



Supporting Public Health and Innovation Through Timely, High Quality Tests: Precertification for Diagnostics February 2019

AdvaMedDx, a Division of the Advanced Medical Technology Association (AdvaMed), applauds Congress for its leadership in advancing critical reform to the regulatory framework for all diagnostics. The diagnostics industry is a cornerstone of today's health care system with rapid advances for patients paving the way for more personalized, targeted patient care. FDA and numerous stakeholders have embraced the concept of "precertification" as a modernized regulatory approach that accommodates the rapid rate of change for novel technologies while maintaining the highest standard for ensuring analytical and clinically valid tests for patients.

AdvaMedDx supports precertification as part of a diagnostics reform framework that achieves the goal of protecting public health and facilitates the development of cutting edge diagnostics. We have specifically commented on the precertification proposal that FDA offered in its technical assistance on the Diagnostic Accuracy and Innovation Act (DAIA). Any diagnostics precertification framework must reflect the following elements:

- **Broad Availability:** The precertification pathway should be available to all test developers on a voluntary basis, ranging from diagnostics companies to independent laboratories and academic medical centers, as long as they are able to demonstrate appropriate quality systems and procedures that will provide a reasonable assurance of clinical and analytical validity for specified test technologies.
- **Flexible Approach:** Precertification should be broadly available to a wide range of test types. The kinds of tests eligible for the program, and the scope of a precertification that FDA will grant, should not be unnecessarily limited in statute. The scope of a precertification should be dictated primarily by the range of validation that a sponsor can demonstrate to FDA. Furthermore, the program should be capable of accommodating rapidly evolving diagnostic technologies and expanding as FDA and stakeholders gain experience with the best approaches to precertification.
- **Efficiency and Predictability:** In order to be effective and to be fully utilized by developers, the precertification program must apply least burdensome principles, provide for timely FDA review of applications, cover an appropriate time period (ideally 3 years or more), and facilitate a streamlined renewal process for precertified developers. The information provided about the developer and the developer's test methods and procedures must be appropriately tailored to demonstrating the basis for precertification and the scope of eligible test technologies. Moreover, FDA should leverage third parties and recognized accrediting bodies and promote global harmonization, such as leveraging of existing standards, wherever possible.

- Rigorous Oversight: Based on the eligibility criteria for the developer and the information supporting precertification for the test technologies included, FDA's precertification process and resulting approval decision should constitute an approval for the tests within the scope of the precertification.
- Transparency: Even under a robust legislative framework, the precertification program will require significant implementation by FDA, and the program will need to evolve along with the continuing innovation in diagnostics. It will be essential that all stakeholders have the opportunity for appropriate input into the agency's development of standards, criteria, and procedures for the program, including developer and test eligibility, timelines, mitigating measures, and renewals.

A well-designed precertification regulatory framework would advance public health by providing FDA a tailored mechanism for regulatory oversight, regardless of developer. We welcome continued dialogue to ensure that this new framework will be optimally suited for FDA to oversee a wide range of developers and the full range of test technologies.