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A photograph of three people standing in a modern law office. On the left is a man with a mustache, wearing a dark suit and a red tie. In the center is a woman with long brown hair, wearing a dark grey suit and black boots. On the right is a man with glasses, wearing a dark suit and a patterned tie. They are all smiling and standing in front of a wood-paneled wall with a framed picture. There are armchairs and a potted plant visible in the background.

Health-care law: An evolving practice

(Left to right): James B. Riley Jr., of McGuireWoods; Kerrin B. Slattery, of McDermott Will & Emery; and Miles J. Zaremski, of Zaremski Law Group.

By Sherry Karabin

It has been more than 40 years since major health-care legislation, in the form of Medicare, took effect. The federally funded health insurance program, which began in 1966, not only changed the face of health care for Americans but it altered the legal field as well.

“Besides Social Security that came into being in 1935, the greatest piece of social legislation in the last 100 years has been Medicare,” said Miles Zaremski, principal at Northbrook-based Zaremski Law Group. “Medicare has been the springboard for social legislation to protect the health-care needs of citizens in the country.”

Zaremski, who started working in health law more than 35 years ago, has witnessed tremendous changes over the years. When he first started practicing, he said, “It wasn’t even recognized as a career specialty. Now it’s not only a mainstream area, it intersects everything.”

For those lawyers already in the field, many find themselves helping their clients navigate their way through increased federal regulations and compliance actions that have been expanding since Medicare.

The American Recovery and Reinvestment Act of 2009 brought with it revisions to the federal False Claims Act and stricter privacy and security regulations, putting more institutions at risk of being slapped with violations.

The federal government is also enlisting private companies to audit institutions to discover overpayments and underpayments.

In addition, physician practices and health care providers must take extra care to ensure in structuring their business arrangements to meet the requirements of the Stark law, which governs the practice of physicians referring Medicare patients to entities in which they have a financial interest.

Illinois nursing homes and extended-care facilities are also facing the wrath of officials as they crack down on safety, fraud and abuse.

The type of clients being represented is also changing. Many firms are doing more work for life sciences companies, including pharmaceutical, biotechnology and medical device manufacturers that find themselves under increased scrutiny by the government. In other cases, attorneys are assisting these entities with patent and corporate matters.

As the need for health law services continues to expand, one company has opened its doors, promising clients more efficient billing arrange-

ments along with a different approach to handling the increased regulatory environment.

Law schools, too, are adapting with expanded offerings designed to meet a growing interest among students who see a bright future in health-care law.

With health-care reform on the horizon, Zaremski said, “The U.S. may be entering yet another historic time when health-care for many more millions of Americans will become a reality in terms of access and affordability. If the length of legislation to reform health care is any indication [1,900-2,100 pages], there will be an even greater need for health-care attorneys to understand and interpret implementing regulations.”

Chicago Lawyer spoke to health-care attorneys here to get their perspectives on the field now and what the future may hold.

Increased federal regulations

James Riley, national health practice chair at McGuireWoods, said the area has grown substantially over the last several years, partially due to the large number of federal and state regulations being imposed on clients. “There has been an increased focus on compliance in the last 10 years,” said Riley, “and we have been developing plans for our clients in response to these changes.”

According to Riley, the firm has expanded its government, regulatory and criminal investigations practice. “Most providers are serious in their efforts to comply with regulations, but it is a complex environment and there are many opportunities for people to misstep and in turn [they] need assistance when the government comes knocking on their doors.”

Kevin Ryan, a partner in the health law practice at Much Shelist, also finds himself spending a lot more time on regulatory matters, which he said are “far more complicated today,” than when he started in the field 22 years ago.

Ryan is now dealing with a lot of Stark law-related matters. On Oct. 1, a new set of revisions took effect, with the rules expected to make it more difficult for doctors and other entities providing health services to do joint ventures built around the services.

“I’m a lot busier than I was partly because of this,” Ryan said. “Each revision requires an analysis of ventures involving health-care providers and physicians. Many of the deals that

were in compliance prior to October now need to be restructured. I’m working with clients to ensure compliance.”

During the last year and a half, Ryan said more deals between health-care providers have not made it to closing, partially because of the economy, but also due to the increased regulations. Construction of health-care institutions has also declined.

However, Ryan said, things may be turning around, as he has noticed “a renewed interest from clients looking to do deals and transactions.”

Robert Neiman, Much Shelist health-care and litigation practice partner, said he has observed a growing trend by the federal government to encourage and reward whistleblowers to report perceived misconduct.

The American Recovery and Reinvestment Act, which became law on May 20, imposes a host of new compliance obligations on institutions, including changes to the federal False Claims Act that expand the definition of what a claim entails and make it easier for the U.S. Department of Justice to investigate and bring suits against companies and entities receiving or paying money to the federal government.

The act also resulted in stricter privacy and security regulations for the Health Insurance Portability and Accountability Act (HIPAA), which requires health-care providers to protect consumers’ health and personal information.

The new rules now state that anyone handling such information, including third-party vendors, must comply or face penalties. The changes also require entities to alert authorities when a breach has occurred, and mandate audits by the U.S. Department of Health and Human Services of HIPAA-covered companies to enforce rules and investigate complaints.

Penalties for such breaches are higher and individuals can now report HIPAA violations to either HHS or their state attorney general. If either brings a suit for the violation and recovers money, the whistleblower is eligible to receive compensation from the government.

“Health-care providers need to be prepared for even more investigations, even if they are doing everything right,” Neiman said.

Fredric Entin, a Polsinelli Shughart shareholder, said he is busy helping clients prepare for the newly implemented Medicare Recovery Audit Contractor program, in which the fed-

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eral government enlists the help of private companies that will be compensated on a percentage basis, to audit health-care institutions in an effort to discover overpayments and underpayments.

"These contractors have the clear economic incentive to go after hospitals and physicians," Entin said.

The program is being expanded to all 50 states no later than 2010 and is already in effect in most. Illinois is one of the few in which it is not. However, Entin said, it would probably be operational in Illinois by early 2010.

In the meantime, he advises hospitals and physician groups to take advantage of this time before the RAC program is operational to engage in critical self-audits.

"Not only is there an opportunity to be prepared for the RAC audits, but the recent amendment of the federal False Claims Act, making it a violation to retain payments that the provider knows or should know they are not entitled to keep, has raised the stakes for identifying overpayments," Entin said. "Self-auditing and if necessary, repayments, self-disclosures, and remediation significantly mitigate the exposure to recoupment or government enforcement."

Entin said there is an increasing trend to tie payment to quality of care. The medical home is one model that incorporates payment for quality.

When the idea was introduced by the American Academy of Pediatrics in 1967, "medical home" referred to the creation of a central location for archiving the medical records of a child. Today it's known as the Patient-Centered Medical Home and is designed to provide comprehensive primary care by putting the patient's primary care physician in charge of coordinating services for all the patient's needs and paying the doctor fees for doing so.

Although no such models exist in Illinois, Entin said he has received inquiries from physicians and physician groups interested in participating.

Richard Raskin, chair of the Chicago health-care practice group at Sidley Austin, said all the increased regulatory activity is keeping attorneys at his firm very busy, so much so that they have not felt the economic downturn. But, he said, the type of clients being targeted by the government is changing.

"Over the last five to 10 years, we have seen a strong shift of emphasis toward enforcement

actions against drug and medical device manufacturers," Raskin said.

"A lot of the Medicare and Medicaid enforcement issues that physicians and hospitals long faced are now front and center for life sciences companies that years ago were less reliant on government business and less heavily regulated," he said.

Raskin said the firm handles a lot of false claims suits and he expects the number of anti-trust actions to rise, as the Obama administration has made it clear that it will be stepping up its investigations of several sectors.

In addition to the new federal regulations that health-care clients are facing, McDermott Will & Emery partner Michael Peregrine said the Internal Revenue Service is also cracking down. "The IRS gives tax-exempt status to nonprofit institutions and there has been a dramatic increase in enforcement and oversight regarding governance and executive compensation."

Nursing homes and long-term care facilities

Firms also handle issues related to the state's geriatric facilities. Much Shelist's Neiman said the violent acts by felons and the mentally ill who reside in geriatric facilities have recently taken center stage in Illinois.

"The state is defending lawsuits seeking to force the state to provide funding for less restrictive, community-based facilities for mentally ill patients, but is simultaneously facing criticism for allowing mentally ill residents to live in more restrictive geriatric long-term care facilities. The state doesn't have the money to do some basic things, let alone money to improve what already exists. Something has to give," Neiman said.

Polsinelli Shughart shareholder Daniel Reinberg also discussed the problems these facilities face. While the state has always played an active role, he said, there have been a growing number of enforcement actions against these institutions involving safety and fraud and abuse issues. The former assistant U.S. Attorney in Chicago said these actions, combined with a general trend of increasing government investigations into fraud and compliance, have been keeping him very busy.

"It used to be that settlements would occur where hospitals were fined, but now the government is prosecuting individual executives. Oftentimes these executives are hit with fines

or may face jail time. In other cases they are being excluded from the Medicare and Medicaid programs, which is a kind of death sentence in this field," Reinberg said.

Polsinelli shareholder Matthew Murer is also handling compliance matters for long-term care facilities and senior housing complexes.

"I act as an outside general counsel for clients and whenever a community is doing strategic planning, joint ventures and even hiring they need to be sure they are complying with government regulations and policies," Murer said.

Murer, who has practiced for over 15 years, said he handles more litigation and civil disagreements than before.

He also noted that there is a big push by labor unions to get more involved in senior housing and long-term care.

"Our firm spends a lot of time dealing with negotiations and campaigning," Murer said.

With baby boomers growing older, he said it will be a real challenge to find enough infrastructure and money to care for them.

"The baby boomers changed just about everything in our culture. We're going to see that same effect on long-term care, including more individualized and lifestyle-oriented care," Murer said.

Client shifts — the wave of the future

Regulatory and compliance changes are far from the only differences in health law today. Many lawyers have seen their clients evolve as well.

For instance, in the beginning of his career, Zaremski said he represented institutional interests in professional liability cases, but these days he works with a lot more individuals and groups, handling commercial disputes, including peer review matters, exclusive contracting in health care, and regulatory issues.

Zaremski said Chicago has always been a mecca for health-care attorneys because it serves as the headquarters for so many pharmaceutical companies, medical societies and professional associations. He said he expects this trend to continue on an even larger scale as health-care reforms create a greater need for legal services.

Riley said he has also noticed a client shift. The McGuireWoods national health chair said that while attorneys continue to represent larger hospitals and health-care systems, they do a lot more work for pharmaceutical companies and medical device manufacturers

that have been the focus of government investigations over the last several years.

“Several years ago, the life sciences area began expanding within our firm, with attorneys representing medical device, pharmaceutical and biotechnology companies in matters ranging from Medicare/Medicaid compliance to patent and antitrust issues,” Riley said.

He said lawyers also represent pharmaceutical companies as they seek FDA approval and government reimbursement for new services and devices they are offering.

Riley said he believes several health-care reform proposals will translate into new opportunities for the firm.

“In the 1990s we dealt with a lot of accountable-care type organizations that were responsible for the overall care of beneficiaries and disease management organizations. With health-care reform, these organizations will make a comeback.

“We also see opportunities for assisting clients in establishing telehealth facilities and helping them comply with the confusing reimbursement regulations in the area,” Riley said. Telehealth facilities use telecommunications technology to deliver services.

Barnes & Thornburg health-care chair Mark Rust, who also is managing partner of the Chicago office, said the firm deals with an increasing number of clients that are looking to combine. As a result, he said, attorneys handle much more governance and management matters for a wide array of clients ranging from large physician groups to hospitals and clinics.

“Large physician groups are attempting to increase their size so they have more of a seat at the table in controlling their financial and management destinies, which are being increasingly impeded by managed-care companies,” he said. “Radiologists, cardiologists etc., who might not have considered merging five years ago now see doing so as their only option as managed-care companies continue to reduce reimbursements.

“Such mergers are subject to many federal regulations that must be closely obeyed since there are anti-self referral, antitrust and other issues related to the way these groups combine,” Rust said.

According to Rust, “Fewer deals are getting done because of financing problems and the degree of uncertainty over what health-care reform will bring. During the last five years,

Chicago has seen an increasing consolidation of hospitals and more physician groups selling out to hospitals or becoming employees.”

Like other firms, McDermott Will & Emery has increased its services to life sciences companies. In addition, partner Kerrin Slattery said many of the community-based hospitals and small stand-alone hospitals have been combined into larger systems. Both she and Michael Peregrine said there has been a major shift in how legal services are being allocated.

“Over the last five to seven years, companies are relying more on their in-house attorneys for less complex matters in an effort to save on costs and enlisting the firm to do more regulatory, executive compensation and transactional work that is beyond the expertise of the in-house staff,” Peregrine said.

At Polsinelli Shughart, the science and technology law group has expanded rapidly and now includes more than 40 lawyers and scientists who specialize in handling the unique needs of biotechnology, chemical, food science, pharmaceutical, technology and new media companies. In August, the firm began a 10-year contract with the National Institutes of Health that may be worth up to \$87 million.

Teddy Scott, Jr., a shareholder in the intellectual property group, oversees the patent prosecution work for the NIH. He routinely manages and leverages patent portfolios and handles the licensing of new products

“Our group has grown tremendously over the past few years,” Scott said. “The biotechnology industry has matured. Fifteen years ago biotechnology companies were mainly start-ups. They have now grown and have sophisticated legal needs that run the gamut. Pharmaceutical companies have also moved into the biotech area.

“Our life sciences group includes attorneys from all different disciplines to accommodate needs that range from patent and regulatory to corporate,” Scott said.

Re-inventing health-care law services

The explosion of changes and growth in health-care law is one of the main reasons principals Kathryn Roe and Jack Rovner started The Health Law Consultancy. The firm, which opened in September, boasts a new business model that helps clients contain costs by charging on a project-by-project basis versus the traditional billable hour standards.

“We wanted to be part of leading the changes, instead of following them,” said Roe, who has been in the field for almost 20 years.

Rovner said the firm encourages clients to look beyond the inconvenience of some of the changes and focus on the underlying reasons. For instance, he explained that medical identity theft is on the rise, whereby health insurance information is stolen and used to purchase services.

“Given the increasing threat of medical identity theft to health insurers and their members, strategic thinking would suggest that a health insurer evaluate potential identity theft vulnerabilities that may be present in its business processes, and then adopt solutions for managing them,” Rovner said.

“That is the policy change message and the public concern underlying the Federal Trade Commission’s identity theft Red Flags Rule [which requires certain businesses and organizations, including many doctors’ offices, hospitals and other health-care providers to develop a written program to spot warning signs of identity theft]. That policy and public concern are real, even if the Red Flags Rule is deemed not to apply to the business,” he said.

Rovner said he believes one of the biggest changes to come in the industry will be in the adoption of information technology.

“It will allow for better coordination of care and eliminate redundancies,” he said. “It will also provide researchers with meaningful ways to collect and better disseminate data directly to providers.”

Rovner said financial incentives are built into the economic stimulus bill for Medicare and Medicaid providers that digitize health records. “Companies need to digitize health records much the way that the financial services sector has done so that one day just as you can take money from any ATM, doctors will have the same type of access to patient information.”

Law school curriculum changes

Attorneys are not the only ones adapting to the evolving health-care field. Area law schools are also making adjustments.

Megan Bess, assistant director of the Beazley Institute for Health Law and Policy at Loyola University Chicago School of Law, said the school has revised its curriculum, adding a few new offerings this year, including an adminis-

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trative law and health-care regulations class.

“There is also a greater focus on teaching new litigation techniques,” she said, “including mediation and alternative dispute resolution and more emphasis on helping students understand business and finance issues in the health-care industry.”

In addition, Bess said more students are expressing an interest in intellectual property and patent law, which she said is connected to the growing work in the life sciences area.

Adjunct law professor Elaine Zacharakis Loumbas said she recently revamped her Life Sciences, Research and the FDA course at Loyola to include more cutting-edge topics.

“Life-sciences companies are developing personalized and unique therapies to treat patients that will revolutionize medicine, such as developing cures for cancer at the molecular level.

“These companies are seeing increased competition abroad, but it is not always healthy competition. For example, certain countries do not prohibit or adequately regulate the production of counterfeit drugs and these products

can enter the stream of commerce with potentially disastrous effects,” said Zacharakis Loumbas.

She said the recent class changes have increased the number of students taking the course by about 40 percent.

Zacharakis Loumbas also teaches Health Information Privacy at Loyola and at The John Marshall Law School.

“Health care is a highly regulated field, but the electronic transmission of information across borders is highly unregulated and creates complicated jurisdictional issues,” she said.

Nanette Elster, director of the Health Law Institute at DePaul University College of Law, said she noticed an increased interest from first-year students who want to take more health-related course offerings, including her Biotechnology, Bioethics and the Law class.

“Advances in biotechnology and the life sciences are reshaping when life begins, how life is lived and when life ends. Developments such as the ventilator, in vitro fertilization, organ transplantation, gene therapy, and now stem cell therapies challenge long-held perceptions

of the intersection of law, medicine and society,” Elster said.

She said the class examines the relationship of these changes and many of the dilemmas facing attorneys who are handling these issues.

“Students can get a certificate in health law and I think that exemplifies how popular the field has become,” Elster said.

As health-care law continues to evolve, lawyers and law professors said they expect even more changes. With some type of health care reform expected to pass, more regulations are all but a given, and as innovative technologies and treatments become more the rule than the exception, life sciences companies are likely to enlist even more help from attorneys. Law schools too are preparing to accommodate an even greater number of students with an interest in all aspects of the field.

Slattery, of McDermott, said if comprehensive reforms are passed, she expects them to “change the way health-care facilities deliver services in general and therefore the landscape of legal services sought and delivered will also change.” ■

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