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PODCAST TRANSCRIPT

Health Care ▪ Life Sciences

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I am Al Cacozza, a partner in the Washington, D.C. office of Ropes & Gray, and a member of the firm's life sciences practice group. Joining me today is my Washington-based healthcare partner, Tom Bulleit to discuss the regulatory outlook for 2017 for healthcare and life sciences companies, especially with regard to actions by the Department of Health and Human Services.

This is part of the Capital Insights podcast series we are hosting to examine the issues and potential regulatory changes emanating from Washington, D.C. as we transition to a new federal administration.

The new administration has indicated it intends to "repeal and replace" the Affordable Care Act, so has Representative Tom Price, the President-Elect's designee for Secretary of HHS. But that may be easier said than done.

Tom, could you comment on how the new administration can actually accomplish this goal, and your sense of a realistic timeframe for such changes?

Tom: Well, Al, if I knew the answer to that, I wouldn't be practicing law for a living. I'd be looking for a private island to which to retire, and that's only partly a "flip" answer because, truly, President-Elect Trump hasn't given us very many clues about how he wants to repeal and replace the ACA/Obamacare. But there are some indications that his partnership with the Republican leadership and Congress, and his need for Democratic support for some of their ideas will prevent a simple slash and burn strategy.

First, the only parts of the ACA that can be repealed without 60 votes in the Senate are those with a budgetary impact. So, in essence, provisions relating to spending and revenue under the process of budget reconciliation, which requires only a majority, and the Republicans will hold 52 of 100 seats, they can get rid of the individual mandate, the medical device excise tax, the Cadillac tax on insurers. They can also get rid of the tax-supported subsidies that allow people to buy private insurance on the exchanges.

However, doing that will throw something like 20 million people out of health insurance. Neither the insurers, nor the hospitals, nor the drug and device makers, nor anyone else involved in the delivery of healthcare is going to like that. So, the "replace" part of repeal and replace calls for a strategy that will bring at least 8 Democratic Senators onboard. Mr. Trump has suggested that he wants to retain some of the popular parts of Obamacare, like kids staying on their parents' policies through age 26, and no denials for pre-existing conditions. But there are no real pay-fors for this.

Al: What's the latest news from Congress on this subject?

Tom: Current scuttlebutt on Capital Hill is to the effect that many people favor an immediate vote to repeal, with a delayed effective date to allow Congress to think up a solution. Solutions posed by Paul Ryan's "Better Way" Roadmap, and by Representative Price's Empowering Patients First Act, involve

selling insurance across state lines, which it is said would bring down prices by improving competition, making healthcare premiums 100% tax deductible, and expanding consumer choice through health savings accounts, and providing refundable tax credits. Most economists I've seen say this wouldn't come close to the amount of money needed to buy healthcare insurance at current prices, but the Republican response is this would bring prices down in the long run. Other healthcare economists suggests that this would throw markets into turmoil since they wouldn't have any idea what to expect, and Congress is not notable for following through on meeting the deadlines it sets for itself in controversial areas – HIPAA is an example of that. I suppose another possibility is a sense of the Congress resolution about repeal, and then the Congress rolling up their sleeves to come up with some replace.

There also isn't perfect agreement between Congressional Republicans, who favor turning Medicare into a premium support or a voucher program, and Democrats and Trump, who vowed to protect Medicare if he were elected. More likely is limiting the federal payment to states under Medicaid.

Al: Thanks Tom. One of the major trends occurring in healthcare is the shift from volume-based reimbursement, to so-called value-based payment, where payment is based on output and quality. HHS secretary-designate Price opposed some of CMS's mandatory value-based pricing programs as a member of Congress. What is the outlook for value-based pricing in 2017?

Tom: Value-based pricing or value-based payment is an idea that was popular with academics and in the private sector even before the Affordable Care Act. I think it's still seen as a way to bend the cost curve by shifting more of the risk to producing good outcomes to healthcare providers. The Republicans' roadmap from last summer, A Better Way, did not call for repealing the Medicare innovation center, which is where the value-based programs are coming from. So, that is some indication that Congress might not be enthusiastic about going straight to fee-for-service medicine. Private payers are offering programs like this. I recently read about one offered by United Healthcare on a voluntary basis. So, I'd say there would probably still be more, not less, value-based healthcare over the next decade regardless of what happens with the ACA.

I don't think the choice of Mr. Price, specifically for HHS Secretary, leads to the dismantling of value-based healthcare, but it may lead to a slow down. His Empowering Patients First Act would echo the approach of the Paul Ryan Better Way offering tax credits to allow the purchase of individual and family health insurance policies. Other similarities include more incentives for health saving accounts, state grants for high risk insurance pools, allowing the sale of insurance products across state lines, and "association health plans" to let unrelated businesses cover their members.

On value-based healthcare in particular, his criticism was of the CMMI's mandatory demonstration programs. Probably his history as an orthopedic surgeon made him particularly critical of the CJR joint replacement program. A similar program for cardiac care is due to begin in 2017. CMS recently announced that it won't proceed with a planned demonstration to apply value-based principles to physician administered drugs. But Price hasn't come out specifically against value-based purchasing as a principle, and my guess is that he won't put a stop to some experimentation with these kinds of programs. More of them might be voluntary, with financial incentives to participate rather than requirements.

Al: What can you tell us about Seema Verma, Mr. Trump's choice to head CMS?

Tom: Unlike past administrators I can think of, she comes from the Medicaid world, and she's also a consultant who has worked on Medicaid waiver programs. This is a place where I fully expect to see more reform that is on the order of the Ryan Better Way - block grants and waivers to allow states to run their own programs. Unlike Medicare, where there is political opposition to turning it into what Democrats call a voucher program, and the Republicans call premium support, Medicaid changes will not likely be forcefully opposed by Mr. Trump, who has pledged to protect Medicare. I don't recall Mr. Trump making such a promise about Medicaid, and with Verma in charge, I would expect more state experimentation under existing waiver authority, and block grant legislation that I'm not sure the Senate would filibuster.

Al: That's all the time we have for now. Thank you, Tom, for you insights, and thank you for listening. Please visit our newly launched Capital Insights page at www.ropesgray.com for additional news and analysis about noteworthy regulatory and enforcement issues.