

# CAPITOL STREET

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## Trump Likely to Abolish Certain Biden-Era Rules

LIFO Is The Rule Here: MedTech, Diagnostics & Nursing Home Relief

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**The incoming Trump administration is expected to undo several significant executive orders and regulations that were set by the Biden admin.** Major policies that will likely be targeted first include the FDA's final laboratory developed test (LDT) rules and the nursing home staffing requirements. The outlook for other Biden era efforts, including Transitional Coverage for Emerging Technologies (TCET), remain unclear at this time, but we could see a pull back of the evidence development plan and evidence generation requirement (closer to a Medicare Coverage of Innovative Technologies (MCIT)). Other expected "day one" Trump non-healthcare priorities include Cabinet appointees and personnel changes, immigration, pardoning Jan. 6 offenders, U.S. withdrawal from the Paris Climate Agreement, and potential tariffs on imported goods.

### »» Key Points

**The FDA's LDT rules are likely scrapped; enforcement discretion will continue for labs.** As a reminder, the FDA intended to regulate Laboratory-Developed Tests (LDTs) as medical devices. The agency planned to phase out its general enforcement discretion approach for LDTs over 4 years (proposed premarket review start in late 2027/2028) so that diagnostics manufactured by a laboratory will fall under the same enforcement approach as other In vitro diagnostics (IVD). The rule was economically "significant" with a primary estimate of \$1.3 B in costs to FDA/industry.

- **The *VALID* Act may be back on the table.** Congress may address *VALID*, which creates a risk-based framework for the premarket, abbreviated premarket, and supplemental application review and approval of tests, provides certain exemptions, and describes a technology certification pathway for moderate-risk in vitro clinical tests (IVCTs) to be certified to offer multiple tests using the same technology. The bill was in play in 2021/2022 along with Cures 2.0 for inclusion with the user fee FDA reauthorization bill, but failed to pass partly due to opposition from academic medical centers (as they did not have a carve-out).
- **Senate *HELP* future Chairman Cassidy's (R-LA) version of the LDT framework is also potentially in the works.** Sen. Cassidy is supposedly drafting his own version of diagnostic oversight. Earlier this year, he released an RFI on FDA's current regulatory framework for diagnostics, and CLIA's (Clinical Laboratory Improvement Amendments) framework for LDTs.

**The nursing home staffing rules will likely evaporate (generates savings of \$22 B over 10).** Earlier this year, CMS finalized the nursing home staffing mandate, with few changes from the proposal. The staffing mandates were a result of a Biden [executive order](#) that intended to address cases of neglect at skilled nursing facilities during COVID-19. The rules are highly controversial due to the lack of clinical staff, and the negative financial and administrative impact on hospitals and facilities. We expect the Trump administration to rescind the rule next year (we note that rules have gone into effect, but major reforms start 2026/2027). The savings also make it an attractive target as the Trump [administration](#) looks to cut government costs. A House bill which prohibits implementation of the staffing rules had [estimated](#) savings of \$22 B over 10.

- **The rule would have required 24/7 onsite RN coverage and to meet minimum staffing standards for RNs and NAs.** There was also a requirement for total nurse staffing where facilities must also ensure registered nurses work a certain number of hours per day based on the number of residents. The final rule [estimates](#) the total cost over 10 years will be \$43 B with an average annual cost of \$4.3 B. See our past analysis [here](#).
- **CMS allowed a 5-year phase-in for rural facilities and 3 years for non-rural facilities.**
  - Phase 1: Enhanced facility assessment requirements, which go into effect 90 days after the publication date of the final rule for both urban and rural sites.
  - Phase 2: RN must be onsite 24/7 AND facilities must meet the 3.48 HPRD total nurse staffing requirement two years after final rule release for urban facilities, three years for rural.
  - Phase 3: Minimum staffing requirement of 0.55 and 2.45 HPRD for RNs and NAs, respectively, three years after publication for urban, five years for rural.

**TCET's fate is unclear, but replacement with Medicare Coverage of Innovative Technologies (MCIT) is possible.** CMS [finalized](#) the TCET pathway in August, outlining coverage for certain FDA-designated Breakthrough Devices (see our analysis [here](#)). CMS maintained the five (5) TCET candidate limit on breakthrough (BT) devices per year and the exclusion of diagnostic laboratory tests. It is possible that the Trump administration may retain TCET for ease of implementation. However, a replacement with the old Trump era, MCIT is also a possibility. We could see Trump administration taking issue with the 5 device limitations and the significant coverage with evidence development requirements which were not seen in MCIT.

- **MCIT was a Trump era CMS coverage rule that provided Medicare coverage for any breakthrough medical devices.** The rule stemmed from a Trump Executive Order (EO) relating to breakthrough therapy devices and was [repealed](#) by the Biden administration in 2021. The pathway was voluntary and provided automatic, immediate coverage for 4 years for breakthrough-designated devices. This was considered unprecedented for medical technology manufacturers in the cardiac, orthopedic and other spaces.
  - **Earlier this year, legislation that mirrors MCIT passed out of House Ways and Means committee.** The [Ensuring Patient Access to Critical Breakthrough Products Act](#), a bill that requires Medicare to temporarily cover all FDA approved, breakthrough medical devices for four years, starting on the day of approval. The bill has not yet been scored by CBO on costs and there is no Senate companion bill at this time.
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