CAPITOL STREET

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Clinical Lab Pay Relief Via SALSA Loses Steam

2-Year Delay Likely As New FDA LDT Pathway On Deck

Relevant Companies

Our Take & Next Up

We view a 1- or 2- year PAMA delay as more likely than SALSA passage, a win for clinical labs in the near-term. The CBO score of SALSA may be cost prohibitive in this environment, but a delay once again would save money as labs look to fight another day. Diagnostic test regulation is on deck this fall, after the *VALID Act* has failed to be passed into law in 2022, and half-heartedly reintroduced in early 2023. The FDA has repeatedly publicly noted its intent to regulate diagnostic tests, and we find the oncology CDx pilot program to be antithetical to the messaging from FDA leadership in public commentary of the last couple of years. Our take on the likely regulatory approach can be found below.

Key Points

We believe that clinical lab reform (SALSA Act) is unlikely by year-end, and rather a 1- or 2-year delay appears to be the most likely outcome. A delay saves dollars while SALSA has a $3-4 B score (cost) which is unattractive in this budget environment. SALSA has bipartisan support, in both the Senate and House by Sen. Brown (D-OH) along with Reps. Pascrell (D-NJ), Peters (D-CA), Hudson (R-NC), Bilirakis (R-FL) and Schrader (D-OR). If history is any guide, Congress will likely provide a fix in the end of the year Medicare bill ahead of Christmas.

ACLA and NILA lead laboratories in advocating for SALSA passage. See here and here. SALSA would decrease budget cuts to the clinical lab industry, addressing PAMA's data reporting, which has proven to be a crucial part of America's public health, especially during the COVID pandemic.

SALSA was drafted to fix the "inaccurate representation" of the market which led to large Medicare cuts to clinical laboratories. PAMA called for CMS to set prices for laboratory tests based on private payor rates so that Medicare would

decrease spending. However, this excluded reference labs which had higher reimbursement rates leading to lower Medicare Clinical Laboratory Fee Schedule (CLFS).

Key SALSA Provisions – reintroduced in both chambers in March 2023

- Establish a representative pool of samples for all widely available tests (tests whose Medicare reimbursement rate is under $1,000 and amount of laboratories who receive payments for this test should exceed 100). Data collection aims to decrease the burden on laboratories and CMS while correcting current below market Medicare rates (starting Jan 1, 2026).
- Prior to each year of data collection, a list of widely available clinical diagnostic laboratory tests must be published to the Federal Register and applicable laboratories required to submit info must be notified. This may be burdensome for CMS.
- Increase of the length between data collection from every 3 years to every 4 years after March 2027. This will further decrease the burden of data collection and increase stability of CLFS.
- Exclude Medicaid managed care rates as they tend to skew the rates downward and not reflect the market.
- Option to exclude manual remittance. This includes physically mailed in payments if they do not exceed 10% of laboratory claims.
- Limitations on annual payment reductions starting January 1, 2024 (0% decrease cap for 2024, 2.5% cap for 2025, and for 2026 and each year following, 5% cap). Implement cap on payment increases (2.5% for 2024 and 2025, 3.75% for 2026 and 2027, and 5% for 2028 and each year following).

Current deadline for Congress intervention is Jan 1, 2024. As a reminder, the *Consolidated Appropriations Act,* passed in December 2022, delayed PAMA payment reductions and Clinical Laboratory Fee Schedule (CLFS) reporting requirements until 2024. In 2018 when PAMA was implemented, it was initially projected by CBO to be $2.5 B in cuts to reimbursement rates over 10 years. However, there has been $4 B in cuts in just three years. PAMA has been delayed several times, but without congressional intervention is said to bring additional cuts as much as 15% starting January 1. These cuts are said to be $600M initially and could rise to $1.5B annually. At this current rate, the cuts could reach $13 B which is three times the amount initially projected.

LDT NEW FDA PATHWAY

We expect the FDA to debut a Laboratory-Developed Test (LDT) regulatory pathway as soon as October 2023. A legislative solution, the *VALID Act*, which was spearheaded by the Senate, is unlikely to pass this year due to disagreements over the right pathway and ongoing funding fights. The FDA has publicly stated for months that without Congressional action the agency will regulate LDTs.

Lawsuits abound if the FDA oversteps, so we think it could be no more than a high-risk test designation. However, some expect that the guidance could simply place LDTs under in-vitro diagnostics to be regulated under medical devices or lay a complex process for LDTs, mirroring the discussion paper released in 2017.

Stakeholders have asked the FDA to issue a Request for Information (RFI) prior to releasing any guidance to assess the impact on academic medical facilities and community labs. Upon final rule release, a lawsuit challenge would not be unexpected if the rules overstep. Major issues remain on whether FDA has the legal standing to regulate LDTs and FDA's ability to enforce any oversight. As a reminder, there are an estimated 160,000 genetic tests available which is one type of LDTs. FDA may be underestimating the resources needed and the industry impact of LDT regulation.

Earlier this year, the FDA launched an oncology pilot program that placed certain companion in vitro diagnostic tests under a CLIA-like framework (creating a policy contradiction). The use of companion diagnostics has increased with the growth of targeted therapies, particularly in oncology. The FDA pilot, launched in June 2023, aims to publish minimum performance standards for a companion diagnostic (CDx) based on performance during the drug product's pivotal clinical trial

and allow diagnostic labs to offer CDx without FDA approval if Clinical Laboratory Improvement Amendment (CLIA) standards are met. This pilot is contradictory to the FDA's concerns that oncology treatment diagnostics are high-risk due to its nature of deciding care, and their assertion that these high-risk tests should face greater oversight than CLIA. FDA intends to accept up to nine Center for Drug Evaluation and Research (CDER)-regulated oncology drug products with companion diagnostics.

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