Health Care Services Practice Group attorneys are prepared to help you succeed in this new challenging world.