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Q&A With Mintz Levin's Karen Lovitch

Law360, New York (June 27, 2012, 2:18 PM ET) -- Karen S. Lovitch is a member of the firm and practice leader of Mintz Levin Cohn Ferris Glovsky & Popeo PC's health law section.

She counsels health care clients on regulatory, transactional and operational issues, including compliance with the health care fraud and abuse laws, Medicare coverage and reimbursement, the development and implementation of health care compliance programs, and licensure and certification matters.

Q: What is the most challenging case you have worked on and what made it challenging?

A: I recently served as health care regulatory counsel to a privately held biosciences company in a very complex transaction valued at over $700 million. A corporation that is publicly traded on a foreign stock exchange acquired part of the company while a different group of investors purchased the other part, resulting in the creation of a new company.

This transaction was more challenging than a typical health care industry transaction, because the company’s subsidiaries operated multiple independent laboratories, which, unlike most other provider types, such as hospitals, offer their services to patients nationwide.

Each laboratory therefore must maintain licenses from multiple states and participate in numerous state Medicaid programs. My team had to determine the filing requirements for nearly 100 different state and federal agencies and then prepare well over 200 filings for submission to a variety of state licensure agencies, accreditation organizations, Medicare administrative contractors and state Medicaid agencies.

Shortly after the transaction, the company changed its name and one of its officers, which triggered a whole new round of filings to these same agencies.

Q: What aspects of your practice area are in need of reform and why?

A: State regulation of the practice of medicine fails to take into account the fact that the practice of telemedicine is now common and that many physicians therefore practice across state lines.

For example, a pathologist who diagnoses cases on behalf of a national pathology laboratory interprets specimens received from a variety of states, many of which require the pathologist to be licensed in the state from which the specimen came, and those states have different licensure requirements.

To ensure compliance, pathology laboratories therefore must constantly monitor the

patchwork of state physician licensure laws and ensure that specimens are routed only to licensed physicians.

Q: What is an important issue or case relevant to your practice area and why?

A: A provision passed as part of the Patient Protection and Affordable Care Act (PPACA) requires providers to return Medicare and Medicaid 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 PPACA sets a clear deadline for doing so and establishes 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 PPACA 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 PPACA, providers were unsure whether the U.S. Centers for Medicare & Medicaid Services (CMS) considered 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.

Proposed regulations recently published by CMS 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.

Q: Outside your own firm, name an attorney in your field who has impressed you and explain why.

A: I admire Susan Alexander, executive vice president, general counsel and corporate secretary of Biogen Idec Inc., not only because she is a savvy, no-nonsense lawyer, but also because she places a high value on diversity and pro bono work.

Susan has assembled a diverse legal team, which includes a number of women who serve in senior roles in various departments, and she holds law firms working with Biogen Idec to the same high standards that she sets for her own team.

Similarly, Susan encourages Biogen Idec's outside law firms to engage in pro bono activities. Mintz Levin and Biogen Idec recently co-sponsored their first fellow through Equal Justice Works, which offers paid public-interest fellowships to law school graduates who commit to providing legal assistance to underserved populations and causes, and have committed to working together on this and other pro bono initiatives.

Q: What is a mistake you made early in your career and what did you learn from it?

A: Early in my health law career, a partner suggested that I should learn everything there was to know about a new set of regulations because this knowledge would present future opportunities. The Federal Register notice containing those regulations was hundreds of pages long, so I took the easy way out and declined to take the partner's advice.

As I became more senior and gained a better understanding of the advantages of developing one or more specialties, I deeply regretted my decision. When I was subsequently offered the chance to learn about regulatory and compliance issues affecting clinical laboratories, I recognized the importance of doing so.

Today, I regularly represent clinical laboratories in state and federal investigations and transactions and counsel them on day-to-day regulatory and compliance matters, so my decision to develop a specialty in this area has proven to be incredibly valuable to my clients.

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