

114TH CONGRESS
1ST SESSION

S. 2187

To establish a third-party quality system assessment program.

IN THE SENATE OF THE UNITED STATES

OCTOBER 21, 2015

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

A BILL

To establish a third-party quality system assessment
program.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA Regulatory Effi-
5 ciency Act”.

6 **SEC. 2. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

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

1 **“SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

2 “(a) ACCREDITATION AND ASSESSMENT.—

3 “(1) IN GENERAL; CERTIFICATION OF DEVICE
4 QUALITY SYSTEM.—The Secretary shall, in accord-
5 ance with this section, establish a third-party quality
6 system assessment program—

7 “(A) to accredit persons to assess whether
8 a requestor’s quality system, including its de-
9 sign controls, can reasonably assure the safety
10 and effectiveness of in-scope devices subject to
11 device-related changes;

12 “(B) under which accredited persons shall
13 (as applicable) certify that a requestor’s quality
14 system meets the criteria included in the guid-
15 ance issued under paragraph (5) with respect to
16 the in-scope devices at issue; and

17 “(C) under which the Secretary shall rely
18 on such certifications for purposes of deter-
19 mining the safety and effectiveness (or as appli-
20 cable, substantial equivalence) of in-scope de-
21 vices subject to the device-related changes in-
22 volved, in lieu of compliance with the following
23 submission requirements:

24 “(i) A premarket notification.

25 “(ii) A 30-day notice.

26 “(iii) A Special PMA supplement.

1 “(2) DEFINITIONS.—For purposes of this sec-
2 tion—

3 “(A) the term ‘device-related changes’
4 means changes made by a requestor with re-
5 spect to in-scope devices, which are—

6 “(i) changes to a device found to be
7 substantially equivalent under subsections
8 (f)(1) and (i) of section 513 to a predicate
9 device, that—

10 “(I) would otherwise be subject
11 to a premarket notification; and

12 “(II) do not alter—

13 “(aa) the intended use of
14 the changed device; or

15 “(bb) the fundamental sci-
16 entific technology of such device;

17 “(ii) manufacturing changes subject
18 to a 30-day notice;

19 “(iii) changes that qualify for a Spe-
20 cial PMA Supplement; and

21 “(iv) such other changes relating to
22 the devices or the device manufacturing
23 process as the Secretary determines appro-
24 priate;

1 “(B) the term ‘in-scope device’ means a
2 device within the scope of devices agreed to by
3 the requestor and the accredited person for pur-
4 poses of a request for certification under this
5 section;

6 “(C) the term ‘premarket notification’
7 means a premarket notification under section
8 510(k);

9 “(D) the term ‘quality system’ means the
10 methods used in, and the facilities and controls
11 used for, the design, manufacture, packaging,
12 labeling, storage, installation, and servicing of
13 devices, as described in section 520(f);

14 “(E) the term ‘requestor’ means a device
15 manufacturer that is seeking certification under
16 this section of a quality system used by such
17 manufacturer;

18 “(F) the term ‘Special PMA’ means a
19 PMA supplement under section 814.39(d) of
20 title 21, Code of Federal Regulations (or any
21 successor regulations); and

22 “(G) the term ‘30-day notice’ means a no-
23 tice described in section 515(d)(6).

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

1 the process and qualifications for accreditation of
2 persons and renewal of such accreditation under sec-
3 tion 704(g) shall apply with respect to accreditation
4 of persons and renewal of such accreditation under
5 this section.

6 “(4) USE OF ACCREDITED PARTIES TO CON-
7 DUCT ASSESSMENTS.—

8 “(A) INITIATION OF ASSESSMENT SERV-
9 ICES.—

10 “(i) DATE ASSESSMENTS AUTHOR-
11 IZED.—Beginning after the date on which
12 the final guidance is issued under para-
13 graph (5), an accredited person may con-
14 duct an assessment under this section.

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

22 “(B) COMPENSATION.—Compensation for
23 such accredited persons shall—

24 “(i) be determined by agreement be-
25 tween the accredited person and the person

1 who engages the services of the accredited
2 person; and

3 “(ii) be paid by the person who en-
4 gages such services.

5 “(C) ACCREDITED PERSON SELECTION.—

6 Each person who chooses to use an accredited
7 person to assess a requestor’s quality system,
8 as described in this section, shall select the ac-
9 credited person from a list of such persons pub-
10 lished by the Secretary in accordance with sec-
11 tion 704(g)(4).

12 “(5) GUIDANCE; CRITERIA FOR CERTIFI-
13 CATION.—

14 “(A) IN GENERAL.—The criteria for cer-
15 tification of a quality system under this section
16 shall be as specified by the Secretary in guid-
17 ance issued under this paragraph.

18 “(B) CONTENTS; CRITERIA.—The guidance
19 under this paragraph shall include specification
20 of—

21 “(i) evaluative criteria to be used by
22 an accredited person to assess and, as ap-
23 plicable, certify a requestor’s quality sys-
24 tem under this section with respect to in-
25 scope devices; and

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

4 “(C) TIMEFRAME FOR ISSUING GUID-
5 ANCE.—The Secretary shall issue under this
6 paragraph—

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

10 “(ii) final guidance not later than 12
11 months after issuance of the draft guid-
12 ance under clause (i).

13 “(b) USE OF THIRD-PARTY ASSESSMENT.—

14 “(1) ASSESSMENT SUMMARY; CERTIFI-
15 CATION.—

16 “(A) SUBMISSION OF ASSESSMENT TO SEC-
17 RETARY.—An accredited person who assesses a
18 requestor’s quality system under subsection (a)
19 shall submit to the Secretary a summary of the
20 assessment—

21 “(i) within 30 days of the assessment;
22 and

23 “(ii) which shall include (as applica-
24 ble)—

1 “(I) the accredited person’s cer-
2 tification that the requestor has satis-
3 fied the criteria specified in the guid-
4 ance issued under subsection (a)(5)
5 for quality system certification with
6 respect to the in-scope devices at
7 issue; and

8 “(II) any waivers or exemptions
9 from such criteria applied by the ac-
10 credited person.

11 “(B) TREATMENT OF ASSESSMENTS.—
12 Subject to action by the Secretary under sub-
13 paragraph (C), with respect to assessments
14 which include a certification under this sec-
15 tion—

16 “(i) the Secretary’s review of the as-
17 sessment summary shall be deemed com-
18 plete on the day that is 30 days after the
19 date on which the Secretary receives the
20 summary under subparagraph (A); and

21 “(ii) the assessment summary and
22 certification of the quality system of a re-
23 questor shall be deemed accepted by the
24 Secretary on such 30th day.

25 “(C) ACTIONS BY SECRETARY.—

1 “(i) IN GENERAL.—Within 30 days of
 2 receiving an assessment summary and cer-
 3 tification under subparagraph (A), the Sec-
 4 retary may, by written notice to the ac-
 5 credited person submitting such assess-
 6 ment certification, deem any such certifi-
 7 cation to be provisional beyond such 30-
 8 day period, suspended pending further re-
 9 view by the Secretary, or otherwise quali-
 10 fied or cancelled, based on the Secretary’s
 11 determination that (as applicable)—

12 “(I) additional information is
 13 needed to support such certification;

14 “(II) such assessment or certifi-
 15 cation is unwarranted; or

16 “(III) such action with regard to
 17 the certification is otherwise justified
 18 according to such factors and criteria
 19 as the Secretary finds appropriate.

20 “(ii) ACCEPTANCE OF CERTIFI-
 21 CATION.—If following action by the Sec-
 22 retary under clause (i) with respect to a
 23 certification, the Secretary determines that
 24 such certification is acceptable, the Sec-
 25 retary shall issue written notice to the ap-

1 plicable accredited person indicating such
2 acceptance.

3 “(2) NOTIFICATIONS TO SECRETARY BY CER-
4 TIFIED REQUESTORS OR ACCREDITED PERSONS FOR
5 PROGRAM EVALUATION PURPOSES.—

6 “(A) ANNUAL SUMMARY REPORT FOR DE-
7 VICE-RELATED CHANGES OTHERWISE SUBJECT
8 TO PREMARKET NOTIFICATION.—A requestor
9 whose quality system is certified under this sec-
10 tion that effectuates device-related changes with
11 respect to in-scope devices, without prior sub-
12 mission of a premarket notification, shall en-
13 sure that an annual summary report is sub-
14 mitted to the Secretary by the accredited per-
15 son which—

16 “(i) describes the changes made to the
17 in-scope device; and

18 “(ii) indicates the effective dates of
19 such changes.

20 “(B) PERIODIC NOTIFICATION FOR MANU-
21 FACTURING CHANGES OTHERWISE SUBJECT TO
22 30-DAY NOTICE.—A requestor whose quality
23 system is certified under this section that effec-
24 tuates device-related changes with respect to in-
25 scope devices, without prior submission of a 30-

1 day notice, shall provide notification to the Sec-
2 retary of such changes in the requestor's next
3 periodic report under section 814.84(b) of title
4 21, Code of Federal Regulations (or any suc-
5 cessor regulation). Such notification shall—

6 “(i) describe the changes made; and

7 “(ii) indicate the effective dates of
8 such changes.

9 “(C) PERIODIC NOTIFICATION FOR DE-
10 VICE-RELATED CHANGES OTHERWISE SUBJECT
11 TO SPECIAL PMA SUPPLEMENT.—A requestor
12 whose quality system is certified under this sec-
13 tion that effectuates device-related changes with
14 respect to in-scope devices, without prior sub-
15 mission of a Special PMA Supplement, shall
16 provide notification to the Secretary of such
17 changes in the requestor's next periodic report
18 under section 814.84(b) of title 21, Code of
19 Federal Regulations (or any successor regula-
20 tion). Such notification shall—

21 “(i) describe the changes made, in-
22 cluding a full explanation of the basis for
23 the changes; and

24 “(ii) indicate the effective dates of
25 such changes.

1 “(D) USE OF NOTIFICATIONS FOR PRO-
2 GRAM EVALUATION PURPOSES.—Information
3 submitted to the Secretary under subpara-
4 graphs (A) through (C) shall be used by the
5 Secretary for purposes of the program evalua-
6 tion under subsection (d).

7 “(c) DURATION AND EFFECT OF CERTIFICATION.—
8 A certification under this section—

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

12 “(2) may be renewed through the process de-
13 scribed in subsection (a)(3);

14 “(3) shall continue to apply with respect to de-
15 vice-related changes made during such 2-year period,
16 provided the certification remains in effect, irrespec-
17 tive of whether such certification is renewed after
18 such 2-year period;

19 “(4) shall have no effect on the need to comply
20 with applicable submission requirements specified in
21 subsection (a)(1)(C) with respect to any change per-
22 taining to in-scope devices which is not a device-re-
23 lated change under subsection (a)(2);

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

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

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

8 “(d) NOTICE OF REVOCATION.—The Secretary shall
9 provide written notification to the requestor of a revoca-
10 tion pursuant to subsection (c)(6) not later than 10 busi-
11 ness days after the determination described in such sub-
12 section. Upon receipt of the written notification, the re-
13 questor shall satisfy the applicable submission require-
14 ments specified in subsection (a)(1)(C) for any device-re-
15 lated changes effectuated after the date of such deter-
16 mination. After such revocation, such requestor is eligible
17 to seek re-certification under this section of its quality sys-
18 tem.

19 “(e) PROGRAM EVALUATION; SUNSET.—

20 “(1) PROGRAM EVALUATION AND REPORT.—

21 “(A) EVALUATION.—The Secretary shall
22 complete an evaluation of the third-party qual-
23 ity system assessment program under this sec-
24 tion no later than January 31, 2021, based
25 on—

1 “(i) analysis of information from a
2 representative group of device manufactur-
3 ers obtained from notifications provided by
4 certified requestors or accredited persons
5 under subsection (b)(2); and

6 “(ii) such other available information
7 and data as the Secretary determines ap-
8 propriate.

9 “(B) REPORT.—No later than 1 year after
10 completing the evaluation under subparagraph
11 (A), the Secretary shall issue a report of the
12 evaluation’s findings on the website of the Food
13 and Drug Administration, which shall include
14 the Secretary’s recommendations with respect
15 to continuation and as applicable expansion of
16 the program under this section to encompass—

17 “(i) device submissions beyond those
18 identified in subsection (a)(1)(C); and

19 “(ii) device changes beyond those de-
20 scribed in subsection (a)(2)(A).

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

23 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
24 tion shall be construed to limit the authority of the Sec-
25 retary to request and review the complete assessment of

1 a certified requestor under this section on a for-cause
2 basis.”.

3 (b) CONFORMING AMENDMENTS.—

4 (1) REQUIREMENTS FOR PREMARKET AP-
5 PROVAL SUPPLEMENTS.—Section 515(d)(6)(A)(i) of
6 the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 360e(d)(5)(A)(i)) is amended by inserting
8 “subject to section 524B,” after “that affects safety
9 or effectiveness,”.

10 (2) REQUIREMENTS FOR 30-DAY NOTICE.—Sec-
11 tion 515(d)(6)(A)(ii) of the Federal Food, Drug,
12 and Cosmetic Act (21 U.S.C. 360e(d)(5)(A)(ii)) is
13 amended by inserting “subject to section 524B,”
14 after “the date on which the Secretary receives the
15 notice,”.

16 (3) REQUIREMENTS FOR PREMARKET NOTIFI-
17 CATION; TECHNICAL CORRECTION TO REFERENCE
18 TO SECTION 510(k).—Section 510(l) of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is
20 amended by striking “of this subsection under sub-
21 section (m)” and inserting “of subsection (k) under
22 subsection (m) or section 524B”.

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

- 1 U.S.C. 352(t)) is amended by inserting “or 524B”
- 2 after “section 519”.

