FDA and CMS Announce Joint Task Force on LDTs

Increased Oversight of Laboratory-Developed Tests Coming Soon to a Lab Near You

Alan G. Minsk, Alan K. Parver and Cathy Fortney

The U.S. Food and Drug Administration recently announced the formation of an interagency task force with the Centers for Medicare and Medicaid Services (CMS) to address issues relating to the regulation of laboratory-developed tests (LDTs). The announcement follows the issuance of draft guidance by FDA in October 2014 that provides a basic framework for increased oversight of LDTs. The draft guidance, "*Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories*," sets the groundwork for the FDA to step up its oversight of LDTs. The announcement of the task force signals the beginning of a collaborative effort by FDA and CMS to develop LDT oversight and regulation policies that are designed to increase patient safety and implement a registration and adverse event reporting system that would apply to all LDTs. The reporting system will have a particular emphasis on those LDTs that pose either a moderate or high rate of risk to the patient, while preserving patient access to low-risk LDTs currently in use today. AGG prepared a Bulletin on the FDA's LDT draft guidance, which can be accessed here[1].

The proposal issued in October was based on feedback received at a 2010 FDA public meeting and other venues. FDA officials indicated that, based on the information they received, stakeholders recommended a risk-based, phased-in approach that would both support continued innovation and patient access and provide the appropriate protections that are essential as modern LDTs have become more complex and widely available. FDA hosted a two-day public meeting in January 2015 to discuss the proposed framework, chaired by Dr. Jeffrey Shuren, Director of the Centers for Devices and Radiological Health, and Katie Serrano, Deputy Director and Acting Director for the Division of Chemistry and Toxicology Devices in the office of In Vitro Diagnostics and Radiological Health. In his opening remarks, Dr. Shuren said that the need for FDA oversight of LDTs has been a topic of discussion for the past 20 years. He said that, beginning in the 1990s and going into the 2000s, the Department of Energy, the National Institutes of Health, two different advisory committees to the Secretary of Health and Human Services, as well as the Institute of Medicine, have each recommended additional oversight of LDTs and identified the FDA as the agency to provide such oversight.

Both CMS and FDA have regulatory authority over LDTs: FDA oversees the quality end, and CMS regulates labs through the Clinical Laboratory Improvement Amendments (CLIA). Each agency plays an important role in ensuring quality laboratory testing. FDA categorizes tests based on their complexity, reviews requests for waivers, and develops rules and guidance for CLIA complexity categorization. CMS is responsible for issuing laboratory certificates, collecting user fees and conducting inspections and enforcing regulatory compliance. In addition, CMS handles approvals of private accreditation organizations for performing inspections, approvals of state exemptions, monitoring of laboratory performance on proficiency testing (PT) and approvals of PT programs.

FDA has the authority to regulate all laboratory tests, and while LDTs are and have been subject to FDA's regulatory authority, the agency has typically exercised enforcement discretion with such products. In its recent draft guidance, FDA proposed a framework for regulatory oversight of LDTs that will impose registration and listing requirements, medical device reporting requirements, and the imposition of premarket review requirements and quality system regulation requirements for

1 http://www.agg.com/latest-developments-on-fda-regulation-of-laboratory-developed-tests-10-28-2014

certain LDTs. FDA and CMS will work together to expand the collaborative effort to streamline the oversight process and work to build in quality control systems for LDTs that have been classified as moderate or high-risk LDTs.

The task force will focus primarily on three areas:

1. Identifying areas of similarity between the FDA quality system regulations and requirements under CLIA;
2. Clarifying responsibilities for laboratories that fall under the jurisdiction of both agencies; and
3. Leveraging joint resources to avoid duplication and to maximize efficiency.

The proposal has received mixed reviews from stakeholders. While most agree that revolutionary advances in biotechnology have changed how LDTs are developed and used today, some are concerned that the proposal and the imposition of new regulatory listing and reporting requirements could curtail the development and use of certain LDTs, and some are calling for continued broad enforcement discretion. FDA officials emphasize that the intention of these requirements is to provide a mechanism by which FDA and device manufacturers can identify and monitor significant adverse events so that problems can be detected and corrected in a timely manner. Ms. Serrano said in her remarks that FDA believes that this is a significant risk mitigation strategy for LTDs, particularly those that will remain under enforcement discretion for premarket and quality system review requirements.

Congress is clearly paying attention. Senator Michael Bennett (D-CO), in a letter dated April 23, 2015 to Dr. Stephen Ostroff, Acting FDA Commissioner, lauded FDA's leadership and commitment to the advancement of regulatory science, but also cautioned that, in the case of LDTs, the agency should: *"promote both transparency and clarity on the scope of FDA's regulatory reach… As the FDA moves to implement additional oversight of LDTs, I would urge the Administration to evaluate and clearly articulate the effect this ruling might have on both medical innovation and patient access to precise, timely and dependable in vitro diagnostic services. This should serve not only to provide guidance to regulated entities, but assurances to manufacturers of those products that FDA does not believe fall within the scope of their risk-based approach."*

FDA is inviting public comment on the proposal, which may be sent to LDTFramework@fda.hhs.gov. No implementation will begin prior to publication of final guidance documents, expected to be released in the summer of 2015.

Authors and Contributors

Alan G. Minsk
Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

Alan K. Parver
Partner, DC Office
202.677.4900
alan.parver@agg.com

Cathy Fortney
Legislative Assistant, DC Office
202.677.4956
cathy.fortney@agg.com

not *if*, but *how*.®

About Arnall Golden Gregory LLP

Arnall Golden Gregory, a law firm with more than 150 attorneys in Atlanta and Washington, DC, employs a "business sensibility" approach, developing a deep understanding of each client's industry and situation in order to find a customized, cost-sensitive solution, and then continuing to help them stay one step ahead. Selected for The National Law Journal's prestigious 2013 Midsize Hot List, the firm offers corporate, litigation and regulatory services for numerous industries, including healthcare, life sciences, global logistics and transportation, real estate, food distribution, financial services, franchising, consumer products and services, information services, energy and manufacturing. AGG subscribes to the belief "not if, but how.®" Visit www.agg.com.

Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
Suite 1000
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: **http://www.agg.com/subscribe/**