CAPITOL STREET

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Final FDA LDT Rule Hits White House Review

Class 3 to 2 Downregulated Test List & Congress Updates (SALSA Act, AI)

Relevant Companies

Our Take & Next Up

LDT rules are under review (here) at The White House budget office, and we believe if finalized as proposed lawsuits will ensure. FDA officials at the ACLA conference (here) yesterday did not discuss the pending rules but Center for Devices (CDRH) leadership has committed to final rules. Other interesting factoids can be found below on SALSA Act priorities in 2024, PAMA data requirements for FY 2026, as well as Congressional updates (1) Sen Cassidy (R-LA) released a RFI on LDTs and (2) Diagnostic Congressional House hearing likely to shine the light on FDA rules to regulate LDTs as medical devices.

Key Points

The FDA is moving forward in down-classifying several in vitro diagnostics (IVDs) from class III to class II. As a reminder, the FDA expects most future companion diagnostic and infectious disease IVDs to be regulated as class II devices, even if they are novel and require *de novo* classification. Specific tests that are currently moving through this process include:

- Nucleic acid and serology-based IVDs for hepatitis B virus (HBV) infection
- Serology-based IVDs to aid in detection of human parvovirus B19
- Cell-mediated immune reactivity IVDs to aid in the identification of in vitro responses to peptide antigens that are associated with Mycobacterium tuberculosis infection and/or use as detection of effector T cells that respond to stimulation by M. tuberculosis agents
- Fluorescence in situ hybridization (FISH) test to diagnose certain cancers.

Congress weighs in ahead of LDT final pathway for regulation as a medical device. Two things to note below:

- **1- HELP Ranking member Cassidy (R-LA) has issued a request for information on lab developed tests (LDTs).** Dr. Cassidy has had various topics of interest over the last two years and in fact has requested reams of comments on the topics of: cell & gene therapy, dual eligibles, AI and 340B.
- **2- House Energy & Commerce Committee will dive into diagnostic regulatory pathway oversight Thurs 3/21 (here).** House Energy & Commerce (Chair McMorris Rodgers, R-WA) has held pro MedTech

and pro innovation hearings in the past and they plan to take the issue up again in 2024. On March 21, the E&C Subcommittee on Health will host a hearing on diagnostic regulations and specifically on the FDA's proposed rule (here). We believe that Congress is trying to pressure FDA on LDT rules, potentially hearkening back to the VALID Act type language from Congress (Senate). VALID is considered to be more palatable to industry versus the current framework proposed by CMS in late 2023. Our LDT rule analysis is here.

On clinical lab reimbursement, CMS leaders reminded the audience that 2019 median rates will inform 2026 reimbursement. PAMA delays have been a constant in DC; with delays to data reporting for about a decade (5 - 6 delays total). Given government savings for delay, SALSA passage may be difficult to do.

SALSA Act (Helpful for LH DHX) is ACLA's top policy priority. The American Clinical Lab Association is pushing permanent reforms to PAMA (here). We believe that unless the CBO score comes down (from ~ $5 B or so) the law may not cross the finish line. Still there is time between now and the lame duck session of Congress to garner support, establish media campaigns to ensure bill passage.

Recap of key SALSA provisions – reintroduced in both chambers in March 2023 (if enacted key start dates would be pushed back by a year).

- 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 exceeding 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 in 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 (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).

AI usage in clinical lab workflow is drawing increased scrutiny & attention from lab developers and regulators. AI is being used across the clinical testing space including decision making on which services to be used by providers and streamlining clinical lab procedures and workflow (a benefit in light of workforce shortages). With increased adoption, federal regulators are also increasing oversight on AI in health. Senate Finance held a hearing last month on AI in healthcare; Chair Wyden (D-OR) pushed for additional guardrails around usage (here).

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