

6 Health Policies A Gridlocked Congress Can Get Behind

By **Jeff Overley**

Law360, New York (March 29, 2013, 5:24 PM ET) -- At least 150 bills affecting the health care and life sciences industries have emerged on Capitol Hill this year, and while most are dead on arrival in a gridlocked Congress, there's a handful of high-profile measures that companies should watch closely, experts say.

Law360 spoke with attorneys to find out which items could cobble together majority votes despite Congress' having approved legislation at the lowest rate in more than 60 years, and six possibilities stood out.

Scrapping Medicare's Reviled Payment Formula

At least two bills have been introduced to do away with Medicare's so-called sustainable growth rate, which ties reimbursements to inflation but has rarely been enforced, leading to mounting financial liabilities for Uncle Sam.

While lawmakers have long wanted to scrap the formula, they got extra motivation to act when the Congressional Budget Office in February said repealing the SGR would carry a \$138 billion price tag, down from at least \$245 billion in its most recent previous estimate. The cost is unlikely ever to be more affordable, and so Congress has a strong incentive to bite the bullet and figure out a way to pay for the SGR's elimination, experts say.

"The consensus seems to be that [this] provides a real opening for a true replacement methodology, as opposed to just delay, delay, delay," said Bruce Merlin Fried, a health partner at SNR Denton, who pegged the odds of near-future action at 50–50. "[There's] certainly a better chance of a real fix than what we've seen in the past six or seven years."

A key hurdle is what payment model would take the place of the existing fee-for-service system. One bill would increase reimbursements over the next four years and test new payment methods aimed at moving the nation away from fee-for-service, but getting buy-ins from both lawmakers and doctors is easier said than done.

Martin A. Corry, head of public policy at Hooper Lundy & Bookman PC, agreed that prospects for repeal look more promising than ever, but cautioned that \$138 billion is "still not chicken feed," and said Congress probably won't act until it can strike a deal with the medical community on how to overhaul reimbursements.

“The cynic in me says we patch the hole each year until physicians [get on board],” Corry said.

Ditching the Medical Device Tax

The Affordable Care Act's 2.3 percent tax on medical device sales, which is expected to raise \$30 billion over the next decade and help bankroll the landmark law, appears to be in trouble following a symbolic 79–20 repeal vote last week in the Senate.

Stephen Paul Mahinka, chairman of the life sciences group at Morgan Lewis & Bockius LLP, said the tax's potential hindering of both economic recovery and development of lifesaving technology makes it “illustrative of the kind of legislation that could pass” despite stark ideological differences in Congress.

“If you have the combination of those two things ... you might be able to make forward motion,” Mahinka said.

Obstacles include the cost of repeal as well as the possibility that hospitals, health insurers and drug firms — all of which had to cough up cash to fund the ACA — would want to return to the negotiating table if the device sector gets a special break.

That said, the lopsided margin by which the nonbinding repeal vote succeeded signals that advocates have a real chance of killing the tax, Corry said.

“What is interesting is the size of the vote,” he said. “The people who are pushing this have done a good job of rallying support. I applaud them for that.”

Revisiting Exclusivity for Biologic Drugs

The ACA stipulated that brand-name biologic drugs get 12 years of exclusivity, and many observers think it's a settled issue, despite the White House's continued campaign to cut back the duration to seven years.

Nonetheless, Mahinka predicted the subject could re-emerge because it combines two areas of shared concern among Republicans and Democrats — namely, cutting costs and improving access to medicines.

The issue's revival is made more likely by looming debt ceiling talks that could send lawmakers scrambling to find some way to make the nation's long-term budget picture look rosier, something they might be able to accomplish by setting the stage for cheaper versions of pricey biologics to hit the market sooner.

“If you're looking around for things that might be potential [cost savers], you've got to look at that simply because it's an administration interest and it's a cost-reduction move,” Mahinka said.

Ramping Up Oversight of Compounding Pharmacies

Bacteria-laced drugs linked to a Massachusetts compounding pharmacy claimed dozens of lives last year, stirring demand for congressional action to better regulate the specialized field. While legislation has yet to emerge, U.S. Food and Drug Administration Commissioner Margaret Hamburg recently said senators are working behind the scenes on a bill, which she called essential.

“I firmly believe that new legislation is necessary to help FDA effectively oversee firms engaged in widespread distribution of sterile compounded drug products in advance of or without receiving a prescription,” Hamburg wrote in a March 22 blog post.

Considerable debate has surrounded whether the FDA simply needs to make better use of existing authority, but the agency's insistence on the need for legislation, and the absence of any particularly powerful lobby opposed to stronger oversight, makes action fairly likely, Mahinka said.

According to Fried, a final bill will probably aim to make clear the respective roles of state regulators, who oversee traditional compounding, and federal inspectors, who monitor compounders engaged in activity that resembles manufacturing.

"There needs to be a policy that clarifies what's permissible and where the responsibility lies," Fried said.

Boosting Ranks of Primary Care Providers as Millions Gain Health Coverage

The ACA could add nearly 30 million Americans to the ranks of the insured, potentially exacerbating a physician shortage, and a bill has been put forward to address the situation by increasing long-stagnant federal reimbursement for residency training.

Also, the U.S. Department of Health and Human Services last year committed \$200 million to train more advanced practice registered nurses, who some observers say can perform many of the functions of primary care physicians.

Fried said it's unclear whether the current Congress will tackle the matter, perhaps taking a wait-and-see approach after the ACA's coverage expansion goes into effect next year. But sooner or later, he said, there will have to be some sort of solution.

"People are still digesting the ACA — seeing what its impacts will be," Fried said. "But on a longer, mid-term basis, the country doesn't have a choice."

Confirming a Leader for Medicare and Medicaid

This item isn't a bill, but observers say Senate confirmation of Marilyn Tavenner as the first permanent chief of the Centers for Medicare and Medicaid Services since 2006 is among the health policies most likely to get bipartisan backing.

Tavenner has served as CMS' acting administrator since late 2011, and during that time, she's traversed the politically explosive gauntlet of health reform and spending on Medicare and Medicaid with the sort of apolitical tact that makes her palatable to both parties.

"She's regarded as competent. She has been a good steward," Corry said. "She's not been controversial, so I think she certainly has a chance."

That solid track record has won Tavenner a small army of allies, including the American Medical Association and the American Hospital Association, both of which have enthusiastically endorsed her confirmation.

In February, the seven living Senate-confirmed ex-heads of CMS wrote to congressional leaders to press for Tavenner's confirmation. Also, while it doesn't matter for vote-counting purposes, she has important political support from House Majority Leader Eric Cantor, R-Va., who got to know Tavenner during her stint running Virginia's Medicaid program and called her "eminently qualified" after her first nomination, which never came up for a vote.

Fried said that the “politics around [Tavener] are much easier” and that lawmakers from both sides believe a permanent leader will be better for the performance of Medicare and Medicaid.

“I think she's got a very good chance of being confirmed, and the agency really needs it,” Fried said. “The agency's been without a confirmed administrator for too many years, and that is not a good thing.”

--Editing by Andrew Park.

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