Legislative Update

AMDM Focus Meeting

October 20, 2022

Diagnostics Regulatory Reform

History

- 2014 FDA Draft Guidance explaining intent to end broad enforcement discretion and actively assert medical device authorities over LDTs.
- ACLA litigation threat
- 21st Century Cures white paper calling for feedback on establishing diagnostics-specific statutory framework for IVDs and LDTs
- Congressional hearings with FDA, CMS/CLIA, and stakeholders
- Multiple legislative iterations released or introduced since, mostly recently as the VALID Act by Senators Richard Burr (R-NC) and Michael Bennet (D-CO) and Reps. Larry Bucshon (R-IN) and Diana DeGette (D-CO)
- Amended version of the VALID Act passed out of the Senate HELP Committee in July

2022 VALID Overview

- Establishes a new regulatory category of products under FDA jurisdiction, separate and distinct from medical devices, known as "in vitro clinical tests" (IVCTs), that would include IVDs and LDTs.

- The level of regulation – including the type of FDA review required, if any, before an IVCT can be offered for clinical use – depends on the test's:
  - Risk classification (high-risk, moderate-risk, low-risk);
  - When it was first offered;
  - Whether and to what extent it has since been modified; and
  - If it is subject to certain exemptions from premarket review and/or other regulatory requirements under VALID.

- Intended to supplement and not overlap CLIA as it relates to tests developed in labs.

Key Provisions

Premarket Review

- Only high-risk tests would be subject to a full PMA-style review where the developer would need to establish the analytical and clinical validity of the test in an application that must include specified data and information.
- Low-risk tests are exempt from premarket review (as are other tests subject to certain exemptions).
- Moderate-risk tests (including those that would be high-risk but mitigating measures are established and able to be applied to sufficiently mitigate such risk but are not sufficient for the test to be considered low-risk) would be subject to an abbreviated application *or* could be eligible for a voluntary alternative pathway known as "technology certification".

Technology Certification

- Developers can seek a "tech cert" order, in lieu of individual applications, that would allow multiple moderate-risk IVCTs that utilize the same underlying technology (e.g., flow cytometry, NGS, etc.) to be offered based on the analytical and clinical validity of one representative IVCT established in the application.

Key Provisions

Exemptions from premarket review

- *Rare disease tests* – intended for diagnosing disease or condition that affects not more than 10,000 individuals in U.S.
- *Custom tests* – performed for not more than 5 patients per year in a CLIA-certified high-complexity lab or to diagnose a unique pathology of specific patients for which no other IVCT is commercially available.
- *Manual tests* – output of which is result of direct observation without automated instrumentation or software needed for intermediate or final interpretation.
- *Public health surveillance tests* – intended solely for surveillance and not for use in making clinical decisions for individual patients
- *General laboratory equipment*
- *Preanalytical instruments*
- *Investigational use tests*
- *Grandfathered tests…*

Key Provisions

Grandfathered tests

- An LDT is exempt from premarket review and other requirements (though would still need to be listed with FDA) if:
  - It was first offered for clinical use before the date of enactment;
  - It was developed by and is performed within the same CLIA-certified high-complexity lab;
  - It is offered with an order from an authorized person;
  - It is not for use with home specimen collection; and
  - It is not significantly modified by its developer after the date of enactment.
- For grandfathered tests – or other tests exempt from premarket review – if FDA identifies specific scientific concerns with an IVCT based on credible information that there is insufficient valid scientific evidence to support that the test is analytically or clinically valid, FDA may initiate an information request process that could lead to submission requirement and/or removal from the market.

Key Provisions

Regulatory transition

- FDA required to hold several public meetings and issue final guidance and regulations within 3 years of enactment (day bill signed into law). There is a delayed effective date of 5 years after date of enactment.
- Prior to the effective date, applications will be submitted pursuant to the device authorities.
- For tests first offered by a CLIA lab after the date of enactment but before the effective date, for which premarket review or tech cert is required, a developer can continue to offer such tests until FDA completes the requisite review so long as such application is submitted no later than 90 days after the effective date.
- Further, a CLIA lab can continue to offer tests after the effective date absent FDA review if the test has been approved by the New York State Department of Health (2 years post-effective date for non-molecular tests and 5 years post-effective date for molecular tests)

VALID Outlook

Politics

- Support: FDA, patient groups, IVD manufacturers, some large reference labs
- Vocal opposition: academic medical centers (AMCs), some in the pathology community

Process

- In June, the House passed legislation that reauthorized FDA's user fee programs (e.g., MDUFA) and included a number of other FDA-related policies, though no VALID.
- The Senate HELP Committee marked up and passed a different user fee package in July, which did include an amended version of VALID. The HELP package did not reach the Senate floor.
- Ultimately it was a "clean reauthorization" that was added to government funding bill signed into law in late September – no policy riders included, large or small.

VALID Outlook

Process (cont.)

- HELP made significant changes to assuage AMC concerns, though not enough to halt an amendment offered by Senator Tommy Tuberville (R-AL) that would have carved AMCs and their broadly defined affiliates out of VALID. While it was defeated, every Republican other than Ranking Member Burr supported it.
- These issues will need to be resolved over the coming month or so in a manner that makes VALID a viable candidate for inclusion on the last legislative train leaving the station in December.
- The November elections will inform scope of this package.

Prognosis

- Steep hill to climb in a very short time.
- FDA would likely need to change the labs' calculus. Life under device regs or life under VALID? Rulemaking?
- If not this year, unlikely to happen in its entirety anytime soon (HELP dynamic, Congressional makeup)
- Piecemeal approach still viable (e.g., "tech cert" bill)

Other Relevant Legislation

Regulatory

- Predetermined change control plans
  - Codify FDA authority to approve such plans submitted by device and diagnostics manufacturers for future modifications without the need for supplemental applications.
- CLIA Waiver/De Novo dual submission
  - Allow developers of at-home tests with an EUA to submit a CLIA waiver request and de novo submission together

Reimbursement

- *Saving Access to Laboratory Services Act (SALSA)*
  - Would reform how Medicare reimburses labs for clinical testing services. Unlikely to move this year, though a patch to stave off lower reimbursement rates for some duration of time is feasible.