Clinical Diagnostic Reform

Developing a Regulatory Framework to Support Clinical Innovation

Key Highlights

- Developing a comprehensive approach to diagnostic reform – one that fosters innovative care delivery – is vital to our ability to tackle the most challenging and complex health needs of the country.
- Meaningful reforms must balance federal oversight with support for cutting-edge innovations and should account for distinct differences between laboratory developed tests (LDTs) and in vitro diagnostics (IVDs).
- *The Verifying Accurate, Leading-Edge IVCT Development (VALID) Act* outlines a new regulatory framework for LDTs and IVDs. While many of the draft's provisions would provide a more modernized approach to diagnostic regulation, some provisions would have significant unintended consequences on patients' access to new and groundbreaking diagnostics.

Advancing Clinical Diagnostics for Patients

With more than nine billion clinical laboratory tests performed in the U.S. every year[i], there is broad recognition around the need for a modernized regulatory framework to support advancing innovations in laboratory and diagnostic services. Meaningful reforms must balance federal oversight with support for cutting-edge innovations and should account for distinct differences between laboratory developed tests (LDTs) and in vitro diagnostics (IVDs).

While IVDs are medical devices that test blood or tissue in order to detect diseases or other health conditions, LDTs are processes developed within and performed by individual laboratories, providing patients with efficient and reliable early diagnoses for rare and complex conditions. In many cases, LDTs are developed in response to unmet clinical needs and are essential to the evolving health care delivery system, paving the way for a new era of highly-tailored medicine.

LDTs exist in many forms – whether genomic tests or simple blood chemistry tests – and play a pivotal role in understanding and managing patient health. For example, recent scientific innovations now allow for targeted tumor-sequencing tests on any tumor – regardless of where a cancer initiated, allowing providers to assess whether a tumor is susceptible or responsive to certain medicines.

To ensure patients continue to benefit from these personalized tests when necessary, the call for comprehensive reforms is both critical and urgent. While ACLA fully supports regulatory reforms for LDTs, it is essential that these tests are not subjected to the same regulatory requirements as medical devices – a step that would fundamentally undermine the purpose and intent of these lifesaving diagnostics. Any new framework to regulate LDTs must be implemented by an authority with diagnostic expertise (such as a diagnostic-specific center within the Food & Drug Administration) and not an authority otherwise charged with medical device or other medical product regulation.

Working Together to Advance Comprehensive Reforms

Building on continued efforts to ensure patients have access to groundbreaking clinical diagnostics, federal policymakers recently introduced several key proposals to advance diagnostic reform. This latest discussion draft, *The Verifying Accurate, Leading-Edge IVCT Development (VALID) Act,* outlines a new regulatory framework for LDTs and IVDs. While many of the draft's provisions would provide a more modernized approach to diagnostic regulation, some provisions would have significant unintended consequences on patients' access to new and groundbreaking diagnostics.

With certain improvements, the *VALID* Act can create a modernized, risk-based model for federal review that accounts for the full range of tests and diagnostics coming to market. A new framework should include:

- Continued recognition of diagnostics as distinct services that require their own regulatory framework for review, rather than being forced into existing and conflicting regulatory frameworks designed specifically for medical devices;
- Inclusion of "grandfathering" and clear transition policies to ensure patients who depend on currently available clinical laboratory services retain access to them;
- A flexible modification policy to exempt many common changes to existing and grandfathered tests from premarket submission absent a meaningful clinical impact; and
- The right regulatory balance to ensure that patients can rely on and have access to innovative and lifesaving tests when they need them while also maintaining the regulatory oversight necessary to ensure the accuracy and reliability of the tests.

[i] *Laboratory Economics* from CMS CLIA database (March 31, 2017).