

Key Health Law Issues for 2011

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Throughout 2010 and continuing through the first quarter of 2011, we have seen the introduction of substantial, new developments in health care laws, policies and initiatives that will impact the health care sector through the remaining months of 2011 and beyond. To cite just one example, on March 31, 2011, which coincided almost precisely with the first anniversary of the passage of the Patient Protection and Affordable Care Act and the Education Reconciliation (together, the ACA), the Centers for Medicare & Medicaid Services (CMS), the Federal Trade Commission (FTC), and the Department of Justice (DOJ) issued hundreds of pages of new, proposed regulations and policies regarding the Medicare Shared Savings Program. That program is just one health reform initiative among many, and the proposed regulations are no doubt the tip of the iceberg of regulations to come.

Beginning with the passage of the ACA, the U.S. health care sector has been readying itself for unprecedented changes in the way that health care is provided, managed and funded. The jury remains out, however, as to whether many stakeholders are actually taking the necessary steps to adjust to the changing landscape. At the end of 2010 and beginning of 2011, two separate U.S. district court decisions that upheld legal challenges to the ACA's constitutionality added to the uncertainty some stakeholders already had about the enormity and permanency of health reform. Obviously, the ACA did not replace existing health care laws; rather, it introduced numerous new programs and modified certain existing laws. Simultaneous with the legal effects of the ACA itself, the recession, other economic forces driven by U.S. demographics, technological developments, state and federal regulatory agencies, and other factors have and will continue to affect the health care sector in profound ways. Given these pressures and converging forces, the following is a summary discussion of what we see on the horizon as the top eleven significant health law issues facing providers, payors and other stakeholders for the remainder of 2011.

Health Insurance Industry Reform

Even the first steps of implementing the ACA in 2010 caused major changes in health insurance that affect all participants, including health insurers and health plans, self-funded employer/union group plans, employers that purchase insurance and individuals who purchase insurance themselves. With the economic downturn as a backdrop, U.S. consumers face increased health care costs and increases in associated premiums. The result has been a relatively sicker insured population with higher health care expenditures. In part because the ACA mandates certain enhancement benefits for individual insurance policies, as well as restrictions on insurers, the individual mandate to purchase health insurance will not begin until 2014, (assuming that court challenges to the ACA fail). In 2011, there will be an increased focus on the state health insurance benefit exchanges. Insurance products and benefit designs will need to be considered by health insurers between now and 2014 while states prepare to deal with a major expansion of Medicaid at a time when state budgets are significantly constrained.

All health insurers will now have to consider compliance issues arising from strict new federal "Medical Loss Ratio" regulations (MLR), which specify that administrative costs and profits may not exceed 15 percent of the premium dollar for large group insurance products and 20 percent for small group and individual insurance products. An insurer that fails to comply risks being required to pay rebates as well as other penalties. However, states may apply for waivers from the MLR requirements. The basis for a waiver is whether application of the MLR will destabilize the individual insurance market in that state. As of March 2011, one state, Maine, has received a waiver and numerous others have applied or intend to apply for waivers.

The U.S. government is intensifying its interest in health insurance rate controls, with the Department of Health and Human Services urging state insurance departments to engage in critical reviews of all proposed insurer premium increases. The insurance commissioners in several states are attempting to delay and reverse proposed health insurance premium increases that they deem "unreasonable," and state legislation is pending to provide insurance departments with greater powers to review and reject premium increases.

Stark Law, Self Disclosure

The Physician Self-Referral Law (Stark Law) self-referral disclosure protocol (SRDP), which is required under the ACA, was released by CMS in late September 2010. The SRDP permits providers and suppliers to proactively disclose actual or potential

violations of the Stark Law. Of note, CMS is explicitly authorized by the ACA to accept payment of less than the full Stark Law measure of damages (i.e., Medicare collections relating to prohibited referrals) in appropriate circumstances with regard to matters disclosed through the SRDP. However, the extent to which CMS will exercise this discretion is still not clear.

The health care community had hoped that the SRDP would provide a meaningful safety valve for so-called technical violations (e.g., failure to obtain a signature on a timely basis) and other violations where there was no improper intent to induce referrals. However, while a number of disclosures have been made pursuant to the SRDP, currently there has been only one publicly disclosed settlement publicized under the SRDP. While in that case CMS settled for a small fraction of the total potential Stark Law damages, the amount paid was still significant, and it remains to be seen what formula CMS will use for determining settlement amounts. As such, providers will continue to struggle with evaluating their options for addressing Stark Law violations, and the efficiency and efficacy of the SRDP will be a hot topic for 2011 as more health care entities seek to disclose and resolve Stark Law violations through this process.

Accountable Care Organizations, Health Care Delivery Models

Consolidation among health care providers and ever-larger health systems is expected to continue at a brisk pace throughout the year. The momentum for new alignments and affiliations among providers is unlikely to slow during 2011 because pressures on the health delivery system, especially medical inflation coupled with aging demographics, are more urgent than ever before. Policymakers and stakeholders increasingly refer to a “new model” of health care intended to do more than just control costs: Accountable Care Organizations (ACOs), Medical Homes, and other physician-integrated organizations are being established to simultaneously deliver high-quality health care, positive patient experience and cost efficiencies.

While ACOs and similar integrated models have enormous promise (they are intended to do nothing less than bend the health care cost curve), that promise is wrapped inside enormous complexity. This year promises to be a watershed year in which many stakeholders involved in ACOs will tighten their focus from the big picture to details. Many leaders who have spent the past several months putting the foundational aspects of an ACO in place, such as making acquisitions, negotiating provider alliances and arranging capital, will need to quickly begin grappling with a myriad of issues that must be addressed.

A key decision ACOs will make in 2011 is whether to join the Medicare Shared Savings Program ACO, or to offer accountable care services to private payors, or both. In the private market, the details of each ACO will vary across the country, reflecting the particulars of a market, variance in laws from state to state, and the strength of physician and medico-administrative leadership and vision. These ACOs, currently negotiating commercial payment terms with payors, including self-funded ERISA plans, will be highly rewarded if they can effectively manage cost and quality. In the short run, a successful ACO will be rewarded with contractual bonuses from payors when the ACO delivers as promised on quality and cost. Successful ACOs that hit quality benchmarks and manage costs in the first measurement periods will have an additional, significant upside as they tout their achievements and thus attract additional membership.

On March 31, 2011, CMS released the initial, proposed regulations under the Shared Savings Program, Medicare’s version of an ACO, which was established by the ACA and is set to begin in 2012. The proposed regulations, which will only be finalized after a sixty-day period for public comment and possible, subsequent revision by CMS, provided considerable details to flush out the ACA’s statutory framework for the Shared Savings Program. The proposed regulations included many provisions that were not necessarily widely anticipated, including the introduction of “downside risk” so that ACOs would absorb losses, if applicable, in addition to potentially sharing in the upside if costs are controlled.

Prior to the release of the proposed regulations, there was speculation that CMS would try to lower the barrier to entry for Medicare ACOs in order to attract a substantial number of entrants willing to sign up for the three-year commitment required by the Shared Savings Program. Based on the initial reaction of stakeholders, either the regulations will substantially change by the time they are in final form, or the Shared Savings Program will attract fewer ACOs than was previously thought. Providers that have been considering participation in the Shared Savings Program will need to evaluate all the particular requirements in the proposed regulations and, following the public comment period, carefully scrutinize the final rule, when released, in order to evaluate the viability of their plans for participation as a Medicare ACO as of January 1, 2012.

Compliance Program Effectiveness and Increased Enforcement

Federal and state regulators demonstrated a heightened commitment to enforcing fraud and abuse laws during the first quarter of 2011 and this will continue throughout the year. The amplified focus on fraud and abuse is driven by a “perfect storm.” The Obama administration has stressed, by philosophy and funding, a robust regulatory climate with increased vigilance and scrutiny just as the prolonged recession, which has left government coffers drained, has helped add to an atmosphere in which high-profile government efforts to combat fraud are both good economics and good politics.

Meanwhile, whistleblowers and regulatory enforcers are better resourced than ever before. Recent developments in the regulatory arsenal aimed at the health care sector include various provisions of and regulations authorized under the ACA, amendments to the federal False Claims Act, the DOJ using the Responsible Corporate Officer Doctrine of imputed senior officer liability, and, of course, bigger enforcement budgets. The result is a substantial new burden across the health care sector. Additionally, while all segments of the health industry will be subject to these increased burdens over the coming months, some parts of the industry will feel the weight of increased enforcement more than others for the remainder of 2011. In particular, pharmaceutical and medical device manufacturers will continue to face a rapidly evolving regulatory landscape for the duration of the year.

While health care fraud enforcement and whistleblower actions seem to be proliferating at all levels, of particular concern for the remainder of 2011 will be efforts to target communication between medical device companies and health care providers, particularly health systems. Both the manufacturers and the health systems may be susceptible to unexpected liability and cost of litigation defense in instances where manufacturers and providers communicate about third-party payor reimbursement for the devices and the medical procedures related to the use of these devices.

Significantly, health care providers may have long-delayed repercussions resulting from these kinds of problematic communications between providers and device manufacturers. Absent a compliance effectiveness program that would identify the risk of any of these high-risk communications before they are received, health care providers may fail to recognize the exposure they have in these circumstances, allowing the communications to continue uncorrected for a period of time. Exposure may, consequently, result down the road. As an example, medical device makers are increasingly the subject of False Claims Act qui tam allegations regarding the device makers' advice to health systems on matters relating to medical device product and procedure reimbursement. Device manufacturer advice in these areas has spawned Department of Justice, HHS OIG and Recovery Audit Contractor activity focused on health systems that is national in scope and consequence.

Another significant development we have observed in recent months, which we expect will continue throughout the remainder of 2011, is of special relevance to officers and even inside counsel who should pay close attention to this developing trend. The DOJ had previously obtained an indictment of a former GlaxoSmithKline (GSK) attorney alleging that she had misled the Food and Drug Administration (FDA). At the end of March 2011, the DOJ had a setback in the case when the presiding court dismissed without prejudice the indictment of that GSK lawyer. She was, however, re-indicted in April and subsequently acquitted. The court found that the DOJ attorneys gave the grand jury an incorrect explanation of the legal relevance of the “advice of legal counsel” defense. Despite the judge’s dismissal in the GSK case, the message to in-house counsel is clear: the DOJ is taking a keen interest in the direct contact that in-house counsel has with government agencies, whether in the ordinary course of business or otherwise, perhaps most especially with regard to representations that in-house counsel makes to these agencies. Moreover, on April 15, 2011, the former GSK attorney was re-indicted, and the case continues.

Assessing compliance effectiveness in 2011 is essential. Of course, the daunting issue can often be the simple realization that there is no single tried and true approach that will work every time and for all situations. Still, it is fair to say that the accuracy of the assessment can be greatly enhanced by a seasoned hand. Depending upon the compliance program at issue and how relatively developed it is, the particulars of the assessment protocol will vary. Simply put, assessing compliance effectiveness is always a tailor-made endeavor—never “off the rack.” And while there are very few broad truisms applicable to these assessments, one paramount ingredient for all such programs is strong board oversight of the process.

Life Sciences Health Reform, Price Reporting, IPAB

The continuing implementation of the ACA raises numerous issues for life sciences companies. ACOs, demonstration programs that expand inpatient bundling, and similar projects involving new payment models are causing a shift in the focus of life sciences reimbursement strategies. Increasingly, reimbursement strategies will view customers as payers, whereas in the past, the government has been viewed as the payer. This is expected to result in life sciences companies looking for opportunities to partner with customers to optimize adoption and use of their products.

Activities of the newly established government organization, the Patient Centered Outcomes Research Institute (PCORI), including its recently constituted Methods Committee, will require companies to develop and disseminate information about the clinical value of their products compared to established—and often apparently less costly—alternatives. With increasing numbers of sources of comparative product information (*e.g.*, Agency for Healthcare Research and Quality, academic “counter-detailing” programs), life sciences companies may be looking for ways to loosen restraints on their ability to translate and disseminate comparative information that may go beyond traditional package labeling statements.

The Prescription Drug/Medical Device User Fee legislation needs to be reauthorized in 2012. The User Fee reauthorization will create opportunities to address other issues under the Food, Drug and Cosmetic Act (FDCA), possibly including new legislation addressing regulatory oversight and reimbursement for diagnostic testing used in personal medicine. A major priority of the device industry is seeking repeal of the device tax provision in the health reform law, while drug manufacturers will be focused on addressing key issues with implementation of the brand prescription drug fees in the health reform law. Implementation of the biosimilars pathway may lead to controversy as the FDA attempts to establish certain criteria, notably (i) when clinical trials will be required for approval of biosimilars, (ii) what the scope of such trials may involve, and (iii) the circumstances under which a biosimilar product will be considered interchangeable with a reference biological.

Patient Safety Organizations and Quality

On December 30, 2010, HHS issued guidance to address questions regarding the obligations of Patient Safety Organizations (PSOs) where they or the organization of which they are a part are legally obligated under existing laws (*i.e.*, the FDCA) to provide the Food and Drug Administration with access to its records, including access during an inspection of its facilities (Guidance). The Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act) and its implementing regulations attach privilege and confidentiality protections to this information, termed “patient safety work product” (PSWP). The PSWP confidentiality protection exists for the obvious reason that providers might otherwise be deterred from making accurate reports out of fear that negative information would be shared outside the context of the Patient Safety Act’s purpose and used to the detriment of the provider.

The upshot of the Guidance is that the PSWP privilege is a shield, but it is not one that eclipses the mandatory reporting obligations that a PSO may independently have under the FDCA. For example, a PSO that is an FDA regulated reporting entity and those PSOs that are organizationally related to an FDA regulated reporting entity may have an obligation to disclose certain PSWP to the FDA. If such an obligation exists, the PSO is obligated to make that disclosure to the FDA, notwithstanding the PSWP privilege. This is consistent both with the Guidance and the Patient Safety Act. We expect to see further refinements in PSO protocols during the coming months.

While many providers will grapple with quality gathering and reporting initiatives this year, some established by the government and still others by private payors, the government is making efforts to invest the general public in the importance of this information. For example, Hospital Compare is a website established by the federal government that provides consumers with information on how well hospitals provide recommended care to their patients. The thrust of Hospital Care, and similar companion websites focused on non-hospital providers, is to facilitate easy, but meaningful comparison of various quality metrics among providers. There are plans to include even more information on these websites with the ultimate goal of empowering individuals with information that can enhance health care decision-making.

Because the ACA has numerous provisions that emphasize and, in some cases, hinge on quality of care, CMS and other federal regulators will remain highly focused on quality and patient safety initiatives throughout the remainder of 2011. As CMS takes steps to link Medicare reimbursements to submission of quality reports, this is likely to be part of a sustained effort to tie payments to performance.

Tax Exemption

Congress enacted Section 501(r) of the Internal Revenue Code almost a year ago, imposing new operational requirements on tax-exempt hospitals which, if not satisfied, will result in the loss of tax-exempt status. Section 501(r), as drafted, is less than clear and, to date, regulations have not been issued by the Department of Treasury.

Despite the lack of clarity in the statute and the lack of regulatory guidance, three of the four provisions of Section 501(r) are already in effect. Recently, the IRS released the 2010 Form 990, Schedule H, which has been revised to take into account the new requirements imposed by Section 501(r). On the positive side, a tax-exempt organization with multiple hospital facilities within its single corporate structure is permitted to aggregate the community benefits provided by all its hospital facilities, as opposed to having to calculate and report the benefits on an individual facility basis. However, for multi-corporate health care systems, any community benefit activities conducted by tax-exempt entities other than the reporting hospital organization are relegated to less visible sections of Form 990 which, in some cases, could lead someone (*e.g.*, the media, the general public, the government) reviewing Form 990 to erroneous conclusions as to the total community benefits provided by the tax-exempt health care system. Both single entity hospitals and multi-corporate health care systems must review their current compliance with Section 501(r). Multi-corporate health care systems should review their current organizational structure to determine whether such structure still makes sense in light of the new Section 501(r) requirements and, in particular, the reporting of community benefits on new Form 990 Schedule H. In addition to preparing for IRS audits, a tax-exempt hospital should expect to have its compliance with the new Section 501(r) requirements reviewed for major corporate transactions and any future bond issues or re-financings.

Physician Practice Acquisitions

Physician practice acquisitions are back on the front burner and will continue as such for the remainder of 2011. More than a decade ago, hospitals were competing with publicly traded practice management companies to acquire physician practices and employ physicians. Much less strategic and much more defensive, hospitals in many instances feared a change in hospital-physician relationships that were decades old.

In these transactions, physicians were paid a "salary" similar to any other employee and often received additional remuneration for the value of the acquired practice. In hindsight, many hospitals realized their limitations for effectively and efficiently managing and operating physician practices. As many expected, hospitals found that running a physician practice and running a hospital were not the same. So, in the prior cycle a decade or more ago, many physicians "repurchased" their practices and returned to private practice.

Now we are seeing a resurgence of interest in the acquisition of physician practices and the employment of physicians. Things have changed in the health care sector in the last ten years and the current acquisitions bear little resemblance to those of the past. This new generation of transactions is decidedly strategic and part of a larger initiative to create clinically integrated delivery systems and to position these systems to provide accountable health care services, and perhaps an ACO. Under that rubric, health systems are not merely pursuing smaller physician practices. Rather, the goal is to acquire larger, often more complex physician-led organizations in order to provide the health system with the "management backbone and infrastructure" to achieve truly effective and meaningful clinical integration. Physician compensation is evolving as well; part productivity-based, part quality-based, the compensation models are shifting from how much you do to how well you do it. In almost every respect, physician practice acquisitions for the remainder of 2011 will not look like those done in the past.

Increased M&A Activity

The ACA has fundamentally changed the future operating landscape for hospitals, health systems, academic medical centers and physician practices, prompting them to re-examine their strategies for achieving their core missions/business objectives. In this new environment, institutions are re-evaluating whether they have the size, scale and market position to meet the new demands that will be imposed upon them as health reform is implemented. In doing so, many have recognized that growth and scale are critical to meeting the new cost, quality and reporting obligations that will be imposed upon them. In light of this, an increasingly important aspect of an institution's strategy will be the active consideration of mergers, acquisitions, member substitutions, joint ventures and clinical affiliations with other hospitals, health systems and academic medical centers. In 2011, healthcare

institutions will see an increasing focus on transactions, and should plan to work with their counsel and financial advisors to develop and implement “Strategic Transactions Plans” which clearly articulate their strategic goals (and, if applicable, charitable goals) in pursuing strategic transactions and to realistically analyze the paths available for meeting these goals in a changing health care environment.

Governance and Responsible Corporate Officer Doctrine

The Responsible Corporate Officer Doctrine (RCOD) is a Supreme Court-grounded strict liability theory interpreted by the government as permitting (in certain circumstances) the prosecution of officers and directors for misdemeanor criminal offenses, without the need to establish their intent or personal involvement in wrongful conduct. Federal healthcare fraud enforcement has, for the past two years, focused not only on corporate actors, but also on holding individuals accountable for corporate noncompliance, either through direct proof of their knowledge of noncompliant practices or through strict liability under the RCOD. Prosecutors believe that attributing responsibility to the highest corporate levels will enhance compliance with federal health care laws. This new expansion of HHS OIG’s authority, together with the aggressive DOJ application of obstruction of justice laws, is likely to bring RCOD exposure to the hospital/health system board room and executive suite.

The October 20, 2010 release by HHS OIG of a new guidance document (Exclusion Guidance), setting forth a series of non-binding factors OIG will consider in deciding whether to impose its “Permissive Exclusion Authority,” was a key development in this area.

On the one hand, the Exclusion Guidance provides that in circumstances where the facts indicate that an owner, officer or managing employee of a sanctioned entity knew or should have known of the prohibited conduct that led to the entity sanction, the OIG will operate with a presumption in favor of excluding the individual from federal health care programs. This presumption may be overcome if OIG finds that significant factors weigh against exclusion.

On the other hand, officers and managing employees may in certain circumstances be held to a higher, RCOD-style standard of conduct than owners. The Exclusion Guidance provides that officers and managing employees may also be subject to exclusion in the absence of evidence that they knew or should have known of the corporate misconduct. In other words, the Exclusion Guidance authorizes a strict liability basis for excluding officers and managing employees, one that does not require satisfaction of the “known or should have known” element. The Exclusion Guidance sets forth four factors OIG will consider in deciding whether to exclude an officer or managing employee in the absence of evidence that the person knew or should have known of the misconduct: (i) the circumstances of the misconduct and the seriousness of the offense; (ii) the individual’s role in the sanctioned entity; (iii) the individual’s action in response to the misconduct; and (iv) certain information about the sanctioned entity.

Time will tell whether HHS OIG will aggressively apply its RCOD-based Permissive Exclusion Authority to hospitals and health systems as a key feature in 2011. Where the evidence suggests that officers and managing employees neither knew nor should have known of the misconduct, it is likely that exclusion will be sought only in extreme fact patterns.

Health Information Technology

Calendar year 2011 is the first year during which eligible hospitals (including critical access hospitals) and eligible providers can begin earning federal incentive dollars in the form of enhanced Medicare and Medicaid reimbursements by establishing “meaningful use” of certified electronic health record technology under the “Stage 1” objectives and criteria. The primary goal of Stage 1 is to provide financial incentives for building electronic health record (EHR) functionalities that will ultimately provide the foundation to support the end goal of “Stage 3” when the full range of EHR objectives will be accomplished.

Eligible providers that can demonstrate meaningful use within the 90-day reporting period began registering for the incentive program in January 2011. For the 2011 payment year, eligible providers must also report quality measures through an attestation methodology.

Under the Health Information Technology for Economic and Clinical Health Act (HITECH Act) enacted in February 2009, about \$20 billion was allocated to health information technology projects, including incentive payments over a five-year span,

beginning in 2011, to eligible professionals and hospitals to acquire EHR technology. In 2015, the incentives turn into penalties by way of reduced reimbursements. On July 13, 2010, CMS and the Office of the National Coordinator for Health Information Technology (ONC) published the final rules on the two coordinated sets of regulations. ONC established the final standards, implementation specifications and certification criteria for EHR technology to qualify as “Certified EHR Technology” to support “meaningful use” for Stage 1. CMS established the final criteria for demonstrating Stage 1 meaningful use of the Certified EHR Technology and the rules for calculation and processing payment of the incentive dollars. Rulemaking for Stage 2 is expected to occur by the end of 2011 and for Stage 3, by the end of 2013.

The coming months will also bring significant activity from the full spectrum of stakeholders involving issues such as the following: possibly participating in health information exchanges or other health information technology (HIT) collaborations; strategic deployment of HIT as part of the evolution to ACOs; and exploring avenues that would enable both providers and vendors to continue to increase efficiencies while improving quality of care and reducing costs, and while achieving the goals of healthcare reform through a variety of means, including hosted IT platforms such as the traditional ASP (application service provider) model, Software as a Service, business process outsourcing, and “cloud computing” (e.g., multi-tenant web-hosted solutions, including public, private and hybrid clouds).

For more information on each of these areas and other health industry topics, please visit www.mwe.com for health care reform developments which can be found at <http://www.mwe.com/info/healthreform/index.html> and a listing of publications and resources which can be found at http://www.mwe.com/index.cfm/fuseaction/publications.nlist/practice_area_id/2dc70b73-0f96-4c96-926b-4879132c8e05.cfm.

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