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Health Law Alert

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Liability, quality assurance, safety and regulatory issues associated with the Affordable Care Act and the need for Pro-Active Risk Management

The Patient Protection and Affordable Care Act (PPACA), H.R. 3590, was signed into law on March 23, 2010. It was amended by the Health Care & Education Reconciliation Act (HCERA) of 2010, H.R. 4872, which was signed into law on March 30, 2010. Together, the legislation constitutes the largest change to America's healthcare system since the creation of Medicare and Medicaid. This paper seeks to summarize the provisions of the law that affects health care organizations and providers, and outline those key areas where failure to adhere to a disciplined compliance program may result in an increase in liability exposure.

The paper will be divided into two sections; the first deals with the Healthcare Delivery System Reform, while the second focuses on Regulatory Oversight.

Healthcare Delivery System Reform

Accountable Care Organizations (Shared Savings Program)
(Sections 3022; 10335).[1]

Titled the "Shared Savings Program", this section of the Act requires the Secretary of HHS to establish, by no later than January 12, 2012, a shared savings program for what is called "accountable care organizations" or ACOs. In short, ACOs are another method of integrating local physicians with other members of the health care system and rewarding them for controlling costs and improving quality.

Over the years, there have been many efforts to promote integrated care systems, in which primary care physicians, specialists, and hospitals work together to manage the overall care of their patients. Commonly cited prototypes include the Kaiser Permanente health plans, the Mayo Clinic, and the Cleveland Clinic. However, the same level of coordination has proved difficult to achieve when doctors and hospitals operate independently. Moreover, many consumers resist network arrangements that restrict their choice of providers, and there are also concerns that the payment models provide incentives to deny care.

Discussions of ACOs have broadened from a focus on hospital-centered systems to include models based on physician practices—including large, multispecialty groups and independent practice associations (IPAs), which bring together solo practitioners and small physician groups in order to share resources and improve their bargaining power. And different people have advanced different ideas about how an ACO might operate—tightly or loosely structured, formed voluntarily or with the organization imposed on providers by Medicare or other insurers, and so on. In the table below are five delivery systems that could become models for ACOs.

[1] A brief section by section listing of the PPACA for healthcare providers is set forth at the end of this paper.

Delivery Systems That Could Become Accountable Care Organizations

Model	Characteristics	Current Examples
Integrated delivery systems	• Own hospitals, physician practices, perhaps insurance plan	Geisinger Health System
	• Aligned financial incentives	Group Health Cooperative of Puget Sound
	• E-health records, team-based care	Kaiser Permanente
Multispecialty group practices	• Usually own or have strong affiliation with a hospital	Cleveland Clinic
	• Contracts with multiple health plans	Marshfield Clinic
	• History of physician leadership	Mayo Clinic
	• Mechanisms for coordinated clinical care	Virginia Mason Clinic
Physician-hospital organizations	• Nonemployee medical staff	Advocate Health (Chicago)
	• Function like multispecialty group practices	Middlesex Hospital (Connecticut)
	• Reorganize care delivery for cost effectiveness	Tri-State Child Health Services (affiliated with the Cincinnati Children's Hospital Medical Center)
Independent practice associations	• Independent physician practices that jointly contract with health plans	Atrius Health (eastern Massachusetts)
	• Active in practice redesign, quality improvement	Hill Physicians Group (southern California)
Virtual physician organizations	• Small, independent physician practices, often in rural areas	Community Care of North Carolina
	• Led by individual physicians, local medical foundation, or state Medicaid agency	Grand Junction (Colorado)
	• Structure that provides leadership, infrastructure, and resources to help small practices redesign and coordinate care	North Dakota Cooperative Network

Importantly, ACOs must take responsibility for the quality, costs, and overall care of the patients assigned to the ACO for no less than three years, and must have a sufficient number of primary care professionals (providers) to care for at least 5,000 beneficiaries.

Patients who receive most of their care from ACO-affiliated providers would be treated as "assigned" to the ACO. At least at the outset, they would not be formally enrolled, would not be required to obtain services through the ACO, and might not even know the ACO existed. The assignment process would allow payers to define a population for which the ACO could be held accountable. ***Key Liability Concern:*** Patients may complain about their lack of choice in participating in such an arrangement. This could lead to litigation over the selection process. Accordingly, informational materials provided to such patients should clearly outline the ACO assignment.

Over some period of time, payers would collect data on utilization and costs for the ACO population and on measures of quality of care and population health. Yet to be determined is how this will be measured, particularly in the early days. ***Key Liability Concern:*** Refusing to admit providers perceived to lack skills needed to optimize performance, or required to meet minimum quality standards in order to continue to participate in the ACO may spawn litigation. Thus, provider credentialing should not be limited to training, licensure checks, claim history and competency.

HHS/CMS Request for Information: Federal Register /Vol. 75, No. 221 /November 17, 2010

Medical Homes
(Sections 3502; 10321)

The Act authorizes HHS to test medical homes among other new care-delivery models. The Secretary will establish a program to provide grants to or contracts with eligible entities to establish community based interdisciplinary, inter-professional teams (referred to as ''health teams'' in the actual law) to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities. Supporters hope patient-centered medical homes will help refocus the U.S. health care system on the benefits of primary care.

The primary care teams may include medical specialists, nurses, pharmacists, nutritionists, dieticians, social workers, behavioral and mental health providers, doctors of chiropractic medicine, licensed complementary and alternative medicine practitioners, and physician assistants. Grant recipients must implement and maintain a health IT system and report quality measures. Though a physician is seen as having primary responsibility for establishing and overseeing a plan of care for each patient in this medical home model, other healthcare team members such as physician assistants or nurse practitioners may interact regularly with a patient. ***Key Liability Concern:*** One will need to be familiar with state licensure laws and be aware of what if any oversight is required of these "mid level providers" on the medical home health team. Additionally, patient handoffs and communication between team members will need to be monitored and looked at to ensure potential liability exposures are adequately addressed and patient care is appropriately documented.

Another issue is accessibility to care, as the expectation is that the patient has access to care providers 24/7 in this model and can get an appointment to be seen in a short period of time. This type of access brings with it additional expectations and liabilities that one needs to monitor to ensure care is available to members of the medical home as stated in the program membership materials.

Patient-centered medical homes will also transition primary care practices away from fee for-service based reimbursement and toward captivated or bundled payment. Given the new payment structures there will likely be, at least for a time, an increase in billing errors creating the potential for more fines and penalties. Thus, one will need to be up to date with the changes and work closely with risk management to implement billing procedures and internal audit programs. There will likely be an uptick in mergers and acquisitions between hospitals and miscellaneous medical facilities as well as in the number of employed physicians. M&A activity of this nature generally results in increased D&O exposure.

Hospital Value-Based Purchasing (VBP)
(Sections 3001, 10335)

Beginning in 2013—for discharges—on or after October 1, 2012—incentive payments will be made to hospitals that meet or exceed performance standards for acute myocardial infarction, heart failure, pneumonia, surgeries, and health care-associated infections. In addition to measuring individual outcomes and diagnoses, hospitals' total performance and levels of achievement and improvement will be measured and benchmarked against like hospitals each year.

The following information must be made available to the public on the Hospital Compare website: (a) the performance of the hospital with respect to each measure that applies to the hospital; (b) the performance of the hospital with respect to each condition or procedure; and (c) the hospital performance score assessing the total performance of the hospital. ***Key Liability Concern:*** The publication of this information will provide plaintiff attorneys with information in which to measure whether parties complied with the standard of care. One will need to ensure that counsel is prepared to address its admissibility.

CMS will ensure that applicable hospitals have the opportunity to review, and submit corrections, prior to the information being made. In addition, the Secretary is required to establish a process by which hospitals may appeal the calculation of a hospital's performance assessment and the hospital's performance score. ***Key Liability Concern:*** Consistent with the above, hospitals will need to timely review the proposed public information to ensure its appropriateness and accuracy.

HHS/CMS Proposed Rule: Federal Register /Vol. 76, No. 9/ January 13, 2011

Hospital Readmission Reduction Program
(Section 3025)

Beginning on or after 10/01/2012, HHS will establish a program designed to reduce hospital readmissions for the treatment of certain conditions. The program will compensate hospitals for treating patients who are readmitted to the hospital at a fraction of the typical DRG rate for such treatment.

The statute states that a readmission will occur when a patient is discharged from an IPPS hospital and then re-admitted to the same or another IPPS hospital within a time period specified by the Secretary from the date of the first discharge. The statute also mandates that the Secretary "make available" a Quality Improvement Program through the use of patient safety organizations for hospitals with a high severity adjusted readmission rate that have not taken appropriate steps to reduce such readmissions. HHS will publicize all hospitals' readmission rates on the Hospital Compare website.

Key Liability Concern: See above comments. Focus should be on improving the preparation of patients for discharge and coordination of after hospital care. Clinical staff, including physicians, nurses, case managers, and others should have a team approach and formulate a discharge plan. Understandable instructions and self-care education should be provided to patients and families using "repeat back" and other effective learning techniques. Post-discharge appointment should be made before the patient leaves the hospital whenever possible. Follow up telephone calls should be made to patients to provide reminders, e.g., compliance to medication regimen, keeping medical appointments, etc., and intervene when necessary. The failure to perform these tasks, in conjunction with the publication of the readmission rates, may lead to |increases in severity for liability cases.

Quality Reporting For Long-Term Care Hospitals, Inpatient Rehabilitation Hospitals and Hospice Programs (Section 3004)

In fiscal year 2014, long-term care hospitals, inpatient rehabilitation hospitals and hospices will be required to make certain quality data submissions to the Secretary. No later than October 1, 2012, the Secretary is required to publish the quality measures selected that will be applicable to and reportable for rate year 2014. Similar to the above, all data submitted will be made available to the public.

HHS/CMS created a special section on its website regarding the new quality reporting programs: http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/

Regulatory Oversight

False Claims Act (FCA)
Section 6402

Forces providers and suppliers to establish policies/processes for preventing fraud. Provisions provide OIG with additional tools to deter and/or investigate fraud and abuse. The Act specifically focuses on high-fraud risk providers, and suppliers, e.g., durable medical equipment (DME) suppliers, home health agencies, and Community Mental Health Centers (by way of further example, these CMHCs will now be required to serve at least 40% non-Medicare beneficiaries to root out centers that only bill Medicare and are otherwise not genuine CHMCs)

The Act establishes the Medicare and Medicaid Integrity Program: Requires entities to provide the Secretary and OIG with performance statistics such as number/amount of overpayments received, and number of fraud referrals. It also provides OIG with authority to impose stronger civil and monetary penalties in cases of proven fraud, and to impose stronger penalties for violations, such as ordering or prescribing items/services while being excluded from a Federal healthcare program, making false statements on applications/contracts to participate in a Federal healthcare program, and identifying Medicare overpayment without returning the overpayment.

Finally, the Act vests the Secretary with authority to preclude providers from participating in Medicare or Medicaid (for example, for providing false information on applications to enroll/participate in a Federal healthcare program). In certain cases, the intent requirement has been revised, e.g., with respect to an applicable violation, a person need not have actual knowledge of the section or specific intent to commit a violation of the section. ***Key Liability Concern:*** This requires one to maintain a strong provider credentialing program, so as to remain updated on participants' eligibility.

Reporting and Returning Overpayments
(Section 6402)

Section 6402 of the Act states that an identified overpayment from the Medicare or Medicaid program must be reported and returned (repaid) within sixty days to the applicable government contractor, intermediary, or carrier. The reason for the overpayment claim must be provided as well. The retention of any overpayment after the sixty-day period will result in liability under the False Claims Act.

Ongoing internal audits and processes for timely reporting of irregularities will be key to ensuring compliance with this section of the act. Risk Managers and legal counsel should be consulted prior to disclosures being made regarding any overpayment and the reason for the overpayment. However, all parties need to be aware of the 60 day time requirement to report the overpayment once it becomes known. This section of the law has already taken effect.

Anti-Kickback Statute
(Section 6402)

The Act made significant amendments to the federal anti-kickback statute (AKS). Those amendments are as follows:

- Specific Intent No Longer Needed – The amendment provides that a violation of the AKS may be established without showing that the individual knew of the statute's proscriptions and specifically intended to violate the statute.
- AKS Violation = False Claim – AKS amended to explicitly state that a violation of the AKS constitutes a false or fraudulent claim under the False Claims Act
- Beneficiary Inducement Provisions – The definition for remuneration is amended for the beneficiary inducement provisions to exclude any remuneration that promotes access to care and poses a low risk of harm to patients and federal healthcare programs

Recovery Audit Contractors
(Section 6411)

The Act expands the Recovery Audit Contractor (RAC) program from Medicare Parts A and B, and mandates the use of RACs to identify overpayments and underpayments and to recoup overpayments made in Medicare Parts C and D and the Medicaid program. As a reminder, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed CMS to conduct a 3-year demonstration project on the use of a new type of contractor—RACs—in identifying underpayments and overpayments, and recouping overpayments in the Medicare program. This was part of efforts to supplement Medicare claims administration contractors in preventing improper payments and to ensure the integrity of the Medicare program. The RAC demonstration program began in 2005.

CMS concluded that "preliminary results indicate that the use of recovery auditors is a viable and useful tool for ensuring accurate payments" and that RACs would be a "value added adjunct" to the agency's programs. (GAO Report 10-864T). Throughout the RAC demonstration, CMS stated its intention to use information on the vulnerabilities found by the RACs to help prevent future improper payments. Subsequently, the Tax Relief and Health Care Act of 2006 required CMS to implement a national recovery audit contractor program by January 1, 2010.

Two of the high risk vulnerabilities identified during the RAC demonstration include: (a) Provider non-compliance with timely submission of requested medical documentation; and (b) Insufficient documentation that did not justify that the services billed were covered, medically necessary, or correctly coded.

With regard to Medicaid, each state is required to enter into a contract(s) with a Recovery Audit Contractor(s) by December 31, 2010, for the purpose of identifying underpayments and overpayments, and recouping overpayments under the State Plan. As regards MA and Part D Plans, the Secretary is required to enter into contracts with RAC contractors that will "ensure that each MA/Part D Plan has an antifraud plan in effect and to review the effectiveness of each such anti-fraud plan.

Key Liability Concerns: Healthcare facilities must develop a plan for responding to Additional Documentation Request (ADR) letters from RACs. They should also provide the RAC with contact information for at least one individual to receive and respond to ADR letters. Providers must also submit medical documentation within 45 days of the date of an ADR.

HHS/CMS Proposed Federal Rule: Federal Register /Vol. 75, No. 217 / November 10, 2010

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