April 3, 2023

Clinical Lab Bill (SALSA Act) Reintroduced

SALSA Could Pass 4Q 2023; VALID Faces Uphill Battle As FDA Moves Ahead

Relevant Companies

Although the SALSA and VALID Acts did not make the cut in the 2022 year-end spending package, both pieces of legislation were re-introduced last week. We see the potential for SALSA to pass into law this year; if the score is acceptable, with another PAMA delay potentially being in the cards. While VALID faces longer odds, FDA intends to regulate on its own. See below for details.

⋙ Our Take & Next Up

We expect that the SALSA Act has potential to be passed by 4Q 2023, if the CBO score is acceptable (In 2022, it was scored around $6B cost over ten). We await a formal CBO score. See text of this memo for SALSA bill updates (versus 2022 version). NOTE: we could also see a PAMA delay, as that has happened about 4x already. VALID Act would have to go through the House Energy & Commerce Committee, and full house chamber. FDA guidance on diagnostics regulation is expected this year, separate from any action on VALID, as FDA intends to regulate these types of tests (LDTs), with or without Congress.

Pandemic bill (PAHPA) could be a legislative vehicle for SALSA Act (Fall 2023). *The Pandemic and All Hazards Preparedness Act* (PAHPA) provisions (here), expire at the end of the current FY (September 30, 2023). PAHPA is a major life science priority as it funds the Biomedical Advanced Research and Development Authority (BARDA), which support medical countermeasure and technology development during public health emergencies. In the House, Energy and Commerce Committee Member Rep. Hudson (R-NC) and Health subcommittee ranking member Eshoo (D-CA) released a Request for Information (RFI) on priorities for the PAHPA reauthorization.

⋙ Key Points

SALSA ACT

***Saving Access to Laboratory Services Act* (SALSA), a positive for clinical labs, was re-introduced this week.** The bill was introduced by Sens. Brown (D-OH) and Tillis (R-NC), along with Reps. Hudson (R-NC), Pascrell, Jr. (D-NJ), Bilirakis (R-FL), Peters (D-

CA), and Brian Fitzpatrick (R-PA. It has bipartisan & bicameral widespread support.

The SALSA Act fixes the 'inaccurate representation of the market', which led to large Medicare cuts to clinical laboratories. Key SALSA provisions are outlined below:

- Establish representative pool of samples for all widely available tests (tests whose (1) Medicare reimbursement rate is under $1,000 and (2) number of laboratories paid for tests exceed 100). Aims to decrease administrative burden on laboratories and CMS while correcting current below-market Medicare rates.
- Each year of data collection, a list of widely available clinical diagnostic laboratory tests must be published to the Federal Register.
- Increase of the length between data collection from every 3 years to every 4 years. This will decrease data collection burdens and increase CLFS payment stability.
- Exclude MA rates as they tend to not reflect the market and skew rates downward.
- Option to exclude manual remittance. This includes physically mailed in payments if they do not exceed 10% of laboratory claims.
- Implement limitations on annual payment reductions

SALSA's ~$6 B prior score is likely to be *lower* this time around, which helps odds of passage in 2023. The CBO back-of-the-envelope cost of the bill was $6 B in 2022, but cosponsors are working to bring this estimate down.

About PAMA & need for action by 2024. At the time PAMA was enacted, the Congressional Budget Office (CBO) projected $2.5 B in cuts to reimbursement rates over 10 years. However, PAMA has already led to nearly $4 B in payment cuts to laboratories after three years of reductions. PAMA of 2014 called for CMS to set prices for laboratory tests based on median private payer rates so that Medicare would decrease spending. However, the formula excluded labs that had higher reimbursement rates, leading to lower Medicare Clinical Laboratory Fee Schedule (CLFS) payments. Absent Congressional intervention, payment for about 800 tests will be cut up to 15% on January 1, 2024. Also, according to the Medicare Payment Advisory Commission, independent labs were overrepresented while hospital and physician office labs were underrepresented.

VALID ACT -- FDA TO REGULATE

VALID Act, a bill to regulate diagnostics via FDA, was also reintroduced last week. *Verifying Accurate, Leading-edge IVCT Development (VALID) Act* sets up a risk-based system for FDA oversight of IVCTs starting in 2027 or 2028 (here).

Academic medical centers would be included in the regulatory pathway. A premarket, abbreviated premarket, and supplemental application review and approval process are outlined in the bill. It also allows for several mitigating measures (appropriate labeling, performance testing, and role of professionals) which lowers oversight and benefits manufacturers and exemptions including exemptions including humanitarian exemptions, high-complexity grandfathered tests, low-risk IVCTs, low-volume IVCTs, and modified IVCTs.

Recall VALID Act was excluded from 2022 year-end spending package but remains on the horizon. We are watching the House Committee on Energy and Commerce, whose new chair is Rep. Cathy McMorris Rodgers (R-WA). While McMorris Rodgers was rumored to be the reason the bill did not pass, she committed to lawmakers holding a hearing on the bill. We are looking out for the regular order of events, with a hearing followed by a markup.

Importantly, FDA wants to regulate diagnostic tests (LDT) even without VALID passage. With another delay of the VALID Act in 2022, FDA is gearing up to enact regulatory oversight via guidance. At the March 1 ACLA annual meeting, FDA representative Elizabeth Hillebrenner, CDRH, echoed the FDA Commissioner's comments earlier this year that the agency will create guidance on diagnostics to ensure there is a minimum standard for tests. The rulemaking is likely to be on all diagnostic tests "regardless of where they are made."

⋙ Background

In the past, clinical labs have received fixes in Congressional legislation in years past: (1) Consolidated Appropriations Act, 2019, (2) Coronavirus Aid, Relief, and Economic Security (CARES) Act - Laboratory Access for Beneficiaries (LAB) Act, year-end spending bill,

2020, (3) another delay to PAMA cuts, 2021 (4) Dec 22 omnibus extended PAMA delay for two years.

Key SALSA provisions are outlined below:

Establish representative pool of samples for all widely available tests (tests whose (1) Medicare reimbursement rate is under $1,000 and (2) number of laboratories paid for tests exceed 100). Aims to decrease administrative burden on laboratories and CMS while correcting current below-market Medicare rates (starting on or after Jan 1, 2027).
Each year of data collection, a list of widely available clinical diagnostic laboratory tests must be published to the Federal Register, which may burden CMS.

- Increase of the length between data collection from every 3 years to every 4 years. This will decrease data collection burdens and increase CLFS payment stability.
- Exclude MA rates as they tend to not reflect the market and skew rates downward.
- Option to exclude manual remittance. This includes physically mailed in payments if they do not exceed 10% of laboratory claims.
- Implement limitations on annual payment reductions (0% decrease cap for 2024, 2.5% cap for 2025, and 5% cap for 2026 and each year following).
- Implement cap on payment increases (2.5% for 2024 and 2025, 3.75% for 2026 and 2027, and 5% for each year following).

Two clinical lab advocacy groups, American Clinical Laboratory Association (ACLA) and National Independent Laboratory Association (NILA) lead laboratories in advocating for SALSA passage. Read ACLA's statement here and NILA's statement here. SALSA would decrease reimbursement cuts to the clinical lab industry, which has been a crucial part of America's public health response, during the COVID-19 pandemic and monkeypox.

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