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Health Law

BLAW Q&A

Health Law

This Month: After two years of implementing the Affordable Care Act, the volume of new regulations and guidance documents has been extraordinary. Which of the ACA-related regulations or guidance documents had the most immediate impact on your health law practice?

ARNOLD & PORTER LLP

Allison W. Shuren, Arnold & Porter LLP

Section 6402(a) of PPACA establishing the new provision of the Social Security Act (§ 1128J(d)) that requires a person who has identified an overpayment to report and return the overpayment by later of (i) 60 days after the overpayment was identified or (ii) the date any corresponding cost report is due has an immediate and chilling impact on every provider and supplier participating in the Medicare program, and the proposed rule implementing this section of the law that was recently published by the Centers for Medicare and Medicaid Services has increased this angst. Particularly since the knowing failure to return an overpayment is subject to liability under the False Claims Act.

No one would disagree that parties who know they have received Medicare dollars incorrectly should return the money to the fisc, but the devil is in the details, more specifically in the way CMS proposes to define "knowing," "overpayment," and "identified." There also is concern regarding how far back in time suppliers and providers must reach to verify whether past payments may have been improper. This rule has significant implications for compliance officers and committees, auditors performing retrospective reviews of services billed to the Medicare program as well as lawyers who counsel clients who may have identified possible problems. The comment period for the proposed rule currently is open and we should expect an influx of opinions to CMS.

Allison Shuren is part of the FDA/Healthcare practice group at Arnold & Porter LLP. Her practice focuses on healthcare regulatory and government enforcement matters.

DrinkerBiddle®

Matthew P. Amodeo, Drinker Biddle & Reath

Of all the ACA-related regulations and guidance published to date, the Medicare Shared Savings Program regulations (commonly referred to as the ACO Regulations) have clearly had the most immediate impact on my practice. While the sheer magnitude and complexity of the ACO Regulations (the combined proposed and final ACO Regulations exceed 1,200 pages in length) have resulted in a tremendous (and immediate) need for legal and

practical advice for clients interested in participating in the Shared Savings Program, the true and longer lasting impact of the ACO Regulations is that they have served as a catalyst for a major transformation in the way health care services are delivered and reimbursed in this country. In anticipation of this transformation, many of my clients are restructuring and retooling their care delivery models in order to succeed in the "accountable care" era.

Initially, provider restructuring has focused primarily on physician alignment and integration. In order to succeed under accountable care, hospitals realize that they must align their financial interests with the physicians whose referrals support them. As a result, hospitals and health systems across the country are partnering with their admitting physicians through a variety of affiliation models such as acquisitions and employment transactions, or through contracted networks that may one-day function as an ACO. These affiliations allow hospitals greater control over physician decisions and costs, such as ordering expensive tests and the latest drugs. In order to be successful under accountable care, health care organizations will need to control costs and manage the care of patient populations to a budget.

Regardless of whether ACOs and the Shared Savings Program are ultimately successful, there can be no doubt that the introduction of the ACO concept has triggered what will likely be the largest transformation of the American healthcare delivery system ever.

Matthew P. Amodeo is a partner in the Health Care Practice Group at Drinker Biddle & Reath, LLP. His practice is focused on hospital-physician integration transactions, health care joint ventures and managed care contracting.

EDWARDS WILDMAN

Les Levinson, Edwards Wildman Palmer LLP

The impact of the Affordable Care Act, passed in March 2010, on our healthcare law practice cannot be viewed in a vacuum. The law has far-reaching implications for many aspects of the healthcare system, and many of our insurance industry clients have been and will be affected by its requirements in designing and marketing their products, but reductions in healthcare reimbursement rates are having a more significant impact on how we counsel clients on a day-to-day basis. These cuts have also affected the M&A and financing markets for the healthcare system.

The effects of these reimbursement reductions, mandated by federal law and the laws of various states, have been exacerbated by the continued weak U.S. economy, turmoil in European debt markets and other domestic budgetary pressures. As a result, our clients have been asking whether these types of cuts will be continuing, what their magnitude will be, and when there will be a bit more stability so that they can figure out how to manage their way through this, plan for needed capital expenditures and other business improvements, and consider making acquisitions or other investments as the flow of dollars from reimbursement sources lessens. Many states have also had to make painful budget choices, resulting in further cuts that our clients are having to grapple with. Unfortunately, this trend in reimbursement is not expected to change in the near term, but our clients will continue to seek ways to operate more efficiently and to work with payors to participate in cost savings generated for the healthcare system.

Les Levinson, a partner in the firm's New York office, serves as Chair of the Firm's Healthcare Practice Group. During his more than 30 years representing public and private companies, Les has completed more than 300 M&A and financing transactions. While he represents a wide range of companies in various industries, Les concentrates his practice on transactions for clients within the healthcare and communications industries.

EPSTEIN BECKER GREEN

Douglas A. Hastings, Epstein Becker & Green, P.C.

The Medicare Shared Savings Program (ACO) Final Rule, issued October 20, 2011, has had the most impact, not only on my practice but on the future of health care payment and delivery in the United States. Accountable Care Organizations represent a confluence of ideas evolving over the last several decades about better ways to organize, coordinate and pay for health care services to produce both better quality care and greater cost efficiency. The debate over the Medicare ACO program, culminating in the Final Rule, reflected a robust and important public-private dialogue that will affect all health care providers, health plans, purchasers and consumers in numerous and important ways.

The Final Rule also evidenced significant coordination among CMS, OIG, FTC, DOJ and IRS regarding future regulation of the health care delivery system. Health care lawyers who understand the nexus of the legal, business and policy issues reflected in the Medicare ACO program and similar commercial insurance programs will be well positioned to assist health care providers and payers in the expansive transactional and contractual work that will be required to respond to the ACO movement and related changes in health care payment and delivery.

Douglas A. Hastings currently serves as Chair of the Board of Directors of Epstein Becker & Green, P.C. and is a Member of the Firm's Health Care and Life Sciences Practice in the Washington, D.C., office. Mr. Hastings provides a wide range of health care organizations with strategic and transactional legal guidance in responding to the legal challenges and opportunities of the rapidly changing U.S. health care system. He has become recognized as one of the nation's leading resources on accountable care, value-based payment and health care delivery system reform.

FOLEY
FOLEY & LARDNER LLP

Fred Geilfuss, Foley & Lardner

Two of the largest changes in the Affordable Care Act are payments based on quality outcomes and enhanced integrity provisions including mandatory reporting of overpayments. These changes are causing providers to examine how care is delivered and how they need to function in the future. New structures and fundamental changes are a result of these activities that received a jump start from the ACA. While too early to determine the final outcome, they point to a clear emphasis on care transformation.

The ACA has served as an early catalyst in the move to transform the health care delivery system from one where payments are based on more care provided to a system with payments are based on quality outcomes. In addition, the ACA included enhanced Medicare and Medicaid integrity provisions. One of the most significant such provisions is the requirement to report and refund to the government any overpayment received by the later of 60 days after the identification of the overpayment or the date the corresponding cost report is due (if the provider files a cost report.) Such an overpayment may result from a billing error, from a violation of the Physician Self-Referral (Stark) law, or other causes. It is now a new violation to withhold identified overpayments. This change demands even more increased and active compliance activities. More than ever, a provider needs to ensure a culture of compliance throughout its organization.

Fred Geilfuss is a partner at Foley & Lardner LLP and member in the firm's Health Care Industry Team, practicing in the Milwaukee, Wisconsin office. He has extensive experience counseling health systems, hospitals, medical clinics, rehabilitation agencies, nursing homes, and other health care providers on a number of complex legal matters including health care acquisitions, integrated delivery service issues, managed care contracting, government enforcement actions, finance, real estate, administrative and medical staff issues, physician recruitment, as well as fraud and abuse matters. Mr. Geilfuss can be reached at 414.297.5650 or fgeilfuss@foley.com.

Fox Rothschild LLP
ATTORNEYS AT LAW

Elizabeth Litten and William Maruca, Fox Rothschild LLP

The shared savings program regulations have certainly occupied more of our time than any other guidance under the ACA, but their impact on our health law practice is still evolving. We believe that the fee-for-service reimbursement system is unsustainable in its current state and that some form of alternative method or methods that reward quality of care and cost-effectiveness over quantity will inevitably rise to prominence in the coming decade. ACOs as envisioned under the CMS Shared Savings model represent a tentative first step toward that goal.

In order to participate in any Shared Savings Program, providers will need to rethink their historical operations, incentives, governance and organizational structure. Adapting to these changes will involve the Stark physician referral law, the Anti-Kickback Statute, HIPAA, the Civil Money Penalties Act, the antitrust laws, and in many cases, tax exemption considerations. Preparing for this revolution in the health care system will require lawyers to unlearn and relearn many previously settled areas of their daily practice and to understand new dynamics at play. Whether or not CMS's efforts succeed, payors are likely to adopt some of the initiatives and concepts included in the Shared Savings Program, particularly the quality measures, the focus on outcomes and the changes in incentives. The advent of ACO-style reimbursement may prove to be as game changing to healthcare reimbursement as was the introduction of DRGs in 1982.

William H. Maruca is a partner at Fox Rothschild LLP in Pittsburgh, PA, and is part of the firm's Health Law Practice Group. He can be contacted at 412-394-5575 or wmaruca@foxrothschild.com.

Elizabeth G. Litten is a partner at Fox Rothschild LLP in Princeton, NJ, and is part of the firm's Health Law Practice Group. She can be contacted at (609) 895-3320 or elitten@foxrothschild.com.

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Karen S. Lovitch, Mintz Levin

The ACA provision underlying the proposed rule on the reporting and return of Medicare and Medicaid overpayments requires providers to return overpayments no later than 60 days after they are "identified" and to detail the reason for the refund. Although providers have always been obligated to return overpayments, the ACA set a clear deadline for doing so and established that the failure to return overpayments can give rise to liability under the False Claims Act and the Civil Monetary Penalties Law. Unlike many other ACA provisions, this one did not specify a delayed effective date, which meant that providers had to immediately comply without clear guidance on how to do so.

Identifying an overpayment is not as easy as it sounds because a provider often must conduct an internal inquiry to confirm and quantify an overpayment, and this process can take some time. After passage of the ACA, providers were unsure whether CMS considers an overpayment to be identified upon receipt of information about a potential overpayment or upon confirmation that an overpayment was in fact received. If the former, then the

internal inquiry would need to be complete within 60 days of learning of the potential overpayment, which could be difficult, depending on the complexity of the issues presented.

The proposed rule recognized that a provider may need to conduct a "reasonable inquiry" upon receipt of information about a potential overpayment, but nevertheless failed to expressly state that the clock would not begin to tick until the provider has confirmed and quantified the overpayment or to establish bright-line rules for providers on this important point. Commenters undoubtedly will ask CMS to give more concrete guidance in the final rule, but, in the meantime, it is helpful to know that CMS understands that providers may need some time to investigate reports of potential overpayments.

Karen S. Lovitch is the Practice Leader of the firm's Health Law Section. Karen counsels health care clients on regulatory, transactional, and operational issues, including Medicare coverage and reimbursement, the development and implementation of health care compliance programs, and licensure and certification matters.

If you have a health law question that you'd like to ask, submit it to blawcontrib@bloomberg.net, subject line "Health Law Q&A." Your question may be selected to be answered in a future column.