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Health Care Regulation To Watch In 2013

By **Rachel Slajda**

Law360, New York (January 01, 2013, 5:13 PM ET) -- With the bulk of the Affordable Care Act going into effect in 12 short months, health care attorneys will be busy preparing for an expected wave of regulations and guidance related to new health insurance exchanges, state Medicaid expansion policies, and other rules that could radically affect provider payments.

Here are the key regulations and policy initiatives to watch for in 2013.

Federally Facilitated Health Insurance Exchanges

In states that do not choose to build their own health insurance exchanges under the ACA, the law calls for the federal government to come in and build its own, known as a federally facilitated exchange. The administration of the federal exchanges, including how insurers are regulated and which benefits plans they must offer, will ultimately determine how affordable and attractive coverage is and, therefore, how many newly covered patients providers will have.

The federal government had been all but silent on the federal model, releasing just a few details in mid-December, and attorneys are eager to see how the details unfold.

"The federal exchange is a major question, how it's going to be managed, how it's going to be staffed. ... This is not something HHS has done before," said Stephen Weiner, chair of the health law practice at Mintz Levin Cohn Ferris Glovsky & Popeo PC.

Many states have said they won't provide a state-based exchange, and several states have delayed making a decision, citing the lack of details from HHS.

The details released in December touched on how the federal and state roles will be split, especially when it comes to insurance regulation, which is generally under the states' purview. HHS said the federal government will only be responsible for managing and certifying plans on its exchanges; states will still have oversight authority.

The agency admitted that it is still working through some other questions. For example, HHS said it was considering how to incorporate some existing state processes, like rate reviews, into the federally facilitated exchanges' certification of health plans.

Expanding Medicaid, State by State

A major concern for providers, especially hospitals, is how many states will expand Medicaid eligibility. The ACA called for Medicaid to be expanded to cover all adults making up to 133 percent of the federal poverty line, with the federal government picking up the entire tab for the first three years. But the Supreme Court's decision in June 2012 made it

so states can easily opt out of the expansion.

It's a troubling prospect for hospitals, who agreed to the ACA's multibillion-dollar cuts for disproportionate-share hospital payments in part because the expansion of Medicaid would balance out the cuts by lowering the hospitals' uncompensated care costs.

Several states have expressed interest in mounting a partial expansion of Medicaid. A common suggestion was expanding eligibility to 100 percent of the poverty line instead of 133 percent.

But CMS said in December that the higher matching rate, covering 100 percent of costs for the expanded population for the first three years, will not be available for partial expansions. States can apply for waivers to do partial expansions starting in 2017, when the match rate will begin to decline, and CMS will consider allowing partial expansions under that match rate, the agency said.

The agency has also given states the option to opt in to the expansion whenever they'd like, and to drop the expansion if they want to do so in the future. But the 100 percent matching rate will only be available through 2016, no matter when a state opts in.

Prescription Drug Coverage Requirements

The health care industry is also waiting to see how HHS finalizes the requirements for prescription drug coverage on the health exchanges, after a proposed rule released in late 2012 raised more questions than answers.

Earlier guidance from HHS said health plans would have to cover one drug per drug class to qualify, which prompted opposition from patient advocacy groups as well as the pharmaceutical industry.

In the proposed rule, however, HHS said health plans would have to cover one drug per class, or the same number of drugs covered in the benchmark plan, whichever is higher. Experts say the proposal is confusing and will need clarification from HHS.

The proposed rule is also unlikely to quell opposition from groups that wanted to see a requirement similar to that in Medicare Part D, where six classes of drugs — including antidepressants, seizure medications and antiretroviral drugs — are considered protected, meaning plans have to cover every drug in those classes.

The concern is that health plans could offer a low number of drugs in those classes, thereby discouraging people with related illnesses from signing up for their plans and ensuring a healthier population and more profit for their plans.

"In the absence of a Part D-like policy, people need to think if there are enough other protections in the proposed rule [to prevent discrimination based on health status]. The question is whether people think that's enough," said Thomas Gustafson, a senior policy advisor at Arnold & Porter LLP and 30-year veteran of HHS.

The Overpayment Rule and False Claims Act

A provision of the ACA called for providers to report and return overpayments to Medicare within 60 days of identifying the overpayments, or face potential False Claims Act liability. A proposed rule was released in February 2012, and providers are waiting to see what CMS does in the final rule.

There are a couple of areas of particular concern, attorneys say. One is the proposed rule's 10-year lookback period, which one expert at the time called a "bombshell." Under the

proposed rule, unreported potential overpayments can be a liability for an entire decade.

"Hospitals would like to think that income from 10 years ago is settled, but now it is potentially not," said Mark Polston, a partner at King & Spalding LLP and former deputy associate general counsel at CMS.

Another issue is how CMS will ultimately define the act of "identifying" an overpayment. In the proposed rule, CMS used language from the FCA, that willful disregard for information or deliberate ignorance could make a provider liable for the overpayment rule, Polston said.

"The CMS perspective is, this is an incentive for providers to exercise reasonable diligence. But the concern for providers is, what does that mean actually?" he said. It raises a lot of questions about when the 60-day clock may start. For example, Polston said, if a provider gets a hotline tip about possible fraud, does the clock start the day it got the tip?

And even though the rule hasn't been finalized, the ACA provision itself is in effect, noted Lawrence Vernaglia, chair of Foley & Lardner LLP's health care industry team. With three years since the law went into effect, Vernaglia said he expects that FCA claims based on the rule will soon surface.

Drugmaker Payments to Doctors

Another proposed ACA rule awaiting finalization is the physician payment sunshine rule, which will require pharmaceutical and device makers to publicly report most payments and gifts they give to doctors.

The rule has long been delayed, with the proposed rule released in December 2011. In May 2012, CMS said it would not begin requiring data collection until Jan. 1, 2013. In August 2012, several industry groups wrote to CMS urging it to release the final rule as soon as possible, saying they would need at least 180 days to prepare.

The final rule has been under White House review since late November, the last step before it is released to the public.

Doctors have expressed several concerns about the proposed rule, saying that there is not enough protection or recourse from false or misleading reports that could damage their reputations.

New Payment Calculations for Safety Net Hospitals

Disproportionate share hospital, or DSH, payments, are made by Medicare and Medicaid to help hospitals offset the costs of caring for poor and uninsured patients. Under the ACA, the payments are scheduled to be cut starting in fiscal year 2014, which begins in October 2013. Some of the cuts will be made up for by new payments that will be based on a hospital's DSH cuts, the change in the uninsured population and a hospital's uncompensated care costs.

Stephanie Webster, a partner with Akin Gump Strauss Hauer & Feld LLP, said hospitals should pay close attention for the rule, expected this summer, that will lay out the new calculations. It's especially important because under the ACA, the estimates used in the calculations will not be subject to either administrative or judicial review, she said.

"It makes it hard to hold the government accountable. There used to be the right to that kind of review in order to keep the government transparent," Webster said. "It makes it all the more important for DSH hospitals to pay really close attention to what CMS is doing."

The DSH payments, already complex, are tied into the Medicaid expansion. CMS officials have said that whether hospitals are in states that choose not to expand will factor into how the agency parcels out DSH payments.

There are also ongoing court cases dealing with DSH calculations that could affect the proposed rule. In one case, the D.C. District Court in November 2012 found that CMS engaged in bad rulemaking when changing the way DSH payments are calculated in 2004, and vacated the rule. Another, to be decided by the Supreme Court this year, deals with whether providers can appeal a payment decision past the 180-day deadline, if CMS hid information showing that the payments were too low.

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