Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2020
Comprehensive Summary - April 24, 2020

Introduction

On March 5, 2020, The "Verifying Accurate Leading-Edge IVCT Development Act" (VALID Act) was introduced in Congress. The VALID Act seeks to modernize U.S. Food and Drug Administration (FDA) oversight of in vitro diagnostics (IVDs) and laboratory developed tests (LDTs) by creating a single, diagnostics-specific, FDA regulatory framework aimed at promoting innovation and improving patient and public health. The framework aims to assure that in vitro clinical tests on the market provide a reasonable assurance of analytical and clinical validity. Although some of the bill language requires clarification, below is a section-by-section summary of the bill's key provisions. This summary is not all-inclusive, and the provisions in the bill will impact each company differently.

Section 2. Definitions (amending current FDCA Definitions section 201)	• Defines "in vitro clinical test" (IVCT) to **include both laboratory developed tests (LDTs) and traditional in vitro diagnostics (IVDs).** • Specifically included as IVCTs: tests, test protocols, test platforms, articles for taking or deriving specimens from the human body, and software (except software excluded from the definition of a medical device) that are intended to be used in the collection, preparation, analysis, or in vitro clinical examination of specimens taken or derived from the human body for the purpose of: identifying, diagnosing, screening, measuring, detecting, predicting, prognosing, analyzing, or monitoring a disease or condition; or selecting, monitoring, or informing therapy or treatment for a disease or condition. • The definition of IVCT does not include: certain IVCT components, including blood, blood components, or human cells or tissues; certain articles used for invasive sampling; laboratory equipment; and personal protective equipment. • Makes conforming changes to the definitions of "drug" and "biological product."
Section 3: Regulation of In Vitro Clinical Tests (New FDCA Subchapter J)	
Adding FDCA Section 587: Definitions *Note: "Adding" indicates the section would be a new section added to the Food, Drug, and Cosmetic Act.*	• Defines relevant terms used throughout the remainder of the subchapter, including: Analytical Validity, Applicable Standard, Clinical Use, Clinical Validity, Cross-Referenced Test, Develop, Developer, First of a Kind, High-Risk, Indications for Use, Instrument, Instrument Family, Laboratory Operations, Low-Risk, Mitigating Measures, Specimen Receptacle, Technology, Test, Valid Scientific Evidence, and Well-Characterized. • Analytical Validity for IVCTs is defined as an IVCT's ability to identify, measure, calculate, or analyze the test's targets, or assist in such efforts. For articles for taking or deriving human specimens, analytical validity means that it performs as intended and will support the analytical validity of an IVCT with which it is used.

	• Applicable Standard is defined as a reasonable assurance of analytical and clinical validity for most IVCTs. For test instruments, it means a reasonable assurance of only analytical validity. For articles for taking/deriving specimens, it means both analytical and clinical validity, as well as safety, where applicable. • Clinical Validity is defined as an IVCT's ability to achieve its intended use, as set forth in the definition of IVCT. • First of a Kind is defined as an IVCT with both a different intended use and indications for use than any legally marketed IVCT. • High-Risk IVCTs are those for which undetected inaccurate results would present potential unreasonable risk for serious or irreversible harm or death to patients, or serious harm to the public health; or is potentially likely to result in the absence, delay, or discontinuation of life-supporting or -sustaining treatment. Excluded from the definition of high-risk IVCTs are those for which mitigating measures are sufficient to mitigate these risks. • Low-Risk IVCTs are those for which undetected inaccurate results would cause minimal, no, or non-life threatening (or immediately or medically reversible) harm or disability, or only a remote risk of adverse patient or public health impact. Low-risk IVCTs include those for which mitigating measures are sufficient to ensure that they are low-risk. • Mitigating Measures are defined as requirements determined by FDA to be necessary for an IVCT or category of IVCTs to meet their applicable standard (generally, to provide a reasonable assurance of analytical and clinical validity) or to mitigate risk of harm from an inaccurate result or misinterpretation of results. These may cover labeling, advertising performance standards, performance testing, clinical studies, submission of clinical data, user comprehension studies, postmarket studies, training, and conformance to standards. • Technology is defined as a developer's grouping of IVCTs that do not significantly differ in control mechanisms, energy sources, or operating principals and for which design, development, and manufacturing, including analytical and clinical validation as applicable, of the tests would be addressed similarly. The definition also provides examples of technologies, such as immunoassay, mass spectrometry, and next generation sequencing.
Adding FDCA Section 587A: Applicability	• This section describes the scope of the law, including the types of tests that may be exempt from premarket review under the regulatory framework.

	• Includes an interstate commerce provision,[1] pursuant to which any IVCT offered for clinical use in the U.S. is deemed to be introduced into interstate commerce.
	• A provision specific to laboratories and blood and tissue establishments provides that the framework will not change or modify the Clinical Laboratory Improvement Amendments (CLIA) program or regulatory authority applicable to blood and tissue facilities regulated under sections 351 and 361 of the Public Health Service Act.
	• Provides that the framework will not limit or interfere with the practice of medicine.
	• Provides conditions for emergency use, which would allow CLIA labs, in the event of a public health emergency, to use a test pending submission of an emergency use authorization, if certain other conditions are met (validation, notification, and labeling).
	• Outlines the types of IVCTs that generally will not require a premarket submission:
	  ○ Components and parts, if intended for further development (or will otherwise be regulated based on its risk when used as intended);
	  ○ Grandfathered tests (except for any for which FDA exercises "clawback" authority, discussed below). The provision sets forth circumstances and criteria for exemption, including that the test be first offered for clinical use before the date of enactment, that it qualifies as an LDT under the VALID criteria, and that it carries a labeling disclaimer, and that the test not be modified;
	  ○ Tests exempt from 510(k), if offered before the date of enactment, or if not offered before the date of enactment, were exempt from 510(k) as of the date of enactment (except that instruments are not exempt from review);
	  ○ Low-risk tests;
	  ○ Manual tests designed, manufactured, and used within a single laboratory that are not high-risk or otherwise meet particular conditions, and are not intended for testing blood or tissue donors or recipients;
	  ○ Tests for humanitarian use, if they meet the definition in the subsection and the developer maintains documentation, which must be made available to FDA upon request. Cross-referenced tests for humanitarian use must submit a request for informal feedback pursuant to section 587H to be eligible for the exemption;
	  ○ Custom tests and low-volume tests, if they meet the definition in the subsection and the developer maintains documentation, which must be made available to FDA upon request.

[1] VALID Act, Section 587A(a)(1)(B).

	The developer must also inform FDA annually (in a manner to be prescribed by guidance) that the test was introduced into interstate commerce; ○ Tests intended to be used solely for public health surveillance activities; ○ Tests intended to be used solely in forensic analysis, law enforcement activities, or for employment purposes; ○ IVCTs under a Technology Certification order (discussed in more detail below); and ○ IVCTs for investigational use. • FDA is directed to issue guidance within 1 year of enactment indicating categories of point-of-care (near-patient) testing that could be exempt under VALID. • General laboratory equipment is not subject to the requirements of this subchapter. • Contains a provision on instrument families, pursuant to which if premarket approval under section 587B(d) of one version of the instrument is obtained, then previous and updated versions within the same instrument family will be deemed to be subject to the approval (unless FDA issues guidance determining otherwise). • Clarifies the types of changes to premarket tests that can be made without additional FDA review. ○ Certain changes are considered modifications that render an IVCT a new test subject to FDA review: modifications that affect analytical validity or clinical validity, modifications that cause the test to no longer comply with mitigating measures, or modifications that affect the safety of a specimen collection article. ○ Certain changes are modifications, but are nevertheless exempt from review: certain software updates, modifications made pursuant to a change protocol, certain labeling changes, and specimen-related modifications made to extend specimen stability. • If a modification is made to an IVCT developed by another person that qualifies for exemption from review, the modification is exempt if it is documented, and such documentation is provided to FDA upon request. Contains a provision on the transfer or sale or IVCTs, pursuant to which the transferee or purchaser becomes the test developer and assumes all applicable regulatory obligations. Transfers or sales of premarket approval and technology certifications are subject to additional criteria, including notice to FDA. • Despite the aforementioned exemptions from premarket review, FDA also has "clawback authority" (deemed a "Special Rule"[2]) for most exempt tests, based on lack of valid scientific evidence to support analytical or clinical validity, deceptive claims, or a reasonable possibility the IVCT will cause serious adverse health consequences.

[2] *Id.* Section 587A(a)(4).

	○ The clawback provision includes a process whereby FDA can request information from the IVCT developer, and provides for continued marketing for clinical use during FDA's review of the response. ○ FDA may issue an order to cease distribution, which triggers an opportunity for an informal hearing for the person subject to the order. ○ FDA also has authority, if necessary, to issue an order to cease distribution.
Adding FDCA Section 587B: Premarket Review	• Details the premarket review and approval process, including the process for amendments, supplements, appeals, and withdrawals of approvals. • Allows for pre-submission meetings or requests for informal feedback pursuant to section 587H to discuss eligibility of an IVCT for premarket review or other information related to filing of an application. • Clarifies that a premarket application may also be used as a representative test for a technology certification, as a way of streamlining applications. • Details the content of applications and other requirements for "full" premarket review as well as "special" premarket review. ○ Raw data is required to be included in a "full" premarket review application. ○ The special premarket approval pathway is available for eligible tests, including test instruments, specimen receptacles, and tests that would otherwise be eligible for review under a technology certification order. ○ Special premarket review does not require raw data unless specifically requested by FDA. ○ Special premarket applications are not subject to preapproval inspection unless specifically requested by FDA. • Outlines the information required in a premarket application for an IVCT (including information demonstrating compliance with any mitigating measures or recognized standards), designed to ensure that the test meets the standards of analytical and clinical validity necessary for marketing. • Directs FDA to issue guidance for premarket and special premarket applications. • Sets forth the process and timelines for FDA action on applications for premarket approval. ○ Full Application: FDA is directed to take action not later than 90 calendar days after a full premarket application is accepted. ○ Special Application: FDA is directed to take action not later than 60 calendar days after a special premarket application is accepted. • With some exceptions, FDA pre-approval of a supplement is required before implementing certain modifications to an approved test. Modifications that fall within an exception must generally be reported to FDA.

	• Change protocols may be adjusted by simply submitting a supplement. • Requires developers of approved IVCTs to submit an annual report to FDA on their IVCTs. • Authorizes FDA to withdraw approval of an approved application (within 10 days after providing due notice and opportunity for informal hearing to the application holder) if FDA finds that the grounds for approval are no longer met, or there is a reasonable likelihood that the test would cause death or serious adverse health consequences. FDA is directed to publish the order on the website, with some exclusions (including for commercial confidential information or trade secrets). Prior to withdrawing approval, FDA may also by order temporarily suspend an application. • Directs FDA to consider the least burdensome means necessary to provide a reasonable assurance of analytical and clinical validity, or applicable standard, and other regulatory requirements.
Adding FDCA Section 587C: Breakthrough In Vitro Clinical Tests	• Breakthrough designation would allow for priority review of, and increased interaction with FDA staff and senior management regarding, IVCTs meeting specific eligibility requirements. • This section is built on the medical device breakthrough designation, with the same tools and 60-day timeline. • Breakthrough designation provisions apply to all review pathways for IVCTs. • FDA is directed to issue guidance within one year of enactment.

Adding FDCA Section 587D: Technology Certification	• Details the process for technology certification review by FDA (formerly referred to as "Precertification").
	  ○ Technology certification allows for IVCT developers to submit a representative test to be reviewed by FDA, along with an assessment of the developer's methods and procedures. FDA will review the processes and procedures related to the design of the test, as well as the clinical and non-clinical data utilized in designing the test.
	  ○ If the technology certification is approved, a developer can use that certification to develop tests within the same scope of approval without going back through FDA review each time.
	• The scope of eligible tests is tied to technology. Technology certifications must be based on a single technology, as defined in section 587 of the Food, Drug, and Cosmetic Act (FDCA or Act), as added by the VALID Act.
	  ○ Contains statutory exclusions: instruments, specimen receptacles, components, blood-related IVCTs, first of a kind IVCTs, home use, high-risk, cross-referenced, and direct-to consumer IVCTs.
	  ○ First of a kind, home use, high-risk, cross-referenced, and direct-to-consumer IVCTs can be made eligible for technology certification via the regulatory pathway designation process.
	• Outlines the parameters and content of a technology certification application, and requirements for eligible developers.

	• Provides the process and timeline for FDA action on an application for technology certification.
	  ○ FDA is directed to take action on an application for technology certification not later than 90 days after receipt. This timeline may be extended by mutual agreement by the applicant and FDA. Technology certification orders remain in effect up to four years, and can be renewed by an application for renewal.
	• Outlines the requirements for supplements relevant to changes to information in an application, and reporting of such changes to FDA in certain circumstances. Authorizes FDA to withdraw a technology certification order under certain circumstances, after due notice and opportunity for an informal hearing.
	• Contains post-enactment requirements for FDA: public docket, public meeting, and guidance.
	  ○ FDA is directed to establish a public docket regarding technology certification within 30 days of enactment.
	  ○ FDA is directed to hold a public meeting for input and recommendations on implementation of the technology certification process within 180 days of enactment.
	  ○ FDA is also directed to issue draft guidance 2 years after enactment, and to submit annual reports to Congress for a 5-year period to provide updates on the status of the technology certification process.

Adding FDCA Section 587E: Mitigating Measures	• Authorizes FDA to establish mitigating measures for IVCTs with the same indications for use. Special controls required for IVCTs regulated as devices before the date of enactment are to remain in effect unless FDA changes or withdraws them, and are deemed mitigating measures. • Developers of IVCTs subject to premarket review are directed to submit documentation demonstrating that mitigating measures have been met, and to maintain and make available to FDA upon request documentation demonstrating that mitigating measures continue to be met following any modifications to the test. • Developers of IVCTs marketed within the scope of a technology certification or other premarket review exemption subject to mitigating measures are directed to maintain and make available to FDA upon request documentation demonstrating that mitigating measures continue to be met following any modifications to the test, and to include the description in the performance summary, if applicable. • FDA is directed to issue mitigating measures for cross-referenced tests within 1 year after implementation of the Act.
Adding FDCA Section 587F: Regulatory Pathway Redesignation	• Authorizes FDA to change the regulatory designation of an IVCT in response to new clinical information (including new mitigating measures) or revoke any exemption of such tests if there is a reasonable probability of severe adverse health consequences.

	• This process could be used to make a previously ineligible type of IVCT eligible for technology certification. • Outlines the process for such actions, including publication of a proposed action in the Federal Register, consideration of comments to a public docket, and publication of final notice in the Federal Register.
Adding FDCA Section 587G: Advisory Committees	• Grants FDA the authority to establish and use advisory committees for purposes related to approval of an IVCT application, effectiveness of mitigating measures, quality requirements, and other purposes as appropriate. The section also includes criteria related to appointments of committee members and meetings, and authorizes FDA to issue guidance on the policies and procedures governing advisory committees established pursuant to the provision.
Adding FDCA Section 587H: Request for Informal Feedback	• Establishes a pathway for IVCT developers, before submitting a premarket application or technology certification application, to request informal feedback from FDA about the submission process, type and amount of evidence needed, or the appropriate regulatory pathway or exemption for a test or tests. • Directs FDA to meet with or respond to the developer's request within 60 days and provide a written record or response to the developer within 15 days of an informal feedback meeting. (This process is similar to the pre-submission process for medical devices, but with a different timeline and sequence of events).
Adding FDCA Section 587I: Registration and Listing	• Requires registration of establishments by developers, contract manufacturers, contract sterilizers, repackagers, relabelers, and distributors of IVCTs. Registration subjects the establishment to inspection. • Listing is required for the same persons/entities, with particular elements and schedules described in subsection (b). • Required elements include: establishment name and registration number; contact information; test listing number and name for the IVCT; CLIA certificate number; whether the IVCT is approved, exempt, or offered under a technology certification order; indications for use; brief summaries of analytical and clinical validity; mitigating measures; and, representative labeling. • Notably, the proposed notification requirements are broader than the current device listing requirements.
Adding FDCA Section 587J: Test Design and Quality Requirements	• Establishes quality requirements applicable to IVCTs, in lieu of Quality Systems requirements applicable to medical devices. • Requires all persons registered under section 587I to maintain quality requirements tailored to the type of IVCT offered, and where it is developed. • Clarifies that quality requirements implemented and enforced by FDA only apply to the design and manufacturing of IVCTs (development, validation, production, preparation, propagation, or assembly

	related to the design, manufacture, and distribution of the test), and that laboratory operations will continue to be regulated by the Centers for Medicare and Medicaid Services (CMS) under CLIA. • Establishes different quality requirements for labs that are and are not CLIA-certified for high-complexity testing, and labs that are distributing IVCTs or test protocols within organizations or public health networks. • Directs FDA, in issuing implementing regulations, to consider whether the developer participates in an audit program in which the US participates or recognizes, or confirms to standards recognized by FDA, and to ensure a least burdensome approach by leveraging appropriate quality assurance requirements applicable to CLIA-certified labs.
Adding FDCA Section 587K: Labeling Requirements	• Provides requirements for IVCT labeling, and exemptions from the labeling requirements. Labeling generally must include adequate directions for use, and other specific content, including the test listing number, adverse event reporting information, instructions for accessing performance summary data, the intended use, and warnings, contraindications, and limitations. This information should generally be made available to the public, with limited exception including for trade secrets and commercial confidential information. • Subsection (d) contains specific exemptions and alternative requirements for certain tests and uses. • FDA is authorized to issue guidance on labeling to help ensure requirements with applicable requirements in the subsection.
Adding FDCA Section 587L: Adverse Event Reporting	• Requires that each IVCT developer establish and maintain an adverse event reporting system, unless otherwise exempt. Reports should be submitted using the process and timeline specified whenever information that reasonably suggests a developer's IVCT is associated with an adverse event becomes known to the developer. The section defines the term "adverse event" as including malfunction reporting. • The section provides time frames for individual adverse event reports: 5 calendar days after an IVCT developer receives or otherwise becomes aware of information that reasonably suggests the adverse event involves a patient death or the event presents an imminent threat to public health. Quarterly reporting is required for all other adverse events.
Adding FDCA Section 587M: Corrections and Removals	• Provides for corrections and removals from the marketing of IVCTs, and defines relevant terms. Generally, IVCT developers and importers must report any correction or removal of an IVCT if it was undertaken to reduce the risk to health posed by the IVCT, or to remedy a violation of the Act caused by the IVCT which may present a risk to health. Reporting is not required if otherwise reported pursuant to adverse event reporting. Reports must be submitted within 15 days of initiating the correction or removal. Recordkeeping requirements apply regardless of whether reporting would be required.

	• Upon the reporting of a correction or removal, FDA is directed to classify it within 15 calendar days, and provide written communication to the developer or importer (either closing or providing reasons why recall cannot be closed) within 45 calendar days.
Adding FDCA Section 587N: Restricted In Vitro Clinical Tests	• Describes the circumstances under which FDA can add certain requirements to the approval of an IVCT to minimize patient risk and ensure analytical and clinical validity of the IVCT, or the safety of a specimen receptacle, due to the potential for harmful effect of the test. • Restrictions may be applied to high-risk IVCTs, prescription home-use IVCTs, direct-to-consumer IVCTs, and over-the-counter IVCTs. • Restricted IVCTs must carry appropriate labeling.
Adding FDCA Section 587O: Appeals	• For "significant decisions," FDA must provide a substantive summary of the rationale for any such decision regarding an application or review of an IVCT premarket application, technology certification, or an exemption. This must be provided upon request to the person seeking to make the submission, and must include a statement regarding consideration and application of the least burdensome requirements. • Any person may request a supervisory review of a significant decision. Requests for review must be submitted not later than 30 days after the decision. FDA must schedule a review not later than 30 days after the request, and must issue a decision not later than 45 days after the request is made, or not later than 30 days after a meeting or teleconference, if requested.
Adding FDCA Section 587P: Accredited Persons	• Provides authority for FDA to accredit qualified entities to review test applications for both premarket approval and technology certification, and to conduct inspections of IVCT developers and other registrants. 2 years after the date of enactment, if there are no applications from persons meeting the criteria, FDA is directed to publish a notice seeking applications. • Provides eligibility criteria for accredited persons. • FDA is directed to issue guidance on eligibility for accreditation and the process for accrediting the entities (draft guidance within 180 days after enactment; final guidance within one year after the close of the draft guidance comment period).
Adding FDCA Section 587Q: Recognized Standards	• Authorizes FDA to establish performance standards that IVCTs can use to demonstrate clinical validity, analytical validity, and safety (as applicable). In establishing standards, FDA may rely on standard setting organizations to utilize all or part of appropriate recognized standards, including international standards, in the review of an IVCT. • If FDA wishes to establish a standard, the agency is directed to issue a draft order proposing to establish the standard, with a comment period of not less than 60 calendar days, and may seek the

	recommendation of an advisory committee in so doing. FDA is directed to issue a final order within 90 days of the close of the comment period.
Adding FDCA Section 587R: Investigational Use	• Directs FDA to implement regulations for IVCTs for investigational use not later than 2 years after the date of enactment. • Generally exempts investigational use IVCTs from the Act's requirements, with the exception of recordkeeping; researchers must document their use of investigational IVCTs and provide research plans for the development of their IVCT to FDA. • Distinguishes between significant risk and nonsignificant risk studies. Significant risk studies require an investigational use application that must be approved by FDA, and are subject to annual reports demonstrating compliance with the conditions of approval. • Nonsignificant risk studies do not require an application or approval, but require compliance with an investigational plan and obtaining informed consent, among other requirements. • FDA is authorized to impose a clinical hold on unsafe investigational use IVCTs in certain circumstances.
Adding FDCA Section 587S: Collaborative Communities for In Vitro Community Tests	• Authorizes FDA to participate in collaborative communities composed of a diverse set of stakeholders, for the purpose of "facilitating community solutions and decision-making with respect to" IVCTs. • Provides for broad representation in collaborative communities including interested private and public-sector stakeholders. • Outlines topics that may be part of recommendations by collaborative communities. • Directs FDA to issue a draft guidance within 180 days of enactment addressing the participation process and framework, and how FDA will consider and implement community recommendations.
Adding FDCA Section 587T: Comprehensive Test Information Systems	• Directs FDA to create and maintain a comprehensive test information system (CTIS) to provide information about IVCTs available on the market, making certain information available to providers and consumers. This should be established within 2 years after enactment. • CTIS is to include the regulatory pathway designation for IVCTs with the same indications for use, registration and listing information, adverse event reports, reports of corrections and removals (recalls), and other information pertaining to IVCTs with the same intended use as determined by FDA. • CTIS will also serve as a secure portal for submission of premarket applications and technology certification applications, as well as registration and listing information and adverse event reports.
Adding FDCA Section 587U: Preemption	• Prohibits State, tribal, and local governments from establishing or continuing any IVCT regulations that are different than or in addition to those established by the VALID Act. Preemption will not affect the authority of state, tribal, or local governments with respect to health care licensing or regulating provider-patient relationships, or enforcing laws of general applicability.

Adding FDCA Section 587V: Adulteration	• Provides criteria used to determine whether an IVCT will be deemed to be adulterated.
Adding FDCA Section 587W: Misbranding	• Provides criteria used to determine whether an IVCT will be deemed to be misbranded.
Adding FDCA Section 587X: Postmarket Surveillance	• Authorizes FDA to issue an order requiring a developer to conduct postmarket surveillance of an IVCT as a condition of approval. FDA may also order postmarket surveillance for exempt IVCTs for which the failure of the test to meet the applicable standard of approval is likely to result in serious or adverse health consequences or death from use of the IVCT. Patient benefit and risk, as well as the least burdensome principles, should inform postmarket surveillance order determinations. • Provides information on the process for conducting and submitting surveillance information to FDA.
Adding FDCA Section 587Y: Electronic Format for Submissions	• Requires all IVCT submissions to include an electronic copy, and provides that upon a date of FDA's choosing, ongoing presubmissions and submissions must be submitted only through the electronic format specified by FDA. • FDA is directed to issue guidance implementing this section, which may include standards for the electronic copy and criteria for waivers of or exemptions from the requirement.
Adding FDCA Section 587Z: Postmarket Remedies	• Authorizes FDA to order IVCT developers to submit a plan to repair, replace, or refund an IVCT if: a premarket-approved IVCT is found to present an unreasonable risk of substantial harm to public health, there are reasonable grounds to believe the IVCT was not properly developed or manufactured, there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than the developer, and notice would not be sufficient to eliminate the unreasonable risk. The developer must first be given an opportunity for an informal hearing. • Provides time frames for FDA approval or disapproval of a plan submitted pursuant to an order to repair, replace, or refund. Also outlines the actions that may be taken pursuant to such a plan. • Authorizes FDA to direct the IVCT developer to immediately cease distribution of the IVCT and notify entities or individuals via a safety notice that use the test if a premarket-approved IVCT is found to cause serious adverse health consequences or death.
Implementing Sections Outside of Subchapter J	
Section 4: Enforcement and Other Provisions	• Details the circumstances under which IVCTs and their developers would be subject to existing penalties and other provisions (such as expanded access) under the FDCA. Includes a debarment provision regarding third-party inspections and reviews.
Section 5: Transition	• The legislation provides a transition plan, culminating with the new framework taking effect beginning the fourth fiscal year following enactment (for example, if the bill were to pass late in 2020, the effective date would be October 1, 2024).

	• During this transition period, FDA is given a series of deadlines to hold public meetings and issue guidances and regulations implementing the framework, addressing topics such as application and Technology Certification requirements, point of care tests, the breakthrough IVCT program, and quality requirements. ○ FDA is required to hold all public meetings listed under the Act within 2 years of enactment, and issue certain regulations and guidance within 3 years of enactment. • IVCTs on the market before enactment must continue to comply with existing laws until the VALID effective date. • Tests under review on the effective date would continue to be evaluated based on the existing device submission standards and regulated according to the pathway through which they were submitted. • Tests cleared via 510(k) or de novo, or approved via PMA, would be deemed approved under VALID as of the effective date (or a later date if desired by the developer). • Five years after enactment, test instruments or a member of the same instrument family must be reviewed and approved by FDA. • Grandfathered IVCTs (qualifying LDTs first offered prior to VALID enactment, as described above) may continue to be marketed after the effective date, as long as they are not modified or are not subjected to premarket review under FDA's "clawback" authority (the special rule). • Transitional IVCTs, which are qualifying LDTs first offered *after* enactment but before the VALID effective date, may continue to be offered after the effective date as long as a marketing submission (if applicable) is made within 90 days after the effective date. FDA retains the authority to enforce the device provisions of the FDCA and the Public Health Service Act for any transitional IVCTs as necessary to protect the public health.
Section 6: Emergency Use Authorization (amending Section 564 of the FDCA) & Section 587A (*as added*)	• Generally permits IVCTs to be developed and used under an emergency use authorization (EUA). • This provision tracks to FDA guidance in effect February 29 such that CLIA labs, in the event of a public health emergency, could use a test pending submission of an EUA, but with no time limits (the guidance provided a 15-day grace period to submit the EUA). • A similar allowance is not available to manufacturers (pp. 27-28); FDA guidance issued subsequent to the introduction of VALID did provide a similar grace period for manufacturer tests to be used pending submission of an EUA.
Section 7: Antimicrobial Susceptibility Tests (amending Section 511A of the FDCA)	• Amends an FDCA provision concerning breakpoints for antimicrobial resistance tests to address issues related to IVCTs developed to help direct the treatment of infectious diseases, and align with the policies established by the 21st Century Cures Act.

Section 8: Combination Products (amending Section 503 of the FDCA)	• Amends an FDCA section concerning combination product regulation to clarify the combination product process for products that include an IVCT.
Section 9: Resources	• Authorizes a user fee program for the review of IVCT applications, and provides requirements for the collection of user fees to review IVCT submissions. • Fees would be developed using the same general process used for MDUFA program for device user fees: FDA would seek public input, meet with the regulated industry and other stakeholders, and then deliver recommendations to Congress that would need to be authorized by legislation. However, the user fees under the program for IVCTs would only be available once FDA issued certain draft guidances mandated within VALID relating to review requirements and exempt categories of IVCTs.