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Health Care Regulation To Watch In 2011

By **Carolina Bolado**

Law360, New York (January 1, 2011) -- Regulators will be busy in 2011 filling in the details of the 2010 health care reform bill, and health attorneys will be watching closely as the federal agencies begin the rule-making process that will shape enforcement of the sweeping legislation.

While there may be efforts in the new Republican-led U.S. House of Representatives to repeal the Patient Protection and Affordable Care Act, or at least alter the legislation significantly, most experts agree that any such efforts will die in the U.S. Senate or face a certain veto from President Barack Obama.

The greater challenge to PPACA is coming from the courts, most recently from the U.S. District Court for the Eastern District of Virginia, which in December struck down a key provision of the landmark law that requires people to purchase health insurance.

The government is set to appeal that ruling, but while the dispute drags out, lawyers will be focusing their attention on how the law's many provisions are to be implemented.

"You may see some peripheral legislation around different topics that are always important," said Susan Berson of Mintz Levin Cohn Ferris Glovsky & Popeo PC. "But given what we've just lived through in the last two years of health care reform, the focus will be on what do we do now that we have this massive law."

Here is the health care legislation and regulation to watch in 2011.

PPACA: Accountable Care Organizations Provision

How the Centers for Medicare and Medicaid Services will implement the accountable care organizations described in the health care reform bill is the most crucial development to watch in 2011. These cost-sharing organizations are designed to coordinate care for Medicare and Medicaid patients, from hospital stays to doctor visits to follow-up care.

The goal, according to Brian McGovern of Cadwalader Wickersham and Taft LLP, is to improve the quality of care while also saving money. CMS expects to roll out the organizations in January 2012, but there are questions the agency will need to answer through regulations in the meantime.

"How will the organizations have to be structured? How are they supposed to share any savings? How are those savings going to be measured? These are all issues that will be fleshed out in the coming year," McGovern said.

McGovern also pointed out that the PPACA recognizes just two groups — hospitals and physicians — that could become part of an accountable care organization, but leaves the door open for CMS to identify other health care providers that could qualify as well.

Antitrust attorneys are also keeping a close eye on accountable care organizations, as they could run afoul of the anti-kickback statute and the Stark Law, which prohibits a physician from referring Medicare and Medicaid patients to other entities in which the doctor has a financial interest.

But according to Susan DeSanti, director of the Office of Policy Planning at the Federal Trade Commission, nothing in the accountable care organizations, as they are defined in the health care law, is inconsistent with antitrust law.

"As with any competitor collaboration, the questions are whether the collaboration is integrated and whether it creates market power," DeSanti said, adding that the FTC will be monitoring the formation of the organizations closely.

The accountable care organization experiment is government-run, but private insurance companies will be watching the results. Several are ahead of the government in that regard and have already begun similar kinds of organizations, according to Ann Vickery of Hogan Lovells.

"If they can crack the organizational issues, my guess is that some of the private insurers would add this model to their own business plan," she said. "It's almost certain to happen, unless it's a disaster."

PPACA: Employer Mandate Provision

The PPACA's employer mandate doesn't go into effect until 2014, but there is sure to be a lot of debate surrounding this provision in 2011, according to Ken Yood of Sheppard Mullin Richter & Hampton LLP.

The mandate requires that businesses with more than 50 employees provide minimum essential health care benefits — which Yood said include ambulatory patient services, hospitalizations, maternity and newborn care, prescription drugs, rehabilitation, preventive care and dental and vision care — or else pay a penalty of $2,000 per employee.

Among the concerns around the mandate is that it incentivizes skirting health care coverage, because paying for a plan that covers the minimum essential benefits would inevitably cost more than the penalty, Yood said.

In 2011, the definition of an essential health benefit, and the amount of the penalty, could be changed, as regulators begin their rule writing, he said.

"People have the expectation that there will be more happening than just tinkering around the edges," Yood said.

Balanced Budget Act: Doctors' Reimbursement Rates

With one stopgap measure after another, Congress has delayed the cutbacks in Medicare and Medicaid physician reimbursement rates, written into the Balanced Budget Act of 1997, each year after the first decrease was made in 2002. The delayed cuts have accumulated each year, so that if they were to take effect now, rates would drop over 20 percent.

The cutbacks, though mandated under another law, have been brought to the forefront because of the health care reform debate, Berson said.

“Physicians would say that those reimbursement rates are way too low, but a lot of folks believe that if there’s going to be a fix to the skyrocketing deficit, that there will need to be cuts, and those include cuts to Social Security and Medicare,” Berson said.

Congress delayed the cuts five times in 2010, for weeks at a time, until finally passing a one-year extension that was signed into law by President Obama on Dec. 15.

Congress could continue to “limp along,” as Marion K. Goldberg of Winston & Strawn LLP said, but there’s pressure this year to finally deal with the issue and come up with a long-term resolution.

“They have to figure out what to do about doctors,” Goldberg said. “This has really soured a lot of the doctors.”

HITECH Act: Privacy Rules

The Health Information Technology for Economic and Clinical Health Act, which passed in 2009 as part of the stimulus bill, extended the privacy and security provisions of the Health Insurance Portability and Accountability Act to business associates of healthcare providers.

These associates now have to abide by all of the privacy and security requirements in HIPAA and are civilly and criminally liable if they fail to comply with the provisions.

The U.S. Department of Health and Human Services has proposed rules that would add patient safety organizations, health information organizations, e-prescribing gateways and vendors of personal health records to the list of business associates.

The proposed rules also include modifications to the privacy and security requirements, to enforcement of violations, and to notification procedures in the event of a security breach.

The comment period for the proposed changes ended in September. The department is in the process of considering comments and drafting the final rule, which should be published in the first quarter of 2011, according to a department spokesman.

According to Vickery, the proposed rules have generated a large number of comments, especially on how electronic medical records need to be protected.

"There's a good deal of controversy about aggregated data, which people do anonymize and then sell," she said. "People who are large data processors for prescriptions might be able to take data and take the names off and sell it to pharmaceutical companies who want to know who is buying what drugs and in what state."

Medical Malpractice Reform and Medical Price Transparency

With Republicans controlling the House in 2011, a medical malpractice reform bill will likely be introduced in 2011, according to Michelle Leeds, a public affairs adviser at Foley & Lardner LLP.

She said it would look much like malpractice reform bills that have been introduced in the past that would cap damages at $250,000, restrict attorneys’ fees, and set a three-year statute of limitations for filing malpractice suits.

Such a bill would certainly pass the House, although its chances wouldn't be good in the Senate, she said.

A bill mandating medical price transparency, however, will have a better shot, as it's a fairly bipartisan issue. Three bills requiring varying degrees of price transparency for health care providers circulated around the House in 2010, but stalled.

According to Leeds, the issue will likely come up again in the House Energy and Commerce Committee, where Michael Burgess, R-Texas, a physician who co-sponsored one of the 2010 bills, has strongly advocated for greater price transparency.