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For the health and life sciences law community

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Health Law Issues 2015

1 ACA Subsidies

—Lisa Salerno, AHLA

Challenges to the Affordable Care Act (ACA) will continue to take center stage in 2015, with both supporters and detractors of the law focused on the upcoming U.S. Supreme Court decision on the validity of offering subsidies to purchase health insurance coverage through the federally facilitated marketplaces.[1]

Under the ACA, federal subsides—in the form of tax credits—generally are available to taxpayers between 100% and 400% of the federal poverty line, depending on family size, to help them purchase health insurance through "an Exchange established by a State." The Internal Revenue Service (IRS) issued a final rule[2] in May 2012 that made subsidies available to individual purchasers on both the state-run and federally facilitated marketplaces. The rule triggered several lawsuits challenging this interpretation as contrary to the plain language of the ACA.

On the same day in July 2014, two federal appeals courts issued conflicting decisions on the issue. A panel of the D.C. Circuit first ruled[3] that the government could only offer subsidies through the state-based marketplaces. Several hours after that ruling, however, the Fourth Circuit handed down an opinion[4] upholding the availability of subsidies through the federally facilitated marketplace. Both rulings essentially boiled down to whether the phrase "an Exchange established by the State" is ambiguous, with the D.C. Circuit finding the meaning of this language clear, and the Fourth Circuit reaching the opposite conclusion and affording deference to the administration's interpretation.

The D.C. Circuit in September 2014 vacated the 2-1 panel decision and agreed to rehear the case en banc. However, after the Supreme Court granted *certiorari* in the *King v. Burwell* case, the D.C. Circuit, as well as the Tenth Circuit where a similar action[5] is pending, agreed to defer further review until the High Court weighs in.

The plaintiffs in the cases argue that the plain text of the ACA dictates that the tax credits should be available only through the state-based marketplaces. According to plaintiffs, the subsidies were set up this way to incentivize states to run their own marketplaces rather than leave their operation to the federal government. The D.C. Circuit panel agreed with this argument, finding the ACA "unambiguously restricts the section 36B subsidy to insurance purchased on exchanges 'established by the State.'" According to the D.C. Circuit, a federal exchange is not an "Exchange established by the State," and "therefore Section 36B does not authorize the IRS to provide tax credits for insurance purchased on the federal exchanges."

The Fourth Circuit, however, found that the ACA is ambiguous. "[B]ased solely on the language and context of the most relevant statutory provisions, the court cannot say that Congress's intent is so clear and unambiguous that it 'foreclose[s] any other interpretation." Given this ambiguity, the Fourth Circuit agreed with the government's position that the IRS' interpretation of the statute is a permissible one.

While no one knows for sure the impact that eliminating the subsidies on the federally run marketplaces would have on the ACA's viability, several studies have projected the insurance coverage and premium effects that such a result would entail in the 34 states that have not established their own marketplaces.

A January 2015 study[6] by the RAND Corporation indicated that if the Supreme Court eliminates the subsides on the federal marketplaces, enrollment in the ACA-compliant individual market, including plans sold inside the marketplaces and those sold outside of the marketplaces that comply with ACA regulations, would decline by 9.6 million, or 70%, in the states with a federally facilitated marketplace. In addition, unsubsidized premiums in the ACA-compliant individual market would increase 47% in those states, RAND said.

In another study,[7] also released in January by the Robert Wood Johnson Foundation and the Urban Institute, researchers said the number of uninsured Americans would jump by 8.2 million in 2016 if the High Court rules that premium tax credits cannot be extended to people living in states with federally facilitated marketplaces. In addition, the annual premium for nongroup insurance coverage in those states would increase on average 35% or $1,460 per person, the study found.

With the Court's decision expected this summer, Republican lawmakers already are drawing up contingency plans should the subsidies be struck from the federal marketplaces. It's safe to say health lawyers, and the American public generally, will be eagerly awaiting the Court's decision on this divisive issue in 2015.

Medicare ACOs at Crossroads

—Charles Buck and Patrick Healy, McDermott Will & Emery LLP

We entered 2015 on the heels of three important developments regarding accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP): (1) the Centers for Medicare & Medicaid Services (CMS) released the final results of the first performance year for the original group of 220 ACOs that commenced operations in 2012 or 2013;[8] (2) 89 new ACOs entered the MSSP on January 1, 2015, all electing the one-sided, upside-only risk model; and (3) CMS published a proposed rule detailing the first major proposed revisions to the MSSP since its implementation.[9] For the reasons discussed below, the first two developments highlight an acute problem in the MSSP today that the proposed rule is designed to address in 2016.

The original group of MSSP ACOs recently entered their third and final performance year. Only five of these ACOs, or 2%, initially selected the current two-sided risk model (so-called Track 2). Under this model, the ACO must repay a portion of losses to CMS above a minimum loss rate but could receive greater potential performance payments than are available under the one-sided risk model (so-called Track 1) that the vast majority of the original ACOs selected. CMS issued a fact sheet in connection with the publication of the final results of the first full performance year of the original 220 ACOs touting the MSSP's successes.[10] Specifically, CMS highlighted that 58 ACOs, or 26% of the total, held spending below their benchmarks and met the minimum savings threshold necessary to receive shared savings payments, and that an additional 60 ACOs held spending below their benchmark but did not meet the minimum savings threshold. CMS also acknowledged that one of the five ACOs under Track 2 owed shared losses to CMS. However, CMS did not highlight that 102 ACOs, or 46% of the total, did not reduce spending relative to their benchmark, and that if the Track 1 ACOs operated under the Track 2 requirements, 54 of these ACOs, or 25% of the total, would have owed shared losses to CMS.

Under current MSSP rules, all of the 215 ACOs from the original group of ACOs that selected Track 1 (including the 74% that generated no shared savings) must transition to Track 2 during their first renewal term. Finally, the selection of Track 1 by all of the new 2015 ACOs marks the second consecutive year that no new ACO has selected the two-sided risk model.

CMS clearly has a problem with respect to the view held in the industry about the wisdom of accepting downside risk under the MSSP. Indeed, most of the original Track 1 ACOs indicated that they would not renew their ACO participation agreement with CMS if they were required to transition to two-sided risk.[11] Yet, CMS acknowledged that it is unlikely

to achieve the policy goals of the MSSP to avoid unnecessary costs while achieving high quality care unless ACOs are subject to the stronger financial incentives to control spending that result from sharing risk.[12]

The proposed MSSP rule is a direct response to this problem. The changes made to the MSSP under this rule will largely determine the near-term viability of the MSSP. Below we highlight some of the significant proposed changes, most of which would be effective in 2016. ACO executives and their advisors will need to evaluate carefully the final changes in 2015 to determine whether the enhanced financial incentives and additional tools to manage the ACO's patient population are sufficient to recoup their investment costs in developing and operating ACOs.

Extension of Track 1 Model

To prevent a potential mass exodus from the MSSP of the original group of ACOs, CMS proposed permitting certain of these ACOs to renew for an additional three-year term under a modified Track 1 offering lower potential shared savings. This renewal option would be available to those ACOs (approximately 75% of the original ACOs) that achieved the quality performance standards in at least one of its first two performance years and did not generate losses in excess of the minimum loss rate in both such years.

New Two-Sided Risk Model with Greater Financial Incentives and Prospective Assignment

CMS proposed a new two-sided risk model (so-called Track 3) with greater potential financial upside and downside than Track 2 and prospective assignment of beneficiaries to permit ACOs to better target their care management efforts. CMS acknowledged the significant beneficiary "churn" that ACOs have experienced under the current retroactive assignment methodology, calculating that on average only 76% of beneficiaries assigned to an ACO at the end of one performance year have been reassigned to the same ACO at the end of the next performance year.[13] In recognition of the greater financial incentives that Track 3 ACOs have to reduce costs, CMS also proposed to waive, for Track 3 ACOs only, various payment and programmatic rules designed to mitigate the risk of overutilization with respect to Medicare fee-for-service (FFS) beneficiaries, such as the skilled nursing facility three-day rule and homebound requirement under the home health benefit.

Updates to Benchmarking Methodology

The manner in which CMS establishes and updates ACO cost benchmarks is crucial because it affects which ACOs will want to enter and remain in the MSSP. Currently, CMS calculates benchmarks based on historical spending updated using national FFS expenditures, and rebases the benchmark every three-year agreement period. This methodology disadvantages historically low-cost ACOs and jeopardizes the sustainability of the MSSP because no ACO could be expected to lower its spending relative to its historical benchmark indefinitely. Although the proposed rule did not include specific changes to the benchmarking or rebasing methodologies, CMS sought comments on a number of alternative methodologies designed to create more equitable benchmarks, including transitioning to benchmarks based solely on regional FFS costs over multiple agreement periods to make the benchmarks gradually less dependent on the ACO's past performance and more dependent on the ACO's success in being cost efficient relative to its local market.

While every indication is that ACO-type initiatives in the commercial market will continue to reshape health care delivery, 2015 promises to be a pivotal year for the success of the MSSP.

3 Big Data in Health Care

—Kristen Rosati, Coppersmith Brockelman PLC

As Arthur C. Clarke said, "It is vital to remember that information is not knowledge; that knowledge is not wisdom; and that wisdom is not foresight. But information is the first essential step to all of these." Health information is not knowledge or wisdom about improving health. But we are in the beginning stages of a revolution in how we can and should use the astounding amount of electronic health information the industry is assembling, to create real knowledge, wisdom, and foresight about how to improve care and reduce the costs of care. The use of "Big Data" in health care promises to fundamentally change the way we provide, measure, and pay for health care.

2014 was a big year for Big Data and 2015 likely will be even bigger:

- Many hospital systems, academic medical centers, and health plans created their own robust, enterprise-wide data warehouses for research, quality improvement, and business analytics, and participated in data-sharing collaborations to support clinical integration efforts and ACOs.
- The Patient-Centered Outcomes Research Institute (PCORI) issued grants to build a patient-centered research network to conduct comparative clinical effectiveness research using Big Data across numerous sources.[14]
- IBM expanded the use of "Watson" for health care. Using this supercomputer, IBM and WellPoint had implemented Watson for utilization management decisions in lung cancer treatment at Memorial Sloan–Kettering Cancer Center.
- A new wave of data services companies emerged to repurpose Big Data for health care analytics.
- Policy groups and academics continued to focus on how we can provide care better and cheaper—and feed those learn-

ings back to practitioners in the field through electronic health information systems—in a "learning" health care system.[15]

Of course, the use of Big Data is not without risk and legal compliance complexities. We saw substantial data breaches in 2014 involving health care, and predictions are that 2015 will be the "year of the hospital hack."[16] If the health care industry wants to continue to assemble large data resources to achieve these incredibly important public purposes, the industry must devote the resources necessary to adequately secure that data in the face of increasingly sophisticated cyber-attacks.

My predictions of what type of organizations will leverage Big Data with less risk in 2015? First, these organizations will have thorough Security Risk Assessments done, revisit those assessments each time their information technology environment changes, and have a risk management plan in place to address any vulnerabilities identified. Security Risk Assessments are the building blocks of good security practices *and* Health Insurance Portability and Accountability Act (HIPAA) Security Rule compliance. Second, these organizations will have an excellent cyber-liability insurance policy. Consensus is that cyber-attacks will happen to every large health care organization—it's just a matter of when. Finally, these organizations will foster a culture of individual responsibility for good data security. Employees must understand that their individual choices can have enormous impact on their organizations; falling for a phishing email, for example, can allow cyber-attackers to gain access to administrative rights in a health care organization's network. Of course, these are good rules to follow for "Small Data" organizations as well!

2015 also will present a plethora of interesting legal compliance issues in utilizing Big Data resources to support data collaborations, clinical integration initiatives, and ACOs. HIPAA compliance pops to the top of legal issues to evaluate in ensuring that the participants in these data sharing arrangements comply with restrictions on data use. Of course, states often impose more restrictive health information confidentiality requirements, and the move to integrate behavioral and medical health are triggering the need to evaluate the application of state mental health confidentiality laws and the federal substance abuse treatment regulations. Sharing Big Data resources between competitors presents antitrust compliance issues. Providing the technology necessary for physicians to participate in shared data resources presents Stark and Anti-Kickback compliance issues, and tax issues for nonprofit organizations. And sharing data resources presents challenging health information management challenges, such as defining the participants' "medical record," controlling responses to subpoenas and other legal requests for the record, and governance issues related to data use. It will be a challenging year ahead!

Emergency Preparedness

—Elisabeth Belmont, Maine Health

The recent experience of certain U.S. hospitals in dealing with Ebola should indicate to health care organizations and professionals across the country the need for being proactive in implementing and routinely drilling on emergency preparedness protocols to confirm readiness. An inherent challenge in planning for the possibility of a public health crisis, terrorist threat, environmental disaster, or other emergency situation is determining what level of preparedness is sufficient. Our country's health care system, like our economy in general, operates on a just-in-time basis. Businesses order or make products only as necessary, rather than maintaining vast inventories. Moreover, the interconnectedness of today's global economy means that a disruption in the availability of workers, products, parts or services could affect significantly health care entities' surge capacity to accommodate a major disaster.

In addition to having an emergency preparedness plan, health care organizations need to ensure that their policies and procedures are continually updated. For example:

- In response to the recent Ebola outbreak, the Department of Health and Human Services (HHS) released a Bulletin on November 10, 2014 "to ensure that HIPAA covered entities and their business associates are aware of the ways in which patient information may be shared under the HIPAA Privacy Rule in an emergency situation, and to serve as a reminder that the protections of the Privacy Rule are not set aside during an emergency." The Bulletin describes situations in which covered entities and business associates may disclose protected health information in an emergency, while also emphasizing that "[i]n an emergency situation, covered entities must continue to implement reasonable safeguards to protect patient information against intentional or unintentional impermissible uses and disclosures."[17]
- CMS also released Guidance on the Emergency Medical Treatment and Labor Act (EMTALA) and Ebola in November which specifically provides that: "It may be the case that hospitals, emergency medical services (EMS), and their State or local public health officials develop protocols for bringing individuals who meet criteria for a suspected case of Ebola only to hospitals that have been designated to handle potential or confirmed cases of Ebola. These pre-hospital arrangements do not present any conflict with EMTALA. This is the case even if the ambulance carrying the individual is owned and operated by a hospital other than the designated hospital, so long as the ambulance is operating in accordance with a community wide EMS protocol."[18]

» The Annals of Internal Medicine recently released guidance that incorporates clinical risk into decisions on how to care for patients with Ebola virus disease. The guidance addresses the following: (1) the need to assess clinician risk; (2) the development of default policies that allow individual clinicians to make decisions instead of going by strict rules; (3) the need to monitor decisions and publicly report them; (4) committee oversight of clinician decisions; and (5) the need to disclose to patients and surrogates why a usually provided therapy is withheld. The authors noted that "[w]hereas standard medical decision-making considers the risks and benefits to the patient, Ebola presents sufficient risk that it is appropriate to simultaneously consider risks to healthcare workers in setting guidelines. This is a relatively new way of thinking that would apply only in certain circumstances with clear and sizeable risks."[19]

To avoid unnecessary confusion at a time when both clarity and a timely response is needed most, it is advisable that health care organizations consider the following in preparing for an emergency: (1) undertaking a hazard vulnerability analysis; (2) promotion of strategies to protect employees and maintain operations; (3) implementation of procedures for the temporary licensing and credentialing of health care workers; (4) determination of whether an altered standard of care applies including potential liability concerns; (5) establishment of billing procedures to maintain cash flow when the computer system (or other infrastructure components) is compromised; (6) obtaining legally valid consent to treatment; (7) review of applicable state regulatory issues; (8) development of internal and external communications plans; (9) integration of public and private response activities; and (10) consideration of ethical issues arising from the rationed allocation of scarce resources.

Since each health care provider is unique, the advance planning will need to be adapted to address the specific needs and capabilities of a particular health care professional or entity. In the melee that accompanies an emergency, novel legal issues may arise and providers will demand an immediate and clear response. It thus is important that health care organizations and their legal counsel stay abreast of both current legal developments and medical guidelines and recommendations as they continue to evolve in response to changing levels of risk—whether for treatment of patients potentially infected with the Ebola virus or other emergency situations.

Fraud and Abuse Enforcement

—Scott R. Grubman, Chilivis Cochran Larkins & Bever LLP

Despite changes in Department of Justice (DOJ) leadership, all indications are that fraud and abuse will once again be a top issue in 2015. That is not surprising considering that, in 2014, the DOJ collected over $2 billion in health care fraud cases and over 700 new False Claims Act (FCA) qui tam actions were filed. Not only will fraud and abuse enforcement continue with full force, but the government's power to investigate and punish alleged "fraud" actually continues to expand.

***Criminal Division to Review All Qui Tams*:** In September 2014, the DOJ announced that all new qui tams will be reviewed by the Criminal Division. Although the DOJ has had parallel proceeding policies in place for years, under which criminal and civil attorneys have been encouraged to work together to investigate allegations of fraud, this new policy raises the stakes for providers who have the misfortune of being named in a qui tam suit. Because much of the conduct that could form the basis of a qui tam action also could lead to criminal liability, health lawyers now should always assume that a criminal prosecutor has reviewed the allegations and likely will receive any relevant information gathered through the course of the civil investigation. This is particularly important when advising a client in connection with giving testimony or information that could later be used in a criminal prosecution.

***The Supreme Court Weighs in*:** The Supreme Court rarely weighs in on FCA matters, but in 2015, SCOTUS will decide two important issues in *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*.[20] The first is whether the Wartime Suspension of Limitations Act (WSLA)—a World War II-era law that tolls statutes of limitations for "any offense" involving "fraud" against the government when the country is "at war"—applies to civil fraud claims brought by private relators where, despite ongoing military hostilities, there has been no formal declaration of war. The Fourth Circuit held that WSLA applies in this situation.[21] The stakes for health care providers are high. Although it might seem absurd that a relator should have more time to file a qui tam because of the conflict in Afghanistan, if the Fourth Circuit is affirmed, the FCA statute of limitations—typically six years—has been tolled for over ten years and will continue to be tolled indefinitely. The Court in *Kellogg* also will decide whether the FCA's first-to-file bar applies where a prior claim is no longer pending at the time of filing.

***Expansion of OIG's Administrative Authority*:** Pursuant to provisions of the ACA, the HHS Office of Inspector General (OIG) issued two proposals in 2014 to expand its permissive exclusion and Civil Monetary Penalty (CMP) authority. Among those provisions, OIG can now exclude providers for making false statements or misrepresentations and for obstructing an audit. Further, OIG now has testimonial subpoena authority in exclusion investigations. OIG's proposed rule also would eliminate any limitations period for exclusions meaning that, even where exclusion is based on a statute with a set limitations period, there would be no effect on OIG's exclusion authority. Additionally, OIG can now impose CMPs for failure to grant timely access to records, ordering or prescribing while excluded, false statements, and failing to report and return overpayments

within 60 days. The DOJ intervened in its first qui tam action based on the 60-day rule in July 2014.[22] The defendants filed motions to dismiss in September 2014. It is likely that the court will rule on those motions sometime in 2015.

***Stark and AKS*:** In 2014, DOJ continued to obtain huge settlements in Stark and Anti-Kickback Statute (AKS) cases, a trend that will certainly continue into 2015. One reason for this trend is the often astronomical dollar amounts at issue in Stark and AKS cases combined with the fact that such cases—especially Stark, which is a strict liability statute—are often easier for the government to prove than other fraud cases. In what might be the only good news for health care providers in relation to fraud and abuse enforcement, in October 2014, OIG issued a proposed rule that would amend the AKS and CMP rules by adding new safe harbors, including a proposal to exempt from potential AKS liability certain Medicare Part D cost-sharing waivers by pharmacies and certain cost-sharing waivers by Emergency Ambulance Services, and allowing providers and suppliers to offer free or discounted local transportation to beneficiaries with certain limitations.

6 HIPAA Compliance Audits

—Adam H. Greene, Rebecca L. Williams, and Anna C. Watterson, Davis Wright Tremaine LLP

HIPAA compliance will remain a top issue for the health care industry in 2015, as covered entities and business associates alike prepare for another round of HIPAA audits.

HHS Office for Civil Rights (OCR) Director Jocelyn Samuels started off 2015 with an announcement affirming that the OCR audits of HIPAA compliance, while delayed, will be forthcoming and "will be an important compliance tool for OCR."[23] According to Samuels, along with OCR's other enforcement tools, the audits will allow OCR to proactively assess industry compliance.[24]

With OCR keeping its cards close to the chest, covered entities and business associates may not know when to expect an audit notification letter, or exactly what the audits might encompass. But, one thing is clear: OCR audits of HIPAA compliance will continue. In addition to audits, we expect OCR investigations stemming from breach notifications will continue to be a primary vehicle for OCR to measure and enforce HIPAA compliance.

In 2014, OCR made multiple announcements about upcoming "Phase 2" audits. OCR recently indicated delays to the initial timeline, but it seems likely that OCR will conduct "desk" audits (limited scope, offsite audits) and perhaps comprehensive onsite audits of covered entities in 2015. OCR audits of business associates are expected as well, although the timing remains unclear. Unlike the pilot audits, for which OCR has not taken any enforcement action, recent comments by an OCR official indicate that future OCR audits may lead to referrals for compliance reviews (e.g., investigations that may lead to enforcement action) when audits indicate serious noncompliance.[25]

The Pilot Audit Program

The industry first experienced OCR audits in 2011 and 2012 through 115 comprehensive onsite audits of covered entities. While the next phase of audits may look very different from the pilot program, OCR has indicated that the pilot audits have informed future audits.

In the two rounds of pilot audits, only 11% of the 115 audits did not result in a finding or observation, according to OCR. Security Rule findings and observations accounted for a disproportionate number of findings and observations. OCR noted that two-thirds of auditees did not have a complete and accurate risk analysis, with 47 of 59 health care providers lacking a complete risk analysis.[26]

Phase 2 Audits—2015

Although some of the audit program's details still are in flux, it is expected that OCR will conduct "desk" audits of both covered entities and business associates in 2015. The return of comprehensive onsite audits appears likely, but when they will begin is one of the biggest questions remaining for the audit program.

OCR announced this fall that it would be conducting approximately 200 limited scope desk audits.[27] We note that this number has changed and may still be in flux. Onsite audits are expected to be much more comprehensive and will be conducted on a resource-dependent basis.[28]

Once a covered entity is selected for an OCR audit, it can expect to receive a request for documentation that demonstrates HIPAA compliance. The request will include a request to identify all of its business associates.[29] OCR has stated that it will give audited entities only *two weeks to respond* to the data request and may not accept late submissions.[30] Also, OCR may not accept documentation created or modified after the date of the data request.[31] Depending on how OCR structures the audits, covered entities may not have additional opportunities to clarify information or communicate with auditors.[32] It is therefore critical that covered entities prepare for HIPAA audits *before* they are selected for an audit.

OCR has indicated that the next round of audits (presumably the limited-scope desk audits) will focus on:

- risk analysis and risk management,
- content and timeliness of breach notifications,
- individual access to protected health information (PHI), and
- notices of privacy practices.[33]

Business Associates

The 2015 audits may provide OCR its first comprehensive look at business associate practices. For many business associates, this may be their first interaction with OCR as well. While

likely further off than covered entity audits, business associates should consider how they will demonstrate compliance with the Security Rule, particularly the risk analysis and risk management requirements. Business associates also should keep in mind Breach Notification Rule and Privacy Rule requirements, such as reporting breaches to covered entities and business associate contracts with subcontractors.

Preparing for a HIPAA Audit

Covered entities may want to consider taking a few steps to prepare for a HIPAA audit:

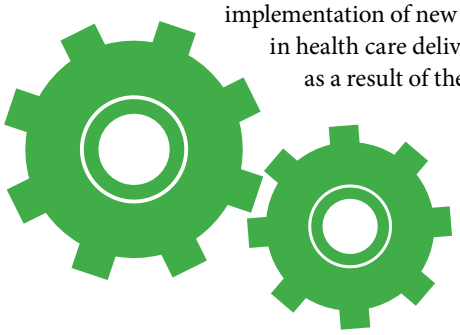
- Update risk analysis assessing potential risks and vulnerabilities for all information systems, devices, and media containing electronic PHI; update risk management plan.
- Verify that appropriate policies and procedures are in place and consistently followed, paying particular attention to individual rights, and the uses and disclosures of PHI described in notices of privacy practices. Covered entities should be able to demonstrate implementation of their policies and procedures.
- Review breach policies and procedures, workforce training and sanctions, documentation of recent security incidents, and, where applicable, documentation of notifications or a breach risk assessment as required by the Breach Notification Rule.
- Review vendor management process; identify all vendors that are business associates; and update business associate contracts to reflect the Omnibus Rule changes.

Covered entities and business associates should use the delay in the next round of audits as an opportunity to review their HIPAA compliance before OCR does.

7 Health Care Mergers and Acquisitions

—Gary W. Herschman, Anjana D. Patel, Victoria A. Vaskov, Sills Cummis & Gross

2014 saw an unprecedented surge in health care mergers, acquisitions, affiliations, and other consolidation transactions, and there appears to be no sign of any slow-down in the year ahead. The recent surge in these transactions has been driven primarily by implementation of new initiatives and changes in health care delivery and reimbursement as a result of the ACA.



The ACA-based initiatives are causing providers to strategically alter their operations to best position themselves in the changing marketplace to, among other things: effectively manage the health of large populations, enhance physician alignment and integration, implement clinical quality/performance-based programs, assume and manage greater risk, enhance information technology and data analytic capabilities, and develop strategies to reduce costs (without jeopardizing quality). Larger systems have greater access to the significant capital necessary to achieve these objectives and to benefit from economies of scale.

2015 will see more of these transactions, which range from small community hospitals combining with large health systems, to major health system-to-health system mergers that form even larger regional (and national) "mega-systems." In the event your organization or client is considering entering into a consolidation transaction, you should be prepared to address the following key issues:

- ***Successor Liability; Due Diligence.*** An important consideration in any consolidation transaction is whether and to what extent a buyer/acquirer is willing to assume liabilities of the seller/target. One way to manage successor liability is through the structure of the transaction—a merger, for example, will pass successor liability on to the buyer as a matter of law, while an asset purchase/sale can endeavor to limit successor liability. Regardless of whether successor liability can be avoided or minimized through transaction structure, it is critical for the buyer to conduct comprehensive due diligence as early as possible, focusing on key areas of potential exposure, such as current litigation, debt structure, physician arrangements, fraud and abuse compliance, coding/billing, quality of care, and other areas of potential regulatory enforcement.
- ***Medicare Enrollment.*** In addition to successor liability considerations, the parties need to be aware of CMS guidance regarding provider enrollment and reimbursement issues that arise when a hospital undergoes a "change of ownership" (or "CHOW"). The level of CMS review/approval of the CHOW depends on the structure of the transaction and whether the new "owner" will accept assignment of the acquired facility's existing provider agreement or will enroll the facility as a new provider.
- ***Regulatory Approvals.*** Another key consideration is to identify early on the regulatory approvals that will be required, understand the process for obtaining each approval, and develop a coordinated timeline for expediting the approval processes (including parallel filings and proceedings wherever possible). At the state level, consolidations involving hospitals may face several types of regulatory review, such as review by the state department of health relating to certificate of need and licensure, and review by the state attorney general of the transfer of a nonprofit hospital's charitable assets.

- ***Antitrust Issues.*** Transactions among competitors in the market may implicate state and/or federal antitrust laws. In fact, the recent increase in health care consolidations has seen a corresponding increase in scrutiny of these transactions by the Federal Trade Commission and DOJ under the Hart-Scott Rodino Act.[34] Antitrust issues also must be carefully considered in connection with due diligence activities, to avoid the exchange of competitively sensitive information.
- ***Stakeholder Approval.*** It is very important for each party to engage their respective boards and other important stakeholders early on and throughout the transaction process, and obtain all approvals required by their respective governance and financing documents. When attorney general review is required, a nonprofit seller must be able to demonstrate that its board engaged in a comprehensive review process, considered all options, and made a decision based on what is best for the institution and the community. In addition, a nonprofit seller may have outstanding tax-exempt bonds secured by the very assets being sold, in which case, trustee, bondholder, or other stakeholder approvals may be required.

Effectuating a consolidation transaction can be an expensive and time-consuming process. Very often, "time is of the essence" and the parties can avoid common roadblocks and prevent unnecessary delays by addressing some of these key issues at the outset.

"Merger-mania" in the health care sector will continue to snowball in 2015. Because the ACA spurred fundamental changes to the health care system as a whole—which changes were inevitable to address flaws in the structure of health care delivery and reimbursement—consolidation transactions are likely to continue at a fast pace, regardless of the outcome of current legal challenges to the ACA.

8 Supreme Court Review of Medicaid Rate Challenges by Private Parties

—Joel M. Hamme, Powers Pyles Sutter & Verville PC and Harvey M. Tettlebaum, Husch Blackwell LLP

This year, the Supreme Court will decide whether Medicaid providers may bring legal challenges to the adequacy of their rates. In *Armstrong v. Exceptional Child Center*,[35] the Court granted *certiorari* to consider whether the Supremacy Clause gives Medicaid providers a private right of action to seek judicial enforcement of 42 U.S.C. § 1396a(a)(30)(A)—the so-called "equal access" provision. This section requires that Medicaid fee-for-service payment rates must be consistent with economy, efficiency, and quality of care and be sufficient to enlist enough providers so that care and services are as available to Medicaid patients as they are to the general public in that same geographic area.

Ordinarily, whether a private party may file litigation to assure compliance with a particular federal enactment depends upon any of three potential enforcement avenues: (1) does the specific provision or the legislation of which it is a part confer an express or implied right of action?; (2) if not, may the provision be enforced through 42 U.S.C. § 1983 (liability for deprivation of constitutional or legal rights, privileges, or immunities under color of state law)?; or (3) if Section 1983 is not available, may the provision be privately enforced pursuant to the Supremacy Clause,[36] which makes the Constitution and laws of the United States the supreme law of the land, preempting contrary state laws and actions?

The Social Security Act, including Medicaid, does not create an express or implied private right of action to enforce its provisions.[37] Ironically, the Supreme Court has never addressed the question of whether the equal access provision may be privately enforced under Section 1983. This is somewhat paradoxical because the circuits have issued fluctuating and inconsistent decisions on the question. Rather, the assumption has been that, given its most recent decisions tightening the conditions under which other federal laws may be privately enforced through Section 1983, the current Court would likely find no such right of action.[38]

The *Exceptional Child Center* case is the second time that the Supreme Court has granted *certiorari* to decide this issue. Three years ago, the Court confronted the same question in *Douglas v. Independent Living Center of Southern California*.[39] In that case, as in the *Exceptional Child Center* case, the Ninth Circuit had ruled that Medicaid providers could use the Supremacy Clause to present an equal access challenge to their rates. Ultimately, the Court narrowly (5-4) averted resolving the question based upon changed circumstances. When oral argument was held, HHS had disapproved the challenged plan amendments but, shortly thereafter, HHS approved some of the amendments on reconsideration, and others were withdrawn. The Court then opted to remand the matter to the Ninth Circuit because the providers were now challenging HHS' approvals of the proposed plan amendments. Notably, however, four members of the Court dissented and indicated that, in their view, the Supremacy Clause may not be used as a vehicle for private rights of action.

Given the dissent in *Independent Living Center*, the providers in *Exceptional Child Center* may face an uphill struggle. But, it is noteworthy that their case arrives on the Supreme Court's doorstep in a different procedural posture from *Independent Living Center*. In that case, California had submitted proposed Medicaid plan amendments adjusting the rates to the challenged levels. In *Exceptional Child Center*, Idaho did not submit a proposed plan or waiver amendment. Instead, according to the providers, Idaho set rates that did not conform to the methodology in its approved waiver, and the state's own consultants had repeatedly and consistently told

the state that its rates were too low. As such, there is no formal HHS review process involved in *Exceptional Child Center.*

The outcome of this case may be extremely consequential in several respects. First, do Medicaid providers have a judicial forum for litigating the sufficiency of Medicaid rates that are supposed to reimburse them for the allowable costs of furnishing services? In a related vein, the Court's decision could also affect whether Medicaid beneficiaries may dispute rates that adversely affect their ability to access needed services. If there is no ability to enforce the equal access provision privately, then Medicaid beneficiaries and providers will be entirely dependent upon HHS to assure compliance through its state plan amendment and waiver processes and its general monitoring of the administration of state plans and waiver programs. Second, the Court's resolution of this issue could also have significant implications as to whether Medicaid beneficiaries and providers may seek to enforce a wide variety of other Medicaid Act requirements pertaining to core program principles such as eligibility, benefits, and cost sharing.

The *Exceptional Child Center* case was argued on January 20, 2015, and a decision is expected by the end of the Court's term in late June or early July.

Mobile Health

—Peter McLaughlin, DLA Piper LLC

One of the key growth areas for 2015 and the foreseeable future is mobile medical technology. We see this through the popularity of "health" apps in online stores as well as regular reports that the Food and Drug Administration (FDA) has approved another mobile health app for use in association with a more traditional medical device. Surveys of providers indicate that the majority of physicians own and use smartphones and tablets, and while the patient population offers different demographic and economic challenges, recent evidence indicates that roughly 40% of Medicaid participants have mobile phones (although not necessarily smartphones).

Follow the money

Beyond the convenience factor for providers and patients, corporate money also has identified digital health as a growth area. A recent report from Rock Health delivers interesting numbers with respect to health IT and digital health investment. And the attention is not limited to traditional venture capital firms, as corporate and insurance investment arms have significant funds dedicated to this sector.

For lawyers handling corporate transactions and investments, this means that the coming year should be busy. The recent JPMorgan Healthcare conference in San Francisco showcased bankers, investors, and established and startup products in the digital health and mobile health spaces. Mobile medical apps, ingestible transmitters, wireless insulin pumps, and more offer lots of investment opportunities.

Security remains elusive and invites regulatory activity

Somewhat lagging the development of mobile medical technology and investor interest, however, has been a reliable means to protect the confidentiality and integrity of the data these devices collect, process, and transmit. Beyond the propensity of mobile phones, tablets, and laptops to be left at airport security, in taxis, and to be stolen, simply the proliferation of devices collecting and moving health information magnifies the challenge of keeping data under control.

Part of this security challenge arises because of the ambiguous regulatory thicket confronting mobile medical technology developers. While the HIPAA Security Rule is familiar enough to providers, many developers in this space are unaccustomed to regulatory scrutiny beyond general consumer protection rules, if that. The convenience of mobile devices can be undermined by complex password requirements or the inability to secure data locally, which can make adoption by patients and providers more difficult. The obvious flip side of the challenge is to store data remotely, in the cloud, where a business associate will host the information, regardless of that company's experience with the securing of health information.

While there is no perfect security, health and technology lawyers will need to help clients identify what rules apply and what might be considered to be reasonable security.

Wearables, less regulated so far

While HHS has begun another year of audits, this will be the first time that HHS anticipates including business associates within the scope of review. Beyond the interest of OCR, the FDA has said it will not regulate consumer wearables such as activity trackers, but increasingly the "wearables" category will be communicating with electronic health records and medical devices. Meanwhile, the Department of Homeland Security's ICS-CERT office will continue to field third-party reports of hacked medical technology and coordinate with medical technology developers and manufacturers to ensure the security of data within the health sector. And it is also worth noting that the Federal Communications Commission—not a familiar name to the health sector—also has jurisdiction over the wireless spectrum, so there will be more news to come from that part of Washington.

The only thing that is fairly predictable, from this gaggle of agencies seeking to protect patients and consumer health information, is that it will be difficult to sort through conflicting and overlapping jurisdictions and requirements. The FDA's current stance of regulatory discretion may not continue for long, as consumer health wearables and other mobile medical technologies interconnect.

Reaching patients

Beyond the cool factor of all this wireless data zipping around and being accessible on demand, there are other aspects of mobile medical technology that should benefit. Specifically, telehealth and the ability of providers and specialists to assist from afar should see continued gains, although regulatory questions about licensing remain open. The benefit will extend, though, beyond the U.S. boundaries to underserved populations where mobile technology is easier to handle because of a non-existent wired infrastructure.

Similarly, patient engagement and home health services should continue to accelerate. As mobile health technology becomes more usable and desirable by patients (rather than just a neat app that holds interest for a week), then we may see greater ability to engage and monitor patient health remotely. To the extent that mobile technology will enable this monitoring and proactive response by providers, then we may be able to see more preventative uses than simply reactive.

Wherever the investments and whatever the regulations, we are likely to see significant growth and activity in the mobile medical technology arena.

Employment-Based Wellness Programs

—Bianca Bishop, AHLA

The popularity of employment-based wellness programs has grown in recent years. The ACA included provisions to encourage the use of wellness programs, which are aimed at curbing unhealthy behaviors such as tobacco use and poor diet that cause or exacerbate costly chronic conditions like diabetes and heart disease. Employers, in turn, view workplace wellness programs as a way to lessen absenteeism, improve productivity, and reduce health care costs.

A comprehensive report on employment-based wellness programs, mandated by the ACA and prepared by RAND Health under contract with HHS and the Department of Labor, found many employers, particularly those with more than 50 workers, used "*wellness screening activities* to identify health risks and *interventions* to reduce risks and promote healthy lifestyles."[40] According to a recent survey by the National Business Group on Health, in 2014, 95% of employers offered a health risk assessment, biometric screening, or other wellness program, three-fourths of which involved incentives to promote employee participation.[41]

Federal agencies issued final regulations on employment-based wellness programs in mid-2013.[42] The final regulations, among other things, set forth standards for nondiscriminatory "health-contingent wellness programs," which generally reward individuals who meet a specific standard related to their health—for example, foregoing or decreasing tobacco use, or achieving a specified health-related goal. The final rules implemented a provision of the ACA increasing the maximum permissible reward under a health-contingent wellness program from 20% to 30% of the cost of coverage. The rules also increased the maximum permissible reward to 50% for wellness programs designed to prevent or reduce tobacco use.

But recent enforcement activity by the Equal Employment Opportunity Commission (EEOC) may call into question the permissible scope of workplace wellness programs. In October 2014, EEOC asked a federal court in Minnesota to enjoin a Honeywell International Inc. wellness program the agency said may violate federal law—namely, the Americans with Disabilities Act (ADA) as an involuntary medical examination that is not job related and the Genetic Information Nondiscrimination Act (GINA) because the program collects medical information from covered spouses.

As described in the EEOC's complaint, under Honeywell's program, employees and their spouses, if they have family coverage, must undergo biometric testing—which measures blood pressure, cholesterol, and glucose levels—or face "surcharges" of up to $4,000. Blood samples also are taken and examined for tobacco use. For its part, Honeywell maintains that its wellness program complies with HIPAA and ACA requirements. The company said it implemented the program so employees would be well informed about risk factors and "because we don't believe it's fair to the employees who do work to lead healthier lifestyles to subsidize the healthcare premiums of those who do not."

The U.S. District Court for the District of Minnesota, where the lawsuit was filed, rejected EEOC's bid to halt the program's implementation for the 2015 plan year while the agency resolves discrimination charges filed by three Honeywell employees.[43] The court ruled in November 2014 that the EEOC failed to meet the requirements for preliminary injunctive relief, but declined to draw any conclusions on the merits, noting "great uncertainty" regarding "how the ACA, ADA and other federal statutes such as GINA are intended to interact." The court did comment that Honeywell's wellness program appeared to comply with the ACA's surcharge limits while also supporting the goal of reducing health care costs.

The National Business Group on Health said it has asked the EEOC for guidance on how the ADA and GINA apply to wellness programs, but the agency has yet to respond. According to the group, the stance EEOC has taken in recent legal action is at odds with HIPAA and the ACA and may have a chilling effect on the adoption and expansion of wellness programs. In its recent regulatory agenda, the agency indicated it planned to issue in February 2015 a proposed rule to amend ADA regulations to address employer wellness programs, including the issue of financial rewards and penalties. Some lawmakers have signaled they will step in if EEOC doesn't clarify its position soon. In a recent hearing on employer wellness programs, Senate Health, Education, Labor and Pensions Committee Chairman Lamar Alexander (R-TN) raised

concerns that the recent lawsuits were discouraging a promising avenue for lowering health care costs and said he would introduce legislation to address the issue if necessary.

During 2015, employers and their advisers will be keeping a close eye on how EEOC's challenges to employment-based wellness programs play out and what, if any, new regulatory or legislative action emerges.[44] For now at least, how these programs must be designed to comply with the ACA, GINA, and other federal requirements remains in limbo.

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