

## Viewpoints

### ML Strategies Health Care Preview

WEEK OF FEBRUARY 4, 2019

The long-awaited [safe harbor proposed](#) rule was published last week as the Administration looks to get out in front of the drug pricing debate that is sure to shape the 116<sup>th</sup> Congress. Under the proposed rule, rebates offered by manufacturers to Part D plans, Medicaid managed care organizations (MCO), and pharmacy benefit managers (PBM) [would not receive safe harbor protection](#) under the Anti-Kickback Statute. Additionally, it would create a new safe harbor for prescription drug discounts offered directly to patients, as well as fixed fee service arrangements between drug manufacturers and PBMs.

The real life effect of the proposal on lowering out-of-pocket costs for prescription drugs remains unclear. HHS ran a [number of projections](#) that found anywhere from an 8 to 22 percent increase in premiums for patients not in low-income subsidized plans. The proposal was largely [met with skepticism](#) from key Democrats who would like to see the government take more direct action on manufactures lower prices.

Of note, Democrats in both chambers are preparing investigations into various practices of drug manufacturers. Senator Bernie Sanders is reportedly eyeing price hikes by Catalyst Pharmaceuticals. Sanders [requested the company](#) answer 16 questions by February 18<sup>th</sup>. House Democrats, led by E&C Chairman Frank Pallone and Rep. Diana DeGette, who chairs the E&C Oversight Subcommittee, requested information from Eli Lilly regarding access and the cost of insulin. Additionally, House Oversight Committee Chairman, Elijah Cummings, [sent letters to a dozen manufacturers](#) requesting detailed information about their pricing practices. As both parties dive into drug pricing proposals and investigations, it's important to monitor the nuances within each proposal and what proposals, if any, have broad support.

#### **TEXAS vs. AZAR**

California and 16 other states, along with the Administration, have requested that the Texas v. Azar case, which in December ruled the Affordable Care Act unconstitutional, be expedited to bring the case before the Fifth Circuit Court of Appeals by July 2019. Expediting the case could mean a case before the Supreme Court sometime in 2020, ensuring health care will remain atop the legislative and political agenda for the foreseeable future, especially as we enter the 2020 election cycle.

#### **THIS WEEK IN THE HOUSE**

[E&C Health Subcommittee](#) – “Hearing on Texas v. U.S.: The Republican Lawsuit and Its Impacts on Americans with pre-Existing Conditions.” (Wednesday, 2/6, @ 10:15am)

[Education and Labor Committee](#)

– “Examining Threats to Workers with Preexisting Conditions.”

(Wednesday, 2/6, @ 10:15am)

[Committee on Appropriations](#) –

“Oversight Hearing: Impact of the Administration’s Policies Affecting the ACA.”

(Wednesday, 2/6, @ 10:00am)

#### **THIS WEEK IN THE SENATE**

[HELP](#) – “How Primary Care Affects Health Care Costs and Outcomes.” (Tuesday, 2/5, @ 10am)

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