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Northern Virginia Health Policy Forum: The Future of Diagnostic Testing

Since their introduction and expanded use throughout the twentieth century, medical diagnostics have typically been defined as tests to aid in the detection or diagnosis of a disease. The basic definition of diagnostics is changing to include not only what they can tell us about disease, but also what they can tell us about wellness.

In 2023, we need to look no further than our wrists to monitor our heart rate, blood pressure, glucose levels, or other minute-to-minute measurements that will either satisfy our curiosity or warn us of serious threats to our health. At the same time, researchers are exploring innovative new approaches, such as blood-based biomarkers, to develop and speed new ways to discover and treat potentially devastating conditions, including Alzheimer's disease and cancer. This rapid innovation has prompted government agencies to examine their approach to potentially regulating the field of diagnostics.

In late September, the Food and Drug Administration (FDA) issued a proposed rule that would extend its oversight of in vitro diagnostics (IVDs) to laboratory developed tests (LDTs). The proposed rule is now undergoing a comment period. Questions remain regarding ensuring accessible and affordable access to novel diagnostic tools while simultaneously sustaining incentives for the companies investing in their development.

Two experts joined the Northern Virginia Health Policy Forum (NVHPF) on Tuesday, October 24, 2023, to discuss proposed options for a path forward. They are:

- Zach Rothstein, Executive Director for AdvaMedDx, an association that represents over 70 manufacturers of in vitro diagnostic tests and works to advance policies to expand innovation and access to quality testing.
- Anna Scrimenti, Associate Director of Public Policy and Advocacy for the Association for Molecular Pathology (AMP), which represents nearly 3,000 medical diagnostics professionals and provides expertise in molecular testing driving patient care.

Below is a summary of the key issues the participants identified. A complete transcript and video summary available on the NVHPF website.

Mr. Rothstein first defined IVDs at the most basic level, where tests are performed on human samples. "These are typically blood or tissue samples that are taken from the human body. We've all had them done. It's what you have done at the doctor's office. It's what hospitals rely on as well . . . and these tests ultimately inform the diagnosis of the disease."

Mr. Rothstein continued, offering his differentiation between IVDs and LDTs. "An LDT is, from a practical perspective, the exact same thing, but from a regulatory perspective at FDA, they are developed and used within a single laboratory. So rather than a commercially developed test that's distributed and then used within a third-party laboratory, these are the tests that labs have developed typically on their own maybe using material from the commercial suppliers. And then they go through a process to bring them to the physicians that they serve in their practices."

The two organizations the NVHPF panelists represented then detailed their different approaches to increased FDA regulation. Mr. Rothstein described the FDA's proposed rule as an extension of what is already the accepted approach. "This proposed rule . . . is laying out what is an update in its policy for how it wants to regulate LDTs . . . Since the seventies, FDA has actually not enforced its regulatory authorities over the LDT community, meaning the FDA medical device regulations were not applied to LDT products. FDA has decided that it no longer wants to follow its old policy. And instead, it wants to update its treatment of LDTs to bring them under FDA's traditional medical device regulations. And it would basically subject LDTs to the same FDA pre-market and post-market requirements that the IVD community currently goes through."

Ms. Scrimenti countered that the FDA's proposed rule is unnecessary because of regulations already in place, its negative impact on patients' access to care, and the unacceptable administrative and financial burdens it would impose on providers. "The rule has quite a few duplicative requirements that are already regulated under the Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments of 1988, also known as CLIA . . . Our members are already having to enforce clear requirements in their labs, such as establishing performance specifications and quality systems, conducting proficiency testing, undergoing inspections, and then correcting and reporting laboratory errors. They're already doing that. And so, if the FDA rule were to be finalized, this would duplicate all of that."

Ms. Scrimenti then noted that the proposed rule would exacerbate workforce shortages. "Many of our members, especially at small and medium sized labs, would have to consolidate their testing menus to very minimal amounts of tests and/or face closure, which would significantly disrupt patient access to care . . . it would also create gaps in care for those with rare diseases and other conditions if the proposed rule was finalized."

The two panelists also commented on legislation that would create a risk-based framework for in vitro clinical test (IVCT) regulation. The Verifying Accurate, Leading-edge IVCT Development (VALID) Act did not pass Congress this past year, but it has since been reintroduced. Mr. Rothstein praised the bill, saying it would subject LDTs "to at least some type of FDA oversight" and it "creates a modernized regulatory environment for diagnostic tests" that currently go through FDA's regulatory process. Mr. Rothstein said that all diagnostic test makers would benefit from this approach.

Ms. Scrimenti offered what AMP sees as a better alternative, i.e., modernizing the regulatory systems that are already in place. Ms. Scrimenti later detailed what AMP sees as essential differences between LDTs and IVDs. "Laboratory develop testing procedures are testing services that hospitals, academic, and clinical labs develop and use in patient care. So, AMP refers to LDTs actually as laboratory develop testing procedures, or LDPs . . . because we feel that best reflects the services that are being provided . . . Our members are health professionals practicing lab medicine, and LDPs are an integral part of the care that they provide to the patients."

Ms. Scrimenti described why these differences, as promoted by AMP, should lead to separate regulatory approaches. "LDPs are not boxed and shipped medical devices, but they're designed, develop, validated, performed, and interpreted by board certified professionals within a single laboratory. And conversely, IVD test kits are more plug and play systems that are massively produced and distributed to customers who are independent from the company that manufactured them. One key distinguishing feature is the role that the professional plays in every single aspect of LDP development, validation, and performance, which greatly reduces risk because molecular pathology professionals have to understand every detail of the services they're providing."

Both panelists supported the Saving Access for Laboratory Services Act (SALSA) which, as the name implies, is designed to protect reimbursement for laboratory tests. Without this legislation, AMP estimates a 15 percent cut in reimbursement for these services. However, as Ms. Scrimenti pointed out, the bill has little chance to pass this year. "It has a high cost associated with it. And so, until the Congressional Budget Office works to lower that score, it's unfortunately not as feasible as a legislative option, at least this Congress. But we are looking forward to its passage. Hopefully soon."

Both panelists predicted that when the FDA releases its final rule, it will be the target of legal action with the potential to be appealed to the Supreme Court.

Ms. Scrimenti closed with a warning on behalf of AMP. "If finalized, the FDA proposed rule would have an incredible upheaval in our healthcare system at large because it

would limit patient access to clinical tests and disrupt the innovation of laboratory develop testing procedures."

The final word from Mr. Rothstein, "The VALID Act is the better way to go."

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This summary was prepared by the Applied Policy® team of health policy experts.