AT THE FOREFRONT
UChicago Medicine

Clinical Laboratories

To: Medical Staff, House Staff, Patient Care Centers, and Outpatient Clinics

From: Jeremy Segal, MD PhD, Medical Director of Molecular Diagnostic Testing
Melissa Pessin MD PhD, CLIA Medical Director of Hyde Park Clinical Laboratories
Daniel Arber, MD, Chair, Department of Pathology

Date: 4/30/2024

Subject: Minimal Initial Impact of FDA Regulation of Laboratory Developed Testing at University of Chicago Clinical Laboratories

---

Effective Date: 4/30/2024

Today, the Food and Drug Administration (FDA) finalized a long-expected rule for oversight of laboratory developed tests (LDTs). LDTs are performed at UCM and at most academic and commercial laboratories across the country, as they are a critical mechanism to offer state-of-the-art testing for patients when FDA-approved platforms are not available or are impractical. They also allow the use of tests where FDA studies have not been done on select patient populations such as pediatrics, or on fluid types that were not included in the FDA approved studies.

There are a few important things to know about the new rule and its potential impact on care services at UCM.

- There is no immediate impact on the availability of testing currently performed today.
- Per the FDA, all existing LDTs (including those at UCM) will be grandfathered under the new rule, meaning that we will not lose access to any tests that currently exist today in the LDT formal.
- FDA will also continue to offer enforcement discretion to tests manufactured and performed by a lab within a healthcare system "to meet an unmet need of patients receiving care within the same healthcare system when an FDA-authorized test is not available", indicating that UCM will retain the ability to innovate and offer up-to-date biomarker testing that follows the latest science.
- The rule will be phased in over 4 years, giving us time to adapt to the changing requirements.

Given that the FDA's justification for this rule rests on potentially questionable legal grounds, we anticipate that there will be legal challenges to this rule, and that this issue will ultimately play out in the courts and in Congress over the next several years. During that time, please trust that we are doing our best adapt to the new requirements and to develop strategies to continue to offer the most up-to-date testing possible for our patients here at UCM.

Questions: If there are any further questions at this time, please contact:

Jeremy Segal at jsegal5@uchicagomedicine.org or
Melissa Pessin at pessinm@bsd.uchicago.edu