II

115TH CONGRESS
1ST SESSION

S. 1183

To establish a third-party quality system assessment program.

IN THE SENATE OF THE UNITED STATES

MAY 18, 2017

Mr. DONNELLY (for himself and Mr. GARDNER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To establish a third-party quality system assessment program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''FDA Regulatory Efficiency Act''.

SEC. 2. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

(a) ESTABLISHMENT OF THIRD-PARTY QUALITY SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 524A (21 U.S.C. 360n–1) the following:

"SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

''(a) ACCREDITATION AND ASSESSMENT.—

''(1) IN GENERAL; CERTIFICATION OF DEVICE QUALITY SYSTEM.—The Secretary shall, in accordance with this section, establish a third-party quality system assessment program—

''(A) to accredit persons to assess whether a requestor's quality system, including its design controls, can reasonably assure the safety and effectiveness of in-scope devices subject to device-related changes;

''(B) under which accredited persons shall (as applicable) certify that a requestor's quality system meets the criteria included in the guidance issued under paragraph (5) with respect to the in-scope devices at issue; and

''(C) under which the Secretary shall rely on such certifications for purposes of determining the safety and effectiveness (or as applicable, substantial equivalence) of in-scope devices subject to the device-related changes involved, in lieu of compliance with the following submission requirements:

''(i) A premarket notification.

''(ii) A 30-day notice.

''(iii) A Special PMA Supplement.

"(2) DEFINITIONS.—For purposes of this section—

"(A) the term 'device-related changes' means changes made by a requestor with respect to in-scope devices, which are—

"(i) changes to a device found to be substantially equivalent under subsections (f)(1) and (i) of section 513 to a predicate device, that—

"(I) would otherwise be subject to a premarket notification; and

"(II) do not alter—

"(aa) the intended use of the changed device; or

"(bb) the fundamental scientific technology of such device;

"(ii) manufacturing changes subject to a 30-day notice;

"(iii) changes that qualify for a Special PMA Supplement; and

"(iv) such other changes relating to the devices or the device manufacturing process as the Secretary determines appropriate;

"(B) the term 'in-scope device' means a device within the scope of devices agreed to by the requestor and the accredited person for purposes of a request for certification under this section;

"(C) the term 'premarket notification' means a premarket notification under section 510(k);

"(D) the term 'quality system' means the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of devices, as described in section 520(f);

"(E) the term 'requestor' means a device manufacturer that is seeking certification under this section of a quality system used by such manufacturer;

"(F) the term 'Special PMA Supplement' means a PMA supplement under section 814.39(d) of title 21, Code of Federal Regulations (or any successor regulations); and

"(G) the term '30-day notice' means a notice described in section 515(d)(5)(A)(ii).

"(3) ACCREDITATION PROCESS; ACCREDITATION RENEWAL.—Except as inconsistent with this section,

the process and qualifications for accreditation of persons and renewal of such accreditation under section 704(g) shall apply with respect to accreditation of persons and renewal of such accreditation under this section.

''(4) USE OF ACCREDITED PARTIES TO CONDUCT ASSESSMENTS.—

''(A) INITIATION OF ASSESSMENT SERVICES.—

''(i) DATE ASSESSMENTS AUTHORIZED.—Beginning after the date on which the final guidance is issued under paragraph (5), an accredited person may conduct an assessment under this section.

''(ii) INITIATION OF ASSESSMENTS.—Use of one or more accredited persons to assess a requestor's quality system under this section with respect to in-scope devices shall be at the initiation of the person who registers and lists the devices at issue under section 510.

''(B) COMPENSATION.—Compensation for such accredited persons shall—

''(i) be determined by agreement between the accredited person and the person

who engages the services of the accredited person; and

''(ii) be paid by the person who engages such services.

''(C) ACCREDITED PERSON SELECTION.—Each person who chooses to use an accredited person to assess a requestor's quality system, as described in this section, shall select the accredited person from a list of such persons published by the Secretary in accordance with section 704(g)(4).

''(5) GUIDANCE; CRITERIA FOR CERTIFICATION.—

''(A) IN GENERAL.—The criteria for certification of a quality system under this section shall be as specified by the Secretary in guidance issued under this paragraph.

''(B) CONTENTS; CRITERIA.—The guidance under this paragraph shall include specification of—

''(i) evaluative criteria to be used by an accredited person to assess and, as applicable, certify a requestor's quality system under this section with respect to in-scope devices; and

''(ii) criteria for accredited persons to apply for a waiver of, and exemptions from, the criteria under clause (i).

''(C) TIMEFRAME FOR ISSUING GUIDANCE.—The Secretary shall issue under this paragraph—

''(i) draft guidance not later than 12 months after the enactment of the FDA Regulatory Efficiency Act; and

''(ii) final guidance not later than 12 months after issuance of the draft guidance under clause (i).

''(b) USE OF THIRD-PARTY ASSESSMENT.—

''(1) ASSESSMENT SUMMARY; CERTIFICATION.—

''(A) SUBMISSION OF ASSESSMENT TO SECRETARY.—An accredited person who assesses a requestor's quality system under subsection (a) shall submit to the Secretary a summary of the assessment—

''(i) within 30 days of the assessment; and

''(ii) which shall include (as applicable)—

"(I) the accredited person's certification that the requestor has satisfied the criteria specified in the guidance issued under subsection (a)(5) for quality system certification with respect to the in-scope devices at issue; and

"(II) any waivers or exemptions from such criteria applied by the accredited person.

"(B) TREATMENT OF ASSESSMENTS.—Subject to action by the Secretary under subparagraph (C), with respect to assessments which include a certification under this section—

"(i) the Secretary's review of the assessment summary shall be deemed complete on the day that is 30 days after the date on which the Secretary receives the summary under subparagraph (A); and

"(ii) the assessment summary and certification of the quality system of a requestor shall be deemed accepted by the Secretary on such 30th day.

"(C) ACTIONS BY SECRETARY.—

"(i) IN GENERAL.—Within 30 days of receiving an assessment summary and certification under subparagraph (A), the Secretary may, by written notice to the accredited person submitting such assessment certification, deem any such certification to be provisional beyond such 30-day period, suspended pending further review by the Secretary, or otherwise qualified or cancelled, based on the Secretary's determination that (as applicable)—

"(I) additional information is needed to support such certification;

"(II) such assessment or certification is unwarranted; or

"(III) such action with regard to the certification is otherwise justified according to such factors and criteria as the Secretary finds appropriate.

"(ii) ACCEPTANCE OF CERTIFICATION.—If following action by the Secretary under clause (i) with respect to a certification, the Secretary determines that such certification is acceptable, the Secretary shall issue written notice to the ap-

plicable accredited person indicating such acceptance.

''(2) NOTIFICATIONS TO SECRETARY BY CERTIFIED REQUESTORS OR ACCREDITED PERSONS FOR PROGRAM EVALUATION PURPOSES.—

''(A) ANNUAL SUMMARY REPORT FOR DEVICE-RELATED CHANGES OTHERWISE SUBJECT TO PREMARKET NOTIFICATION.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a premarket notification, shall ensure that an annual summary report is submitted to the Secretary by the accredited person which—

''(i) describes the changes made to the in-scope device; and

''(ii) indicates the effective dates of such changes.

''(B) PERIODIC NOTIFICATION FOR MANUFACTURING CHANGES OTHERWISE SUBJECT TO 30-DAY NOTICE.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a 30-

day notice, shall provide notification to the Secretary of such changes in the requestor's next periodic report under section 814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

''(i) describe the changes made; and

''(ii) indicate the effective dates of such changes.

''(C) PERIODIC NOTIFICATION FOR DEVICE-RELATED CHANGES OTHERWISE SUBJECT TO SPECIAL PMA SUPPLEMENT.—A requestor whose quality system is certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a Special PMA Supplement, shall provide notification to the Secretary of such changes in the requestor's next periodic report under section 814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

''(i) describe the changes made, including a full explanation of the basis for the changes; and

''(ii) indicate the effective dates of such changes.

''(D) USE OF NOTIFICATIONS FOR PROGRAM EVALUATION PURPOSES.—Information submitted to the Secretary under subparagraphs (A) through (C) shall be used by the Secretary for purposes of the program evaluation under subsection (e)(1).

''(c) DURATION AND EFFECT OF CERTIFICATION.—A certification under this section—

''(1) shall remain in effect for a period of 2 years from the date such certification is accepted by the Secretary, subject to paragraph (6);

''(2) may be renewed through the process described in subsection (a)(3);

''(3) shall continue to apply with respect to device-related changes made during such 2-year period, provided the certification remains in effect, irrespective of whether such certification is renewed after such 2-year period;

''(4) shall have no effect on the need to comply with applicable submission requirements specified in subsection (a)(1)(C) with respect to any change pertaining to in-scope devices which is not a device-related change under subsection (a)(2);

''(5) shall have no effect on the authority of the Secretary to conduct an inspection or otherwise de-

termine whether the requestor has complied with the applicable requirements of this Act; and

''(6) may be revoked by the Secretary upon a determination that the requestor's quality system no longer meets the criteria specified in the guidance issued under subsection (a)(5) with respect to the in-scope devices at issue.

''(d) NOTICE OF REVOCATION.—The Secretary shall provide written notification to the requestor of a revocation pursuant to subsection (c)(6) not later than 10 business days after the determination described in such subsection. Upon receipt of the written notification, the requestor shall satisfy the applicable submission requirements specified in subsection (a)(1)(C) for any device-related changes effectuated after the date of such determination. After such revocation, such requestor is eligible to seek re-certification under this section of its quality system.

''(e) PROGRAM EVALUATION; SUNSET.—

''(1) PROGRAM EVALUATION AND REPORT.—

''(A) EVALUATION.—The Secretary shall complete an evaluation of the third-party quality system assessment program under this section not later than January 31, 2021, based on—

"(i) analysis of information from a representative group of device manufacturers obtained from notifications provided by certified requestors or accredited persons under subsection (b)(2); and

"(ii) such other available information and data as the Secretary determines appropriate.

"(B) REPORT.—Not later than 1 year after completing the evaluation under subparagraph (A), the Secretary shall issue a report of the evaluation's findings on the website of the Food and Drug Administration, which shall include the Secretary's recommendations with respect to continuation and as applicable expansion of the program under this section to encompass—

"(i) device submissions beyond those identified in subsection (a)(1)(C); and

"(ii) device changes beyond those described in subsection (a)(2)(A).

"(2) SUNSET.—This section shall cease to be effective October 1, 2022.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Sec-

retary to request and review the complete assessment of a certified requestor under this section on a for-cause basis.''.

(b) CONFORMING AMENDMENTS.—

(1) REQUIREMENTS FOR PREMARKET APPROVAL SUPPLEMENTS.—Section 515(d)(5)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(5)(A)(i)) is amended by inserting ''subject to section 524B,'' after ''that affects safety or effectiveness,''.

(2) REQUIREMENTS FOR 30-DAY NOTICE.—Section 515(d)(5)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(5)(A)(ii)) is amended by inserting ''subject to section 524B,'' after ''the date on which the Secretary receives the notice,''.

(3) REQUIREMENTS FOR PREMARKET NOTIFICATION; TECHNICAL CORRECTION TO REFERENCE TO SECTION 510(k).—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended by striking ''of this subsection under subsection (m)'' and inserting ''of subsection (k) under subsection (m) or section 524B''.

(4) MISBRANDED DEVICES.—Section 502(t) of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 352(t)) is amended by inserting ''or 524B'' after ''section 519''.

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