Lame Duck: Clin Labs, Telehealth, Specialists & VBC Win

Dialysis Help May Not Materialize

As the House and Senate final outcome is largely known, lame duck activities start in earnest. Here is the updated list of provisions that may pass by Dec 16, 2022.

Likely in Lame Duck

- **One year extension of telehealth**. We think that one year post PHE is likely given telehealth's importance and utility gleaned during COVID.

- **One year value-based care MACRA bonus**. Congress passed MACRA in 2015 as a solution to the yearly physician SGR payment adjustments, which consists of a 5% advanced alternative payment model path for providers or the MIPS quality reporting program. Funding for the AAPM 5% bonus expires at the end of 2022 and costs about $600 M per year to extend the program. Hospital, physician and specialty groups are advocating for a 1-to-2-year extension.

- **Some clinical lab relief is likely to pass by year-end, but it is less likely to be the SALSA Act and more likely to be a one year delay**. The SALSA Act has wide bipartisan support, in both the Senate and House by Sens. Brown (D-OH) and Burr (R-NC), along with Reps. Bill Pascrell (D-NJ), Scott Peters (D-CA), Richard Hudson (R-NC), Gus Bilirakis (R-FL) and Kurt Schrader (D-OR). The SALSA Act score is about $6 B, which is an untenable score for year-end policies. With a mixed Congress post mid-terms, we do not see major policy passing during the lame duck session of Congress. A more likely scenario is PAMA delay. A one year delay saves ~ $780 M. Given the savings score, we see higher odds of passage, along with a commitment to work on SALSA/permanency more generally in the next Congress.

- **Specialist physician pay restoration (partial) from the physician fee schedule.** As finalized by the Physician Fee Schedule (2023) rule included a 4.42% payment adjustment for many clinicians. There is a push by hospitals and some physician groups to delay of the cut, estimated to cost $6 B for one year, or mitigate the reduction to something closer to 2.5%.

- **R&D amortization impacts MedTech, Biopharma.** Healthcare and non HC companies have ased lawmakers to repeal a change in the tax code that requires businesses to spread their R&Dcosts over five years rather than deduct them immediately. But under a provision of the 2017 TCJA that took effect this year, R&D expenses must be amortized over five years domestically and 15 years for international costs.

Possibilities in Lame Duck

- **The dialysis (DVA, FMS) industry was dealt a blow by the Supreme Court in June 2022 and may not see relief if the score is a cost**. In a 7-2 ruling the Court held that the Marietta Plan coverage terms do not violate the statute because those terms apply uniformly to all covered individuals (same coverage for those with end stage renal disease and those without). A recently introduced bill would obligate health plans to cover dialysis the same way they do treatments for

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other chronic illnesses and would increase reimbursement. It would also impact a multibillion-dollar line item in the Medicare budget, but could cost up to $8 B, which is not attractive to lawmakers.

- **Mental health reform**. Low-to-no score policies may make it at year end. However we view 2-3 behavioral health packages as passing over the next 1-2 years. The Senate finance committee is taking the lead with bipartisan work groups, and the topic is a bipartisan priority area.

- **Both VALID Act and PREVENT Pandemics Act stalled in 2022 despite passage in the Senate HELP committee earlier this year**. We noted previously that either bill could pass in the end of the year package as a tribute to the retiring Richard Burr (R- NC), ranking member in Senate HELP. Recall that VALID Act would regulate laboratory-developed tests and in vitro diagnostics and would adopt a risk-based framework that would require premarket FDA review for high-risk tests. PREVENT Pandemics Act aims to counter future pandemics by providing funding for supply chain reform and government stockpiles, modernizing FDA's infrastructure, establishing a new federal office for pandemic preparedness, and improving collection of public health data.

- **FDA riders (AA reform, clinical trial diversity, generic flexibilities, rare disease provisions) are expected to come back**. Several FDA riders are expected to be revisited in the end of the year package. These include provisions for accelerated approval reform which allows the FDA to require post-approval studies, provisions to improve clinical trial diversity including improving access to decentralized trials, provisions to change the proposed labeling requirements for generics, and provisions to clarify orphan designations which became restricted following the SC's decision on *Catalyst Pharms., Inc. v. Becerra.*

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